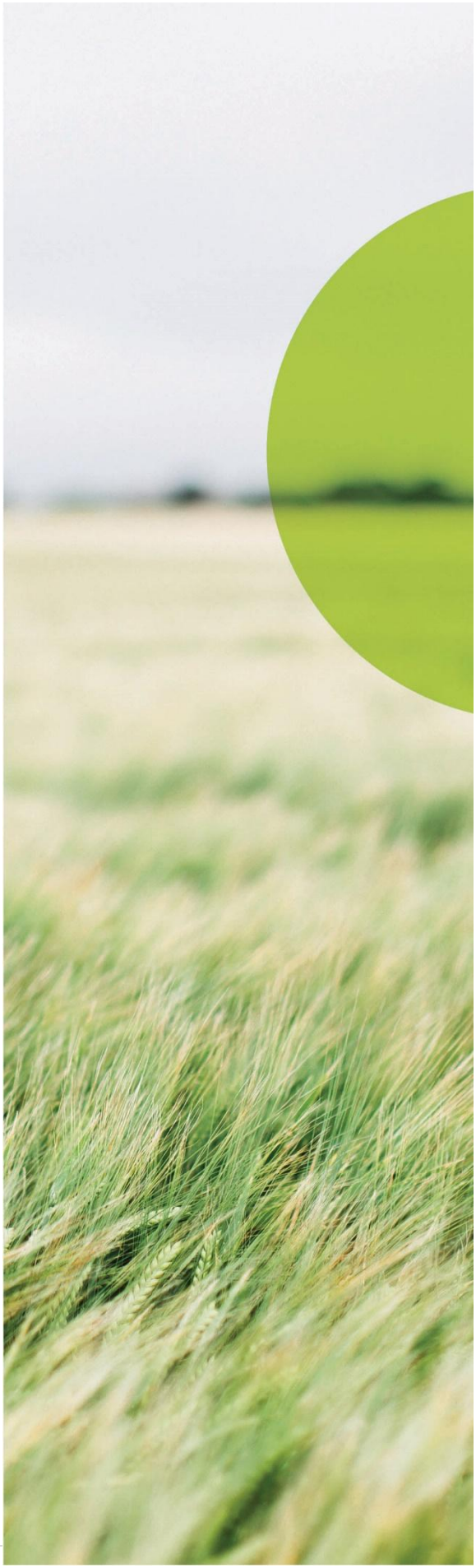


MedImpact **Clinical Document**

Kentucky Medicaid
Prior Authorization Criteria

VERSION: OCTOBER 2026

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Prior Authorization Criteria

Kentucky Medicaid

INTRODUCTION

The following document contains prior authorization criteria for agents on the Kentucky Medicaid Preferred Drug List. MedImpact's Clinical Team works closely with the Kentucky Pharmacy and Therapeutics (P&T) Committee to provide regular Therapeutic Class Reviews (TCR) to determine the State's Preferred Drug List (PDL) pursuant to KY statute 205.564. MedImpact follows an evidence-based approach when evaluating medication literature and developing recommendations for the P&T Committee. In addition to evaluating available clinical evidence, cost analyses are performed, and recommendations are developed within each therapeutic class to keep overall net costs manageable. Please note that all non-preferred agents on the PDL must meet the criteria for non-preferred agents in addition to brand or generic medically necessary criteria when applicable.

During regularly occurring meetings, the Kentucky Medicaid P&T Committee reviews information provided by MedImpact related to prior authorization criteria for new to market agents as well as recommendations on changes to the PDL. Once their review is complete, the P&T Committee submits their recommendations to the Kentucky Commissioner for final approval. MedImpact also works closely with the Pharmacy Director for the Department of Medicaid Services (DMS), or their designee, to develop and implement prior authorization criteria for medications already on the market. Clinical criteria may be updated if deemed appropriate when new information becomes available.

For a Managed Care Organization (MCO) member, prescribing providers may request a peer-to-peer review and/or an internal (first level) appeal upon denial of an initial prior authorization request. Appeal requests received from a prescribing provider, member, and/or member's representative (with the member's permission) may be submitted via phone, fax, or US mail within sixty (60) days of the receipt of the initial denial letter. Internal (first level) appeals will be reviewed and determined within 30 days. External (second level) appeals review by a third-party will be processed in accordance with 907 KAR 17:035 and must be made within thirty (30) days of an upheld internal (first level) appeal decision.

For a Fee-for service (FFS) member, providers may request a peer-to-peer review, a reconsideration, or an internal appeal on behalf of the member. Peer-to-peer requests may be initiated by phone or fax.

If needed, clinical support is available to assist with questions 8:00AM – 7:00PM Eastern Standard Time seven days per week and may be reached at:

- For MCO members:
  - Phone: (844) 336-2676
  - Fax: (858) 357-2612

- For FFS members:
  - Phone: (877) 403-6034
  - Fax: (858) 357-2612

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CARDIOVASCULAR: ANGIOTENSIN RECEPTOR MODULATORS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires ≥ **30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Epaned [CC] Qbrelis [CC, QL]	• NPD criteria; **OR** • Unable to swallow whole or consume crushed generic tablets. **Quantity Limit:** 40 mL per day (Qbrelis)

CURRENT PDL STATUS

ACE INHIBITORS

Preferred Agents	Non-Preferred Agents
benazepril	Accupril
enalapril tablet, solution	Altace
lisinopril	captopril
quinapril	Epaned [CC]
ramipril	fosinopril
trandolapril	Lotensin
	moexipril
	perindopril
	Qbrelis [CC, QL]
	Zestril

ACE INHIBITORS + DIURETIC COMBINATIONS

Preferred Agents	Non-Preferred Agents
benazepril/HCTZ	Accuretic
enalapril/HCTZ	captopril/HCTZ

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Preferred Agents	Non-Preferred Agents
fosinopril/HCTZ	Lotensin HCT
lisinopril/HCTZ	quinapril/HCTZ
	Zestoretic

ANGIOTENSIN RECEPTOR BLOCKERS (ARB)

Preferred Agents	Non-Preferred Agents
irbesartan	Arbli QL
losartan	Atacand
olmesartan	Avapro
sacubitril/valsartan QL	azilsartan medoxomil
telmisartan	Benicar
valsartan tablet	candesartan
	Cozaar
	Diovan
	Edarbi
	Entresto QL
	Entresto Sprinkle
	Micardis
	valsartan solution

ARB + DIURETIC COMBINATIONS

Preferred Agents	Non-Preferred Agents
irbesartan/HCTZ	Atacand HCT
losartan/HCTZ	Avalide
olmesartan/HCTZ	Benicar HCT
valsartan/HCTZ	candesartan/HCTZ
	Diovan HCT
	Edarbyclor
	Hyzaar
	Micardis HCT
	telmisartan/HCTZ
	Widaplik QL

DIRECT RENIN INHIBITORS

Preferred Agents	Non-Preferred Agents
N/A	aliskiren
	Tekturna

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CARDIOVASCULAR: ANTI-ANGINAL & ANTI-ISCHEMIC AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Corlanor CC
ivabradine CC
	• Diagnosis of chronic heart failure that is symptomatic; **AND**
	• Documentation (e.g., progress note) of:
	  ○ Left ventricular ejection fraction (LVEF) ≤ 35%; **AND**
	  ○ Resting heart rate ≥ 70 beats per minute (bpm); **AND**
	• Used in combination with maximally tolerated doses of a beta blocker (e.g., bisoprolol, carvedilol, or metoprolol succinate); **OR**
	• Documentation (e.g., progress note) of clinical rationale preventing use of a beta-blocker.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
ranolazine ER	Aspruzyo Sprinkle ER QL
	Corlanor CC
	ivabradine CC

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CARDIOVASCULAR: ANTIARRHYTHMICS (ORAL ANTI-ARRHYTHMICS)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Sotylize [CC]	• NPD criteria; **OR** • Unable to swallow sotalol/sotalol AF tablets.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
amiodarone	Betapace
disopyramide	Betapace AF
dofetilide	Multaq
flecainide	Norpace
mexiletine	Norpace CR
propafenone	Pacerone
Sorine	propafenone SR/ER
sotalol	quinidine sulfate
sotalol AF	quinidine gluconate ER
	Sotylize [CC]
	Tikosyn

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CARDIOVASCULAR: BETA BLOCKERS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Hemangeol CC	• Diagnosis of Infantile Hemangioma (ICD-10 Disease Group D18).

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
atenolol	acebutolol
atenolol/chlorthalidone	betaxolol
bisoprolol 2.5 mg QL, 5 mg, 10 mg	Bystolic
bisoprolol/HCTZ	carvedilol ER
carvedilol	Coreg CR
Hemangeol CC	Coreg
labetalol	Inderal LA, XL
metoprolol succinate ER	Innopran XL
metoprolol tartrate (except 12.5 mg tablet)	Kapspargo sprinkle
nadolol	Lopressor
nebivolol	metoprolol tartrate 12.5 mg tablet QL
propranolol ER capsule	metoprolol/HCTZ
propranolol solution, tablet	pindolol
	propranolol/HCTZ
	Tenoretic
	Tenormin
	timolol maleate tablet
	Toprol XL

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CARDIOVASCULAR: CALCIUM CHANNEL BLOCKERS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Katerzia AE, CC, QL	• Patient has ONE of the following diagnoses:
	  ○ Hypertension; **OR**
	  ○ Coronary Arterial Disease; **AND**
	• Unable to swallow whole, or consume crushed generic tablets; **AND**
	• Clinical documentation for trial and failure trial, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents in any sub-class, unless otherwise specified; **AND**
	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Norliqva.
	
	Age Limit: ≥ 6 years
	Quantity Limit: 10 mL per day

nifedipine IR CC	• Diagnosis of premature labor; **OR** • NPD criteria.
nimodipine CC	• Diagnosis of subarachnoid hemorrhage; **OR** • NPD criteria.
Nymalize CC	• Diagnosis of subarachnoid hemorrhage; **AND** • Unable to swallow capsules.

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Agent(s) Subject to Criteria	Criteria for Approval

Sdamlo AE, CC, QL	• Patient has ONE of the following diagnoses:
	  ○ Hypertension; **OR**
	  ○ Coronary Arterial Disease; **AND**
	• Unable to swallow whole, or consume crushed generic tablets; **AND**
	• Clinical documentation for trial and failure trial, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents in any sub-class, unless otherwise specified; **AND**
	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Norliqva.
	
	Age Limit: 2.5 mg per 15 mL (≥ 6 years old)
	5 mg per 15 mL (≥ 6 years old)
	10 mg per 15 mL (≥ 10 years old)
	
	Quantity Limit: 1 per day

CURRENT PDL STATUS

CALCIUM CHANNEL BLOCKERS

Preferred Agents	Non-Preferred Agents
amlodipine	diltiazem ER 12HR capsule
Cartia XT	diltiazem ER (LA) tablet
diltiazem	isradipine
diltiazem CD capsule	Katerzia AE, CC, QL
diltiazem ER 24HR capsule	levamlodipine
diltiazem XR	Matzim LA
Dilt-XR	nicardipine
felodipine ER	nifedipine IR CC
nifedipine ER	nimodipine CC
Tiadylt ER	nisoldipine ER
verapamil tablet	Norliqva
verapamil ER tablet	Norvasc
	Nymalize CC
	Procardia XL
	Sdamlo AE, CC, QL
	Sular ER
	verapamil ER capsule
	verapamil ER PM capsule
	verapamil SR capsule

ANGIOTENSIN MODULATOR AND CALCIUM CHANNEL BLOCKER COMBINATIONS

Preferred Agents	Non-Preferred Agents
amlodipine/benazepril	amlodipine/valsartan/HCTZ
amlodipine/olmesartan	Azor
amlodipine/valsartan	Exforge HCT
	Exforge
	Lotrel
	olmesartan/amlodipine/HCTZ
	telmisartan/amlodipine

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Preferred Agents	Non-Preferred Agents
	trandolapril/verapamil
	Tribenzor

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CARDIOVASCULAR: ANTICOAGULANTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Eliquis tablet, dose pack	Arixtra
dabigatran	Eliquis tablet for suspension QL
enoxaparin	Eliquis sprinkle QL
Jantoven	fondaparinux sodium
warfarin	Fragmin
Xarelto dose pack, tablet	Lovenox
	Pradaxa capsule, pellet pack
	rivaroxaban
	Savaysa
	Xarelto suspension

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CARDIOVASCULAR: PLATELET AGGREGATION INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
cilostazol	aspirin/dipyridamole
clopidogrel	Brilinta
dipyridamole	Effient
prasugrel	Plavix
ticagrelor	

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CARDIOVASCULAR: PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS, ORAL AND INHALED

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Alyq CC, QL ambrisentan CC bosentan tablet CC, QL sildenafil suspension CC sildenafil tablet CC tadalafil CC, QL	• Diagnosis of pulmonary hypertension (ICD-10 Disease Group I27).

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Opsynvi CC, QL	• Diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1; **AND**
	• Patient is WHO functional class (FC) 2 or 3; **AND**
	• Prescribed by, or in consultation with, a cardiologist, pulmonologist, or other specialist in the treatment of pulmonary arterial hypertension (PAH); **AND**
	• Patient has had at least a 30-day trial and failure, allergy, or contraindication (including potential drug-drug interactions with other medications), or intolerance of the following agents:
	  ○ ambrisentan; **AND**
	  ○ sildenafil or tadalafil; **AND**
	• Patient meets the minimum age recommended by the package insert for use in PAH; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Patient will not be using with other phosphodiesterase-5 inhibitors (e.g., sildenafil, tadalafil). **Renewal Criteria:** • Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms. **Quantity Limit:** 1 per day
Tracleer tablet for suspension CC, QL bosentan tablet for suspension CC, QL	• PDP criteria; **AND** • Unable to swallow Tracleer tablet; **AND** **Quantity Limit:** 4 per day
Tyvaso CC Tyvaso DPI CC Yutrepia CC	**Pulmonary Arterial Hypertension (PAH):** • Diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1; **AND** • Prescribed by, or in consultation with, a cardiologist or a pulmonologist; **AND** • Patient has trial and failure, allergy, contraindication, or intolerance to 2 or more preferred agents for at least 1 month. **Pulmonary Hypertension Associated with Interstitial Lung Disease:** • Diagnosis of Pulmonary Hypertension Associated with Interstitial Lung Disease WHO Group 3; **AND** • Prescribed by, or in consultation with, a cardiologist or a pulmonologist; **AND** • Baseline forced vital capacity < 70% for patients with connective tissue disease; **AND** • Patient had a right heart catheterization (documentation required); **AND** • Results of the right heart catheterization confirm the diagnosis of WHO Group 3 interstitial lung disease associated with pulmonary hypertension. **Renewal Criteria (all indications):** • Patient has a documented response to therapy.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Alyq CC, QL	Adcirca QL
ambrisentan CC	Adempas QL
bosentan tablet CC, QL	bosentan tablet for suspension CC, QL
sildenafil suspension CC	Letairis
sildenafil tablet CC	macitentan QL
tadalafil CC, QL	Opsumit QL
	Opsynvi CC, QL
	Orenitram ER
	Revatio tablet CC

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Preferred Agents	Non-Preferred Agents
	Tadliq
	Tracleer tablet QL
	Tracleer tablet for suspension CC, QL
	Tyvaso CC
	Tyvaso DPI CC
	Uptravi QL
	Ventavis
	Yutrepia CC

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Repatha CC	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Prescribed initially by, or in consultation with a cardiologist, lipid specialist, endocrinologist, vascular medicine or other applicable specialist; **AND**
	• Documentation of low-density lipoprotein cholesterol (LDL-C) prior to/without PCSK9 inhibitor therapy; **AND**
	• Documentation of trial and failure to achieve LDL goal after 3 months of maximum dose statin therapy recommended for patient age; **OR**
	• Prescriber attestation that patient does not tolerate statins (≥ 2 statin trials of any length were unsuccessful due to adverse effects); **AND**
	• Medication is prescribed for ONE of the following:
	  ○ To reduce the risk of Major Adverse Cardiovascular Events (MACE) (e.g., cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in a patient at increased risk for these events; **OR**
	  ○ Diagnosis of hyperlipidemia including Heterozygous and Homozygous familial hypercholesterolemia (HoFH); **AND**
	• Prescriber attestation that maximum tolerated doses of lipid-lowering therapies (e.g., statin, ezetimibe, omega-3-acid ethyl esters) to reduce LDL-C will continue to be used in combination with PCSK9 therapy; **AND**
	• Prescriber attestation that patient has been counseled to initiate and maintain diet and exercise modifications to reduce LDL-C in combination with PCSK9 therapy; **AND**
	• Patient meets the minimum age recommended by the package insert for the provided indication.
	
	Renewal Criteria:
	• Documentation (e.g., progress note or lab report) that demonstrate a reduction in LDL-C when compared to the baseline values.

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
amlodipine/atorvastatin CC, QL	• Trial and failure (e.g., poor adherence) of individual, generic components. **Quantity Limit:** 1 per day

Juxtapid CC	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Diagnosis of homozygous familial hypercholesterolemia (HoFH); **AND**
	• Prescribed by a cardiologist, lipid specialist, endocrinologist, vascular medicine or other applicable specialist; **AND**
	• Documentation (e.g., lab report) of cholesterol panel, including low density lipoprotein, cholesterol (LDL-C) prior to initiation; **AND**
	• Failure to achieve LDL-C goal on at least 3 of the following, unless contraindication:
	  ○ Maximally tolerated or high-dose statin (e.g. atorvastatin 80mg, rosuvastatin 40mg)
	  ○ Ezetimibe
	  ○ PCSK9 inhibitor (e.g., alirocumab, evolocumab)
	  ○ Bempedoic acid.
	
	Renewal Criteria:
	• Documentation (e.g., progress note or lab report) that demonstrate a reduction in LDL-C when compared to the baseline values.

Nexletol AE, CC, QL
Nexlizet AE, CC, QL
	• Prescribed initially by, or in consultation with a cardiologist, lipid specialist, endocrinologist, vascular medicine or other applicable specialist; **AND**
	• Patient will be using Nexletol or Nexlizet for ONE of the following:
	  ○ Diagnosis of primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH); **OR**
	  ○ To reduce the risk of myocardial infarction and coronary revascularization for those unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD) or a high risk for a CVD event but without established CVD; **AND**
	• Patient meets at least ONE of the following:
	  ○ Trial and failure to achieve LDL goal after 3 months of high intensity statin therapy (e.g., rosuvastatin 40 mg daily); **OR**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Patient does not tolerate statins (≥ 2 statin trials of any length were unsuccessful due to adverse effects). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Leqvio AE, CC	**Approval Duration:** 6 months initial; 1 year renewal • Patient is at least 18 years old; **AND** ○ Diagnosis of hypercholesterolemia; **OR** • Patient is at least 12 years old; **AND** ○ Diagnosis of one of the following conditions: ▪ Heterozygous familial hypercholesterolemia (HeFH); **OR** ▪ Homozygous familial hypercholesterolemia (HoFH); **AND** • Prescribed initially by, or in consultation with a cardiologist, lipid specialist, endocrinologist, vascular medicine or other applicable specialist; **AND** • Documentation of low-density lipoprotein cholesterol (LDL-C) prior to/without PCSK9 inhibitor therapy; **AND** • One of the following: ○ Trial and failure to achieve LDL goal after 3 months of high intensity statin therapy (e.g., rosuvastatin 40 mg daily); **OR** ○ Patient does not tolerate statins (≥ 2 statin trials of any length were unsuccessful due to adverse effects); **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Repatha. **Renewal Criteria** • Documentation (e.g., progress note or lab report) that demonstrates a reduction in LDL-C when compared to the baseline values. **Age Limit:** ≥ 12 years (HeFH or HoFH) **Age Limit:** ≥ 18 years (hypercholesterolemia)
Praluent CC	**Approval Duration:** 6 months initial; 1 year renewal • Diagnosis of primary hyperlipidemia, including heterozygous and homozygous familial hypercholesterolemia (HeFH); **AND** • Prescribed initially by, or in consultation with a cardiologist, lipid specialist, endocrinologist, vascular medicine or other applicable specialist; **AND** • Documentation of low-density lipoprotein cholesterol (LDL-C) prior to/without PCSK9 inhibitor therapy; **AND** • One of the following: ○ Trial and failure to achieve LDL goal after 3 months of high intensity statin therapy (e.g., rosuvastatin 40 mg daily); **OR** ○ Patient does not tolerate statins (≥ 2 statin trials of any length were unsuccessful due to adverse effects); **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Repatha. **Renewal Criteria:** • Documentation (e.g., progress note or lab report) that demonstrate a reduction in LDL-C when compared to the baseline values.

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CURRENT PDL STATUS

LIPOTROPICS: OTHER

Preferred Agents	Non-Preferred Agents
cholestyramine, cholestyramine light	colesevelam
colestipol tablet	Colestid
ezetimibe	colestipol granules, packet
fenofibrate micronized capsule 67mg, 134mg, 200mg (generic Lofibra capsule)	fenofibrate capsule 50mg, 150mg (generic Lipofen)
fenofibrate nanocrystallized tablet 48mg, 145mg (generic Tricor)	fenofibrate micronized capsule 43mg, 130mg (generic Antara)
fenofibric acid DR capsule	fenofibrate tablet 40mg, 120mg (generic Fenoglide)
gemfibrozil	fenofibrate tablet 54mg, 160mg (generic Lofibra tablet)
niacin ER tablet	fenofibric acid tablet
omega-3 acid ethyl esters capsule	Fibricor
Prevalite	icosapent ethyl
Repatha CC	Juxtapid CC
	Leqvio AE, CC
	Lipofen
	Lopid
	Lovaza
	Nexletol AE, CC, QL
	Nexlizet AE, CC, QL
	Praluent CC
	Questran, Questran Light
	TriCor
	Trilipix DR
	Vascepa
	WelChol
	Zetia

LIPOTROPICS: STATINS

Preferred Agents	Non-Preferred Agents
atorvastatin QL	Altoprev QL
lovastatin QL	amlodipine/atorvastatin CC, QL
pravastatin QL	Atorvaliq
rosuvastatin QL	Caduet QL
simvastatin QL	Crestor QL
	Ezallor Sprinkle QL
	ezetimibe/simvastatin QL
	Flolipid QL
	fluvastatin QL
	fluvastatin ER QL
	Lescol XL QL
	Lipitor QL
	Livalo QL
	pitavastin QL
	Vytorin QL
	Zocor QL
	Zypitamag QL

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GASTROINTESTINAL: ANTIEMETICS AND ANTIVERTIGO AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
dronabinol capsule CC, QL	• Diagnosis of nausea and/or vomiting (N/V) associated with cancer chemotherapy; **AND** ○ Trial and failure of ≥ 1 non-cannabinoid antiemetic (e.g. ondansetron); **OR** • Diagnosis of anorexia associated with weight loss in a patient with acquired immune deficiency syndrome (AIDS) or cancer. **Quantity Limit:** 2 per day
Diclegis CC, QL	• Patient is a pregnant female; **AND** • Diagnosis of nausea and vomiting of pregnancy. **Quantity Limit:** 4 per day

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **4** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
doxylamine/pyridoxine CC, QL	• Patient is a pregnant female; **AND** • Diagnosis of nausea and vomiting of pregnancy. **Quantity Limit:** 4 per day

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Agent(s) Subject to Criteria	Criteria for Approval

dronabinol solution [CC, QL]	• Diagnosis of nausea and/or vomiting (N/V) associated with cancer chemotherapy (CINV); **AND**
	  ○ Inadequate response to conventional antiemetic treatments; **AND**
	  ○ Trial and failure of, or contraindication/intolerance to, ≥1 additional conventional non-cannabinoid antiemetic from a different drug class (e.g., 5-HT3 receptor antagonist, NK1 receptor antagonist, corticosteroid, dopamine receptor antagonist); **OR**
	• Diagnosis of anorexia associated with weight loss in a patient with acquired immune deficiency syndrome (AIDS-Anorexia) **AND**
	• Unable to swallow whole dronabinol capsule; **AND**
	• Member has documentation for trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents in any sub-class, unless otherwise specified; **AND**
	• The requested dose does not exceed FDA approved dosing for diagnosis.
	
	Quantity Limit:
	(CINV): 30 mL per day
	(AIDS-Anorexia): 4mL per day

Gimoti [AE, CC, QL]	**Approval duration:** 8 weeks (initial and renewal)
	
	• Diagnosis of diabetic gastroparesis; **AND**
	• Prescribed by an endocrinologist, gastroenterologist or other specialist in the diagnosis and treatment of diabetic gastroparesis; **AND**
	• Prescriber attests that patient does NOT meet ANY of the following conditions:
	  ○ History of signs or symptoms of tardive dyskinesia (TD);
	  ○ History of a dystonic reaction to metoclopramide;
	  ○ Known or suspected circumstances where stimulation of gastrointestinal (GI) motility could be dangerous (e.g., GI hemorrhage, mechanical obstruction, or perforation);
	  ○ Known or suspected pheochromocytoma or other catecholamine-releasing paraganglioma;
	  ○ Diagnosis of epilepsy or any other seizure disorder;
	  ○ Hypersensitivity to metoclopramide (e.g., angioedema, bronchospasm);
	  ○ Moderate or severe renal impairment (creatinine clearance [CrCl] < 60 mL/minute);
	  ○ Moderate or severe hepatic impairment (Child-Pugh B or C); **AND**
	• Prescriber attests that each course of treatment, with all dosage forms and routes of administration of metoclopramide, will NOT extend beyond 12 weeks; **AND**
	• Adequate (e.g., 2-4 week) trial and failure of oral (e.g., tablet, solution, orally disintegrating tablet) or injectable (e.g., intramuscular) metoclopramide; **OR**
	• NOT a candidate for oral metoclopramide (e.g., demonstrated or documented erratic absorption of oral medications).

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Agent(s) Subject to Criteria	Criteria for Approval
	Renewal Criteria: • Must continue to meet initial authorization criteria; **AND** • At least 2 weeks have passed (i.e., drug holiday) since completion of a previous course of metoclopramide treatment of any dosage form; **AND** • Demonstrated improvement in signs and symptoms of diabetic gastroparesis (e.g., nausea, vomiting, early satiety, postprandial fullness, bloating, upper abdominal pain); **AND** • Prescriber attestation that the patient is being monitored for extrapyramidal symptoms (e.g., tardive dyskinesia, dystonia) or other serious adverse events (e.g., suicidal ideation, fluid retention). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 bottle per 28 days

Nereus AE, CC, QL	• Nereus is being used for prevention of vomiting induced by motion; **AND**
	• Member has been counseled on non-pharmacological interventions; **AND**
	• Member has a planned event expected to cause vomiting induced by motion; **AND**
	• Patient has tried and failed, or has an allergy, contraindication, (including potential drug-drug interactions with other medications), or intolerance of ≥ 2 preferred agents, including BOTH of the following:
	  ○ Transdermal scopolamine; **AND**
	  ○ ≥ 1 preferred or over-the-counter (OTC) first-generation antihistamine (e.g., meclizine, dimenhydrinate) verified by pharmacy claims.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 14 capsules per fill; 36 capsules per year

Sancuso CC, QL	• NPD criteria; **OR** • Used for preventing nausea and vomiting associated with moderately- or highly- emetogenic cancer chemotherapy.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
aprepitant QL	Akynzeo capsule QL
Diclegis CC, QL	Antivert
dronabinol capsule CC, QL	Bonjesta
meclizine tablet (RX)	Compro
metoclopramide solution, tablet	doxylamine/pyridoxine CC, QL
ondansetron ODT (except 16 mg), solution, tablet	dronabinol solution CC, QL
prochlorperazine tablet	Emend QL
promethazine suppository, syrup, tablet	Gimoti AE, CC, QL
Promethegan 12.5 mg, 25 mg suppository	granisetron tablet
scopolamine patch	meclizine chewable tablet (RX)

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Preferred Agents	Non-Preferred Agents
	Marinol CC, QL
	Nereus AE, CC, QL
	ondansetron ODT 16 mg QL
	prochlorperazine suppository
	Promethegan 50 mg suppository
	Reglan
	Sancuso CC, QL
	Transderm-Scop
	trimethobenzamide

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GASTROINTESTINAL: ANTIDIARRHEALS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Mytesi AE, CC, QL	**Approval Duration**: 6 months initial; 1 year renewal • Diagnosis of human immunodeficiency virus (HIV); **AND** • Current use of antiretroviral therapy for the treatment of HIV; **AND** • Active infection has been ruled out via fecal collection and microbiologic culture; **AND** • Trial and failure of 2 preferred agents. **Renewal Criteria:** • Documented reduction in the frequency and quantity of liquid stool volume for the previous 6 months; **AND** • Documented monitoring/follow-up plan that includes re-culture for microbiologic agents if breakthrough diarrhea occurs while on crofelemer therapy. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
diphenoxylate-atropine tablet	diphenoxylate-atropine liquid
loperamide capsule	Lomotil

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Preferred Agents	Non-Preferred Agents
	Motofen
	Mytesi AE, CC, QL
	Opium tincture

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GASTROINTESTINAL: ANTISPASMODICS/ANTICHOLINERGICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Cuvposa CC	• BMN criteria; **OR** • Inability to swallow whole or consume crushed glycopyrrolate tablets.
glycopyrrolate solution CC	• NPD criteria; **OR** • Inability to swallow whole or consume crushed glycopyrrolate tablets.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
dicyclomine capsule, solution, 20 mg tablet	chlordiazepoxide/clindinium capsule
ED-Spaz ODT	Cuvposa CC
glycopyrrolate tablet	Dartisla ODT
hyoscyamine sulfate drops	dicyclomine 40 mg tablet
hyoscyamine sulfate elixir	Glycate tablet
hyoscyamine sulfate ER tablet	glycopyrrolate solution CC
hyoscyamine sulfate ODT	Hyosyne elixir
hyoscyamine sulfate SL tablet	Levsin tablet
hyoscyamine sulfate tablet	Levsin/SL tablet
methoscopolamine tablet	Phenohytro tablet
NuLev ODT	Robinul Forte tablet
Oscimin SL tablet	Robinul tablet
Oscimin tablet	

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GASTROINTESTINAL: ANTI-ULCER PROTECTANTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Carafate suspension	Carafate tablet
misoprostol tablet	Cytotec tablet
sucralfate suspension	
sucralfate tablet	

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Bylvay CC, QL	**Progressive familial intrahepatic cholestasis (PFIC):**
	• Patient is diagnosed with progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2, confirmed by a genetic test; **AND**
	• Odevixibat is prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist, dermatologist); **AND**
	• Patient has elevated serum bile acid concentration; **AND**
	• Patient experiences persistent moderate to severe pruritus; **AND**
	• Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to at least 1 pruritus treatment (e.g., ursodiol, cholestyramine, rifampin, naloxone, naltrexone, antihistamine) *Note: use of these agents is off-label.*
	
	Renewal Criteria (PFIC):
	• Patient has experienced a reduction in serum bile acids from baseline; **AND**
	• Patient has experienced an improvement in pruritus.
	
	Alagille syndrome:
	• Patient is diagnosed with Alagille syndrome; **AND**
	• Odevixibat is prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist, dermatologist); **AND**
	• Patient has evidence of cholestasis, as evidenced by ≥ 1 of the following:
	  ○ Seum bile acid > 3 times upper limit of normal (ULN) for age;
	  ○ Conjugated bilirubin > 1 mg/dL;
	  ○ Gamma glutamyl transferase (GGT) > 3 times ULN for age;

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Fat soluble vitamin deficiency not otherwise explained; ○ Intractable pruritus only explained by liver disease; **AND** • Patient experiences persistent moderate to severe pruritus; **AND** • Patient has a history of trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to at least 1 pruritic treatment (e.g., ursodiol, cholestyramine, rifampin, naloxone, naltrexone, antihistamine). *Note: use of these agents is off-label.* **Renewal Criteria (Alagille syndrome):** • Patient has experienced a reduction in serum bile acids from baseline. **Quantity Limit:** • 200 mcg oral pellets: 2 per day; 60 per 30 days • 400 mcg capsule: 2 per day; 60 per 30 days • 600 mcg oral pellets: 5 per day; 150 per 30 days • 1,200 mcg capsule: 6 per day; 180 per 30 days
Cholbam CC, QL	**Approval Duration:** 6 months initial; 1 year renewal **Bile acid synthesis disorders due to single enzyme defects (SEDs):** • Patient is ≥ 3 weeks of age; **AND** • Patient is diagnosed with a bile acid synthesis disorder due to a single enzyme defect (SED), confirmed by one of the following: ○ Urinary or serum bile acid analysis by mass spectrometry (e.g., fast atom bombardment mass spectrometry [FAB-MS], liquid chromatography-tandem mass spectrometry [LC-MS/MS], or electrospray ionization tandem mass spectrometry); **OR** ○ Genetic testing confirming a pathogenic variant in a gene encoding an enzyme involved in bile acid synthesis (e.g., HSD3B7, AKR1D1, CYP7B1, AMACR, CYP27A1, BAAT); **AND** • Cholbam is prescribed by or in consultation with a hepatologist or pediatric gastroenterologist; **AND** • Patient has evidence of liver disease or malabsorption, as evidenced by ≥ 1 of the following: ○ Elevated serum transaminases (AST and/or ALT); **OR** ○ Elevated bilirubin (conjugated hyperbilirubinemia); **OR** ○ Abnormal INR/PT; **OR** ○ Evidence of steatorrhea; **OR** ○ Fat-soluble vitamin deficiency (A, D, E, or K); **AND** • Patient does not have complete biliary obstruction. **Renewal Criteria (Bile acid synthesis disorders due to SEDs):** • Documentation (e.g., progress notes, labs) of improvement or stabilization in liver function (e.g., AST, ALT, GGT, alkaline phosphatase, bilirubin, INR); **AND** • Prescriber attests that the patient continues to require Cholbam therapy. **Peroxisomal disorders (PDs) including Zellweger spectrum disorders:** • Patient is ≥ 3 weeks of age; **AND** • Patient is diagnosed with a peroxisomal disorder (PD) including Zellweger spectrum disorder, confirmed by one of the following:

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Biochemical testing (e.g., elevated very-long-chain fatty acids [VLCFAs], elevated bile acid intermediates [THCA/DHCA]); **OR** ○ Genetic testing confirming a pathogenic variant in a PEX gene or peroxisomal enzyme gene; **AND** • Cholbam is prescribed by or in consultation with a hepatologist or pediatric gastroenterologist; **AND** • Patient exhibits manifestations of ≥ 1 of the following: ○ Liver disease (e.g., elevated transaminases, hepatomegaly, cholestasis); **OR** ○ Steatorrhea; **OR** ○ Complications from decreased fat-soluble vitamin absorption; **AND** • Patient does not have complete biliary obstruction. **Renewal Criteria (PDs):** • Documentation (e.g., progress notes, labs) of improvement or stabilization in liver function (e.g., AST, ALT, GGT, alkaline phosphatase, bilirubin, INR) or fat-soluble vitamin levels; **AND** • Prescriber attests that the patient continues to require Cholbam therapy. **Quantity Limit:** 50 mg capsule: 4 per day 250 mg capsule: 4 per day
Iqirvo CC, QL	• Diagnosis of primary biliary cholangitis (PBC); **AND** • Prescribed by, or in consultation with a gastroenterologist, hepatologist, or other disease state specialist; **AND** • Patient meets one of the following: ○ Patient has had a 12-month trial and failure of ursodiol, and will take Iqirvo in addition to current therapy; **OR** ○ Patient has a contraindication or intolerance to ursodiol and will take Iqirvo as monotherapy; **AND** • Patient has an alkaline phosphatase (ALP) level greater than 200 IU/L; **AND** • Patient does not have decompensated cirrhosis; **AND** • Patient meets the minimum age recommended by the package insert. **Renewal Criteria:** • Documentation (e.g., progress notes, labs) of improvement or stabilization in alkaline phosphatase (ALP); **AND** • Patient meets one of the following: ○ Patient has had a 12-month trial and failure of ursodiol, and will take Iqirvo in addition to current therapy; **OR** ○ Patient has a contraindication or intolerance to ursodiol and will take Iqirvo as monotherapy. **Quantity Limit:** 1 per day
Livdelzi AE, CC, QL	• Diagnosis of primary biliary cholangitis (PBC); **AND** • Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or other disease state specialist; **AND** • Patient meets one of the following: ○ Patient has had a 12-month trial and failure of ursodiol, and will take Livdelzi in addition to current therapy; **OR**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Patient has a contraindication or intolerance to ursodiol and will take Livdelzi as monotherapy; **AND** • Patient has an alkaline phosphatase (ALP) level greater than 200 IU/L; **AND** • Patient does not have decompensated cirrhosis; **AND** • Patient meets the minimum age recommended by the package insert for the FDA-approved indication. **Renewal Criteria:** • Documentation (e.g., progress notes, labs) of improvement or stabilization in alkaline phosphatase (ALP); **AND** • Patient meets one of the following: ○ Patient has had a 12-month trial and failure of ursodiol and will take Livdelzi in addition to current therapy; **OR** ○ Patient has a contraindication or intolerance to ursodiol and will take Livdelzi as monotherapy. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Livmarli CC, QL	• Diagnosis of one of the following conditions: ○ Alagille Syndrome; **OR** ○ Progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2, confirmed by a genetic test; **AND** • Maralixibat is prescribed by or in consultation with a specialist (e.g., gastroenterologist, hepatologist, dermatologist); **AND** • Patient has evidence of cholestasis, as evidenced by ≥ 1 of the following: ○ Serum bile acid > 3 times upper limit of normal (ULN) for age; ○ Conjugated bilirubin > 1 mg/dL; ○ Gamma glutamyl transferase (GGT) > 3 times ULN for age; ○ Fat soluble vitamin deficiency not otherwise explained; ○ Intractable pruritus only explained by liver disease; **AND** • Patient experiences persistent moderate to severe pruritus; **AND** • Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to at least 1 pruritus treatment (e.g., ursodiol, cholestyramine, rifampin, naloxone, naltrexone, antihistamine, sertraline). *Note: use of these agents is off-label;* **AND** • Patient must meet the minimum age recommended by the package insert for the FDA-approved indication. **Renewal Criteria:** • Prescriber attests that the patient has experienced an improved clinical response (e.g., a reduction in serum bile acids from baseline, an improvement in pruritus). **Quantity Limit:** • 9.5 mg/mL oral solution: 3 mL per day • 19 mg/mL oral solution: 2 mL per day • 10 mg, 15 mg, 20 mg oral tablet: 2 per day • 30 mg oral tablet: 1 per day

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CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
ursodiol	Bylvay CC, QL
	Cholbam CC, QL
	Ctexli
	Iqirvo CC, QL
	Livdelzi AE, CC, QL
	Livmarli CC, QL
	Reltone
	Urso
	Urso Forte

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GASTROINTESTINAL: HELICOBACTER PYLORI (H. PYLORI) TREATMENT

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure of a complete course of therapy, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of the preferred agent **OR** combination therapy comprised of individual, generic agents (e.g. lansoprazole and amoxicillin and clarithromycin).

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Voquezna Dual Pak AE, CC, QL Voquezna Triple Pak AE, CC, QL	**Approval Duration:** 30 days • Diagnosis of diagnostically confirmed *H. pylori* infection; **AND** • Prescribed by, or in consultation with, a gastroenterologist or other specialist in the diagnosis and treatment of *H. pylori*; **AND** • Patient has had a ≥ 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Pylera. **Age Limit:** ≥ 18 years **Quantity Limit:** • Voquezna Dual Pak: 1 carton of 28 tablets and 84 capsules per 14-day supply • Voquezna Triple Pak: 1 carton of 56 tablets and 56 capsules per 14-day supply

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Pylera QL	bismuth subcitrate potassium/metronidazole/ tetracycline capsule QL
	lansoprazole/amoxicillin/clarithromycin pack QL
	Omeclamox-Pak QL

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Preferred Agents	Non-Preferred Agents
	Talicia
	Voquezna Dual Pak AE, CC, QL
	Voquezna Triple Pak AE, CC, QL

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GASTROINTESTINAL: HISTAMINE II (H2) RECEPTOR BLOCKERS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
famotidine suspension, tablet	cimetidine solution, tablet
	nizatidine capsule
	ranitidine tablet QL

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GASTROINTESTINAL: LAXATIVES AND CATHARTICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure **or** failed bowel preparation course, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Clenpiq solution	alvimopan capsule
constulose solution	
enulose solution	
Gavilyte-C	
Gavilyte-G	
Gavilyte-N	
generlac solution	
GoLytely solution	
Kristalose packet	
lactulose packet	
lactulose solution	
PEG 3350/Electrolyte solution	
PEG-3350 and Electrolytes	
PEG 3350/Sod Sul/NaCl/KCl/AsbC powder packet	
sodium sulfate/potassium sulfate/magnesium sulfate solution	
Suflave solution	
Suprep solution	
Sutab tablet	

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GASTROINTESTINAL: GASTROINTESTINAL MOTILITY AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

lubiprostone AE, CC, QL	• Diagnosis of one of the following conditions:
	  ○ Chronic idiopathic constipation (CIC); **OR**
	  ○ Irritable bowel syndrome with constipation (IBS-C); **OR**
	  ○ Opioid-induced constipation (OIC) associated with the treatment of chronic, non-cancer pain [including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation]; **AND**
	• Trial and failure of ≥ 1 over-the-counter (OTC) laxative (e.g., polyethylene glycol 3350).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 2 per day

Linzess AE, CC, QL	• Patient is at least 2 years old; **AND**
	  ○ Diagnosis of functional constipation (FC); **OR**
	• Patient is at least 7 years old; **AND**
	  ○ Diagnosis of irritable bowel syndrome with constipation (IBS-C); **AND**
	• Patient is at least 18 years old; **AND**
	  ○ Diagnosis of chronic idiopathic constipation (CIC); **AND**
	• Trial and failure of ≥ 1 over-the-counter (OTC) laxative (e.g., polyethylene glycol 3350) required for all indications above.
	
	Age Limit:
	72 mcg capsule: ≥ 2 years
	145 mcg capsule: ≥ 7 years
	290 mcg capsule ≥ 18 years
	
	Quantity Limit: 1 per day

Movantik AE, CC, QL	• Diagnosis of opioid-induced constipation (OIC) associated with the treatment chronic, non-cancer pain [including patients with chronic pain related to prior cancer or its treatment who do NOT require frequent (e.g., weekly) opioid dosage escalation]; **AND** • Trial and failure of ≥ 1 over-the-counter (OTC) laxative (e.g., polyethylene glycol 3350). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

alosetron AE, CC, QL
Lotronex AE, CC, QL
	• Diagnosis of severe irritable bowel syndrome with diarrhea (IBS-D); **AND**
	• Patient is female; **AND**
	• Trial and failure of the specified length of, contraindication or intolerance to, ≥ 3 agents among the following drug classes (used separately or in combination):
	  ○ Antidiarrheals (e.g., diphenoxylate/atropine, loperamide) for ≥ 1 month
	  ○ Bile acid sequestrants for ≥ 1 month
	  ○ Antispasmodics (e.g., dicyclomine, hyoscyamine) for ≥ 1 month.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 2 per day

Amitiza AE, CC, QL	• Diagnosis of one of the following conditions:
	  ○ Chronic idiopathic constipation (CIC); **OR**
	  ○ Irritable bowel syndrome with constipation (IBS-C); **OR**
	  ○ Opioid-induced constipation (OIC) associated with the treatment of chronic, non-cancer pain [including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation]; **AND**
	• Trial and failure of ≥ 1 over-the-counter (OTC) laxative (e.g., polyethylene glycol 3350); **AND**
	• Patient has had at least a 1-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents; **AND**
	• Patient has had a trial and failure (e.g., allergy or intolerance to an inactive ingredient) with at least **TWO** manufacturers (if available) of the corresponding generic.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 2 per day

Ibsrela AE, CC, QL	• Diagnosis of severe irritable bowel syndrome with constipation (IBS-C); **AND** • Patient does NOT have known or suspected mechanical GI obstruction; **AND** • Patient does NOT have severe diarrhea; **AND** • Patient has failed on 1 of the following regimens: ○ Osmotic laxatives; **OR**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Antispasmodics; **AND** • Patient has had at least a 1-month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day
Symproic AE, CC, QL	• Diagnosis of opioid-induced constipation (OIC) related to chronic non-cancer pain [including patients with chronic pain related to prior cancer or its treatment who do NOT require frequent (e.g., weekly) opioid dosage escalation]; **AND** • Patient has been using opioids for at least 150 days within past 180 days; **AND** • Trial and failure of ≥ 2 preferred agents in this class; **AND** • Trial and failure of ≥ 2 different laxative drug classes, such as: ○ Stool softeners (e.g., docusate); ○ Stimulant laxatives (e.g., bisacodyl, sennosides); ○ Osmotic or saline laxatives (e.g., polyethylene glycol 3350); ○ Bulk forming laxatives (e.g., psyllium); ○ Lubricant laxatives (e.g., mineral oil). • Patient does NOT have any the following conditions: ○ Known or suspected gastrointestinal obstruction; ○ Pregnancy; ○ Severe hepatic impairment (Child-Pugh Class C). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Viberzi AE, CC, QL	• Diagnosis of irritable bowel syndrome with diarrhea (IBS-D); **AND** • Trial and failure of the specified length of, contraindication, or intolerance to, ≥ 3 agents among the following drug classes (used separately or in combination): ○ Antidiarrheals (e.g., diphenoxylate/atropine, loperamide) for ≥ 1 month; ○ Bile acid sequestrants for ≥ 1 month; ○ Antispasmodics (e.g., dicyclomine, hyoscyamine) for ≥ 1 month. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Linzess AE, CC, QL	alosetron AE, CC, QL
lubiprostone AE, CC, QL	Amitiza AE, CC, QL
Movantik AE, CC, QL	Ibsrela AE, CC, QL
	Lotronex AE, CC, QL
	Motegrity AE, CC, QL
	Prucalopride AE, QL
	Symproic AE, CC, QL
	Viberzi AE, CC, QL

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 2-week** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Konvomep [CC, QL]	• Patient had at least a 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 2 preferred agents; **OR**
	• For G-tube administration, the patient had at least a 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to the preferred liquid agent of Nexium suspension packets [Rx only].
	
	For twice daily dosing:
	• Patient has at least one of the following:
	  ○ Diagnosis of *H. pylori;* **AND/OR**
	  ○ Had at least a 2-week trial and failure of once daily dosing.
	
	Renewal Criteria:
	• Patient has been on this medication and the request is for once daily dosing; **OR**
	• Patient has a reconfirmation diagnosis of *H. pylori* infection or a trial of once daily dosing after initial course of therapy; **OR**
	• Patient has undergone diagnostic testing (i.e., endoscopy, UGI, EGD with biopsy, serum gastrin or serum secretin stimulation test) to confirm one of the following diagnoses
	  ○ Barrett's Esophagus
	  ○ Schatzki's Ring
	  ○ A hypersecretory condition (including but not limited to Zollinger-Ellison Syndrome, Multiple Endocrine Adenoma, Systemic Mastocytosis)
	  ○ Hyperacidity in Cystic Fibrosis Recipients, Achalasia, CREST syndrome, Scleroderma, Sarcoid; **OR**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Patient has attempted 'step-down' therapy at any time from multiple to single daily dosing for at least 2 weeks. **Quantity Limit:** 20 mL per day
Voquezna AE, CC, QL	**Erosive Esophagitis:** **Approval Duration:** 8 weeks initial; 6 months renewal • Diagnosis of diagnostically confirmed erosive esophagitis; **AND** • Prescribed by, or in consultation with, a gastroenterologist or other specialist in the diagnosis and treatment of erosive esophagitis; **AND** • Patient has had a ≥ 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 2 preferred agents in this PDL class. **Renewal Criteria (Erosive Esophagitis):** • Diagnosis of diagnostically confirmed erosive esophagitis; **AND** • Prescribed by, or in consultation with, a gastroenterologist or other specialist in the diagnosis and treatment of erosive esophagitis; **AND** • Patient has experienced symptom improvement or control during initial treatment course. **Non-Erosive Gastroesophageal Reflux Disease:** **Approval Duration:** 4 weeks initial; 20 weeks renewal • Diagnosis of non-erosive gastroesophageal reflux disease; **AND** • Prescribed by, or in consultation with, a gastroenterologist; **AND** • Patient has had a ≥ 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 2 preferred agents in this PDL class. **Renewal Criteria (Non-Erosive GERD):** • Diagnosis of non-erosive gastroesophageal reflux disease; **AND** • Prescribed by, or in consultation with, a gastroenterologist; **AND** • Patient has received no more than one 20-week authorization in the past 365 days; **AND** • Patient has experienced symptom improvement or control during initial treatment course. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
esomeprazole capsule QL	Aciphex tablet QL
lansoprazole capsule QL	Dexilant capsule QL
Nexium suspension QL	dexlansoprazole DR capsule QL
omeprazole capsule QL	esomeprazole suspension QL
pantoprazole tablet QL	Konvomep suspension CC, QL
	lansoprazole ODT QL
	Nexium capsule QL
	omeprazole/sodium bicarbonate capsule QL
	omeprazole/sodium bicarbonate packet QL
	pantoprazole suspension QL
	Prevacid capsule QL
	Prevacid tablet QL
	Prilosec suspension QL
	Protonix suspension QL

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Preferred Agents	Non-Preferred Agents
	Protonix tablet QL
	rabeprazole tablet QL
	Voquezna tablet AE, CC, QL

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GATROINTESTINAL: ULCERATIVE COLITIS AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
balsalazide	Azulfidine
Lialda	budesonide ER tablet
mesalamine	budesonide rectal foam
Pentasa	Canasa
sulfasalazine tablet	Dipentum
sulfasalazine DR tablet	mesalamine DR/ER
	Rowasa enema kit

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RESPIRATORY: ANTIBIOTICS, INHALED

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Arikayce [AE, CC, QL]	**Approval Duration:** 3 months initial; 1 year renewal
	
	• Diagnosis of mycobacterium avium complex (MAC) lung disease as determined by the following:
	  ○ Chest radiography or high-resolution computed tomography (HRCT) scan; **AND**
	  ○ At least 2 positive sputum cultures; **AND**
	  ○ Other conditions such as tuberculosis and lung malignancy have been ruled out; **AND**
	• Patient has failed a multi-drug regimen with a macrolide (clarithromycin or azithromycin), rifampin, and ethambutol. (Failure is defined as continual positive sputum cultures for MAC while adhering to a multi-drug treatment regimen for a minimum duration of 6 months); **AND**
	• Patient has documented failure or intolerance to aerosolized administration of amikacin solution for injection, including pretreatment with a bronchodilator (cavitary or advanced/severe bronchiectatic or macrolide-resistant MAC pulmonary disease ONLY); **AND**
	• Arikayce will be prescribed in conjunction with a multi-drug antimycobacterial regimen.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 1 kit per 28 days (1 vial per day)

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CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Bethkis QL	Arikayce AE, CC, QL
Kitabis Pak QL	Cayston QL
tobramycin inhalation solution QL (generic for TOBI)	TOBI QL
	TOBI Podhaler QL
	tobramycin inhalation solution QL (generic for Bethkis and Kitabis Pak)

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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RESPIRATORY: ANTIHISTAMINES, MINIMALLY SEDATING

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
cetirizine solution	Clarinex tablet
levocetirizine tablet	Clarinex-D 12 HR tablet
	desloratadine ODT
	desloratadine oral solution
	desloratadine tablet
	levocetirizine solution

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RESPIRATORY: INTRANASAL RHINITIS AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Xhance CC	• Diagnosis of chronic rhinosinusitis with or without nasal polyps; **AND** • Trial and failure of high-dose generic fluticasone nasal spray.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
azelastine nasal spray	azelastine/fluticasone nasal spray QL
Dymista nasal spray QL	flunisolide nasal spray QL
fluticasone propionate nasal spray QL	mometasone nasal spray QL
ipratropium bromide nasal spray	oloptadine nasal spray
	Omnaris nasal spray QL
	Qnasl Children HFA QL
	Qnasl HFA QL
	Ryaltris nasal spray
	Xhance nasal spray CC

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RESPIRATORY: LEUKOTRIENE MODIFIERS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
montelukast granules AE, CC, QL	• Under 6 years of age: no authorization required. • 6 years of age and older: clinical rationale that chewable or tablet cannot be used.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
montelukast granules AE, CC, QL	Accolate QL
montelukast chewable tablet QL	Singulair QL
montelukast tablet QL	zafirlukast QL
	zileuton ER QL
	Zyflo QL

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RESPIRATORY: BRONCHODILATORS, BETA-AGONIST

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 14-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent within the same sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
AirDuo Respiclick AE, CC, QL	• Trial and failure of at least two preferred agents, one of which must be Advair Diskus or Advair HFA. **Age Limit:** ≥ 12 years **Quantity Limit:** 1 inhaler per 30 days
arformoterol AE, CC, QL formoterol AE, CC, QL	• Diagnosis of chronic obstructive pulmonary disorder (COPD); **AND** • Documentation of spirometry measurement; **AND** • NOT using any other long-acting beta adrenergic agonists (LABAs); **AND** • Must have a prescription for rescue therapy. **Age Limit:** ≥ 18 years **Quantity Limit:** 4 mL per day

CURRENT PDL STATUS

BETA AGONISTS: COMBINATION PRODUCTS

Preferred Agents	Non-Preferred Agents
Advair Diskus QL	AirDuo Respiclick AE, CC, QL
Advair HFA QL	Breo Ellipta QL
Dulera HFA QL	Breyna HFA QL

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Preferred Agents	Non-Preferred Agents
Symbicort HFA QL	budesonide/formoterol HFA QL
	fluticasone/salmeterol 55-14mcg, 113-14mcg, 232-14mcg (generic AirDuo Respiclick) QL
	fluticasone/salmeterol 100-50mcg, 250-50mcg, 500-50mcg (generic Advair Diskus) QL
	fluticasone/salmeterol HFA 115-21mcg, 230-21mcg, 45-21 mcg (generic Advair HFA) QL
	fluticasone/vilanterol QL
	Wixela Inhub QL

LONG-ACTING BETA$_2$ ADRENERGIC AGONISTS

Preferred Agents	Non-Preferred Agents
Serevent Diskus QL	arformoterol solution AE, CC, QL
	Brovana solution CC, QL
	formoterol solution AE, CC, QL
	Perforomist CC, QL
	Striverdi Respimat QL

SHORT-ACTING BETA$_2$ ADRENERGIC AGONISTS

Preferred Agents	Non-Preferred Agents
albuterol sulfate inhalation solution QL, syrup QL	Airsupra HFA QL
albuterol sulfate HFA (except NDC 66993-0019-68) QL	albuterol sulfate HFA (NDC 66993-0019-68) QL
terbutaline tablet QL	albuterol sulfate ER tablet QL
	albuterol sulfate tablet QL
	levalbuterol inhalation concentrate/solution QL
	levalbuterol HFA QL
	ProAir Respiclick QL
	Ventolin HFA QL
	Xopenex HFA QL

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RESPIRATORY: GLUCOCORTICOIDS, INHALED

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
budesonide inhalation suspension AE, CC, QL	• Under 8 years of age: no prior authorization required. • 8 years of age and older: clinical rationale (e.g., trial and failure, comorbid condition) that a metered dose inhaler (e.g., Asmanex HFA/Twisthaler) cannot be used. **Quantity Limit:** 1 ampule (2 mL) per day

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Arnuity Ellipta QL	Alvesco QL
Asmanex HFA QL	beclomethasone dipropionate HFA
Asmanex Twisthaler QL	fluticasone furoate ellipta QL
budesonide inhalation suspension AE, CC, QL	fluticasone propionate Diskus QL
	fluticasone propionate HFA QL
	Pulmicort Respules QL
	Qvar Redihaler

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RESPIRATORY: EPINEPHRINE, SELF-INJECTABLE

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
epinephrine 0.3 mg autoinjector QL	Auvi-Q QL
epinephrine 0.15 mg autoinjector QL	Neffy QL
EpiPen QL	
EpiPen Jr. QL	

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RESPIRATORY: CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Breztri Aerosphere AE, CC, QL	**Asthma:** • Diagnosis of asthma; **AND** • 4-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to dual-combination therapy (i.e., ICS/LABA such as Advair Diskus, Advair HFA, Dulera HFA, or Symbicort HFA); **AND** • Patient meets the minimum age recommended by the package insert for this indication. **COPD:** • Diagnosis of chronic obstructive pulmonary disorder (COPD); **AND** • 4-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to dual-combination therapy (i.e., LABA/LAMA such as Anoro Ellipta or Stiolto Respimat); **AND** • Patient meets the minimum age recommended by the package insert for this indication. **Quantity Limit:** 1 inhaler per 30 days
roflumilast CC, QL	• Diagnosis of chronic obstructive pulmonary disorder (COPD); **AND** • Documentation (e.g., progress notes) of $FEV_1 \leq 50\%$ of predicted. **Quantity Limit:** 1 per day
Trelegy Ellipta AE, CC, QL	**Asthma:** • Diagnosis of asthma; **AND** • 4-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to dual-combination therapy (i.e., ICS/LABA such as Advair Diskus, Advair HFA, Dulera HFA, or Symbicort HFA); **AND** • Patient meets the minimum age recommended by the package insert for this indication. **COPD:** • Diagnosis of chronic obstructive pulmonary disease (COPD); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• 4-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to dual-combination therapy (i.e., LABA/LAMA such as Anoro Ellipta or Stiolto Respimat); **AND** • Patient meets the minimum age recommended by the package insert for this indication. **Quantity Limit:** 2 blisters (1 inhalation) per day

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 14-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Daliresp AE, CC, QL	• Diagnosis of chronic obstructive pulmonary disorder (COPD); **AND** • Trial and failure of ≥ 1 inhaled therapy; **AND** • Documentation (e.g., progress notes) of FEV_1 ≤ 50% of predicted. **Quantity Limit:** 1 per day

Ohtuvayre AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Diagnosis of moderate to severe chronic obstructive pulmonary disorder; **AND**
	• Trial and failure of at least a 2-week trial of standard of care therapy:
	  ○ Triple-ingredient therapy (inhaled corticosteroids [ICS], long-acting beta agonist [LABA], and long-acting muscarinic antagonist [LAMA]); **OR**
	  ○ Dual-ingredient therapy (long-acting beta agonist [LABA]/long-acting muscarinic agent [LAMA])
	AND
	• Patient meets the minimum age recommended by the package insert.
	
	Renewal Criteria:
	• Clinically significant improvement or stabilization in signs and symptoms.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 5 mL per day

Yupelri AE, CC, QL	• Diagnosis of chronic obstructive pulmonary disorder (COPD); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Demonstrate treatment failure with 1 other long-acting muscarinic antagonist (LAMA) agent due to technique/delivery mechanism (e.g., cannot use inhaler) **Age Limit:** ≥ 18 years **Quantity Limit:** 1 vial (3 mL) per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
albuterol-ipratropium inhalation solution QL	Bevespi Aerosphere QL
Anoro Ellipta QL	Daliresp AE, CC, QL
Atrovent HFA QL	Duaklir Pressair
Breztri Aerosphere AE, CC, QL	Incruse Ellipta QL
Combivent Respimat QL	ipratropium bromide HFA QL
ipratropium inhalation solution QL	Ohtuvayre AE, CC, QL
roflumilast CC, QL	Spiriva Respimat QL
Spiriva Handihaler QL	tiotropium QL
Stiolto Respimat QL	Tudorza Pressair QL
Trelegy Ellipta AE, CC, QL	umeclidinium ellipta QL
	umeclidinium-vilanterol QL
	Yupelri AE, CC, QL

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CENTRAL NERVOUS SYSTEM: ALZHEIMER'S AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 1-week** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
donepezil 23 mg CC	• Use of donepezil 10 mg tablets for ≥ 90 days.
Leqembi IQLIK AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal • Patient has a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) or mild dementia associated with AD dementia; **AND** • Prescribed by, or in consultation with, a neurologist, geriatrician, psychiatrist, or other dementia specialist; **AND** • Patient has completed 18 months of intravenous (IV) infusions of Leqembi; **AND** • Prior to initiation of Leqembi IV, there was confirmation of beta-amyloid plaques; **AND** • Prior to initiation of Leqembi IV, there was documentation of baseline disease severity utilizing one of the following scores: ○ Mini-Mental Status Exam (MMSE); **OR** ○ Montreal Cognitive Assessment (MoCA); **OR** ○ Clinical Dementia Rating (CDR)-Global; **AND** • Prior to initiation of Leqembi IV, there was documentation of a brain MRI; **AND** • Prior to initiation of Leqembi IV, there was genotype testing for ApoE ε4 status; **AND** • Leqembi IQLIK will not be combined with other amyloid beta-directed antibodies (e.g., aducanumab).

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Agent(s) Subject to Criteria	Criteria for Approval

	Renewal Criteria:
	• Positive clinical response as evidenced by stabilization or slowing of disease progression as documented by ONE of the following:
	  ○ MMSE (e.g., decline of 3 points or less per year); **OR**
	  ○ MoCA (e.g., score of greater than or equal to 15); **OR**
	  ○ CDR-Global Score (i.e., score of 0.5 or 1).
	
	Age Limit: ≥ 50 years of age and ≤ 90 years of age
	Quantity Limit:
	250 mg auto-injector: 10 mL per 28 days (1 syringe per week)
	360 mg auto-injector: 7.2 mL per 28 days (1 syringe per week)

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
donepezil ODT	Adlarity patch
donepezil 5 mg, 10 mg tablet	Aricept
Exelon patch	donepezil 23 mg tablet CC
memantine tablet, dose pack	galantamine solution, tablet
rivastigmine capsule	galantamine ER capsule
	Leqembi IQLIK AE, CC, QL
	memantine/donepezil ER sprinkle capsule
	memantine ER sprinkle capsule
	memantine solution
	Namenda
	Namenda XR
	Namzaric
	rivastigmine patch
	Zunveyl QL

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GUIDELINES FOR USE

Approval Duration: 1 year (non-preferred approval)

1. MAXIMUM DURATION (MD) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
alprazolam IR tablet MD chlordiazepoxide MD diazepam oral solution, tablet MD diazepam oral concentrate MD lorazepam MD Loreev XR CC, MD alprazolam ER/XR CC, MD alprazolam intensol CC, MD alprazolam ODT CC, MD clorazepate MD diazepam intensol CC, MD lorazepam intensol CC, MD oxazepam MD Xanax MD Xanax XR CC, MD	Preferred antianxiety benzodiazepines are available without a prior authorization for up to 60-day supply (cumulative) per rolling year. Approve for **1 month** for the following diagnosis: • Acute alcohol withdrawal Approve for **6 months** for the following diagnoses / situations: • Agoraphobia • Anxiety • Anxiety disorder • Chemotherapy-induced nausea & vomiting • Depression • Panic attacks or panic disorder • Social phobia • Status epilepticus Approve for **1 year** for the following diagnosis: • Seizures/Epilepsy **NOTE:** Prescriber (not pharmacy) must submit prior authorization request.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
alprazolam intensol oral concentrate CC, MD alprazolam ODT CC. MD	• Therapeutic failure to at least a **ONE**-month trial of the tablet formulation of the drug being requested; **OR** • Clinical reason why the tablets cannot be used.

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Agent(s) Subject to Criteria	Criteria for Approval
diazepam oral concentrate CC, MD lorazepam intensol oral concentrate CC, MD	
Loreev XR capsule CC, MD Xanax XR tablet CC, MD alprazolam XR tablet CC, MD alprazolam ER tablet CC, MD	• NPD criteria; **AND** • ONE of the following: ○ Documented therapeutic failure of an adequate trial (at least one month) of IR formulation of the same drug at optimized dosing (i.e., multiple daily doses), with evidence that the extended-release formulation would address the reason for failure (e.g., breakthrough symptoms between doses, adherence issues related to multiple daily dosing); **OR** ○ A documented clinical reason that IR formulation of the same drug given multiple times daily cannot be used (e.g., documented significant non-adherence to multi-dose regimens contributing to treatment failure, despite interventions to improve adherence).

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
alprazolam IR tablet MD	alprazolam ER tablet CC, MD
buspirone tablet (except 2.5 mg and 12.5 mg) MD	alprazolam intensol oral concentrate CC, MD
chlordiazepoxide capsule MD	alprazolam ODT CC, MD
diazepam oral solution MD	alprazolam XR tablet CC, MD
diazepam tablet MD	Bucapsol capsule
lorazepam tablet MD	buspirone 2.5 mg, 12.5 mg tablet MD
	clorazepate dipotassium tablet MD
	diazepam oral concentrate CC, MD
	lorazepam intensol oral concentrate CC, MD
	lorazepam oral concentrate MD
	Loreev XR capsule CC, MD
	meprobamate tablet
	oxazepam capsule MD
	Xanax tablet MD
	Xanax XR tablet CC, MD

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval
Banzel CC, QL	• Diagnosis of Lennox-Gastaut Syndrome (LGS); **OR** • Trial and failure of 1 anticonvulsant.
brivaracetam AE, CC, QL	• Diagnosis of partial-onset seizures; **AND** • ≥ 1 month of age. **Quantity Limit:** **Solution:** 20 mL per day **Tablet:** 2 per day

Epidiolex AE, CC	• Patient is ≥ 1 year old; **AND**
	• Diagnosis of:
	  ○ Lennox-Gastaut syndrome (LGS); OR
	  ○ Dravet syndrome (DS); **OR**
	  ○ Tuberous Sclerosis Complex (TSC).

phenobarbital CC	**Approval Duration:** Lifetime • Diagnosis of epilepsy or seizure/convulsive disorder (ICD-10 Disease Group G40). **Approval Duration:** 1 month • Diagnosis of alcohol withdrawal (ICD-10 Disease Group F10).
primidone CC	**Approval Duration:** Lifetime • Diagnosis of epilepsy (ICD-10 Disease Group G40) • Diagnosis of tremor [G25.0 (essential tremor) or R25.1 (tremor, unspecified)].
Sabril CC, QL	• Diagnosis of infantile spasms (IDC-10 = G40.401, G40.409, G40.411, G40.419); **OR** • Trial and failure of 1 anticonvulsant **Quantity Limit:** 6 packets/tablets per day

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Briviact AE, CC, QL	• Diagnosis of partial-onset seizures; **AND** • Trial and failure of at least 1 preferred agent; **AND** • ≥ 1 month of age. **Quantity Limit:** **Solution:** 20 mL per day **Tablet:** 2 per day

clobazam syringe AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS); **AND**
	• Provider has submitted documentation supporting medical necessity for the 10mg/4mL syringe over the preferred 2.5mg/mL suspension, due to at least **ONE** of the following:
	  ○ Volume/dosing limitations: Patient requires smaller volumes per dose for accuracy or compatibility with specialized devices (e.g., G-tube);
	  ○ Intolerance: Documented adverse effects (e.g., GI upset, flavor aversion) impacting adherence;
	  ○ Measurement barriers: Inability to accurately measure doses with the 2.5mg/mL syringe due to calibration limitations.
	
	Renewal Criteria:
	• Patient continues to meet the above criteria; **AND**
	• Provider attests to improvement in seizure control or other relevant clinical outcome from baseline.
	
	Age Limit: ≥ 2 years
	Quantity Limit: 16mL per day

Diacomit CC, QL	• Diagnosis of Dravet syndrome; **AND** • Prescriber is, or has a consultative relationship with, a neurology/epilepsy specialist; **AND** • Medication will be used in combination with clobazam; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Trial and failure (e.g., incomplete seizure control) of ≥ 2 anticonvulsants.
Spritam CC, QL levetiracetam tablet for suspension CC, QL	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to levetiracetam solution, levetiracetam tablet, and Spritam tablet suspension; **AND** • Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with at least 2 manufacturers (if available and covered) of levetiracetam solution and levetiracetam tablet; **AND** • Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the brand Spritam tablet suspension. **Quantity Limit:** 2 per day
Sympazan AE, CC, QL	• Diagnosis of Lennox-Gastaut syndrome (LGS); **AND** • Clinical rationale that clobazam suspension or tablets cannot be used. **Age Limit:** ≥ 2 years **Quantity Limit:** 2 per day
Vigafyde CC, QL	• Diagnosis of infantile spasms (IDC-10 = G40.401, G40.409, G40.411, G40.419); OR • Trial and failure of 1 anticonvulsant; **AND** • Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in Sabril.
Xcopri AE, CC, QL	• Diagnosis of partial-onset seizures; **AND** • Trial and failure of ≥ 1 preferred agent; **AND** • NOT have familial QT syndrome; **AND** • NOT have severe hepatic impairment (Child-Pugh Class C). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day: 25 mg, 50 mg, 100 mg tablets; titration blister packs 2 per day: 150 mg, 200 mg; 250 and 350 mg maintenance blister packs
Ztalmy AE, CC, QL	**Approval Duration:** 1 year (initial and renewal) **Initial Approval Criteria** • Patient is ≥ 2 years of age; **AND** • Patient has a diagnosis of seizures associated with cyclin dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) confirmed with genetic testing; **AND** • Patient has tried ≥ 2 other anticonvulsant medications; **AND** • Patient will avoid concomitant therapy with moderate or strong CYP450 inducers (e.g., carbamazepine, phenobarbital, phenytoin, omeprazole), or if concomitant therapy is unavoidable, dose adjustments will be considered; **AND** • Ganaxolone is prescribed by or in consultation with a neurologist.

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Agent(s) Subject to Criteria	Criteria for Approval
	Renewal Criteria: • Patient must continue to meet the above criteria; **AND** • Prescriber attests to stabilization of disease or reduction in seizure frequency from baseline. **Age Limit:** ≥ 2 years **Quantity Limit:** 1800mg (36mL) per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Banzel CC, QL	Aptiom QL
brivaracetam AE, CC, QL	Briviact AE, CC, QL
carbamazepine tablet, chewable tablet	carbamazepine suspension
carbamazepine ER	Carbatrol ER
Celontin	clobazam syringe 10 mg/4mL AE, CC, QL
clobazam oral suspension 2.5 mg/mL QL	clonazepam ODT QL
clobazam tablet QL	Depakote sprinkle
clonazepam tablet QL	Depakote ER/DR
diazepam rectal gel QL	Diacomit CC, QL
divalproex sodium DR sprinkle capsule	Dilantin
divalproex sodium DR/ER tablet	Elepsia XR QL
Epidiolex AE, CC	Eprontia
Equetro	eslicarbazepine QL
ethosuximide	Felbatol
felbamate	Fintepla AE, QL
lacosamide solution QL	Fycompa suspension
lacosamide tablet QL	Fycompa tablet QL
lamotrigine tablet (except dose packs)	Keppra solution
lamotrigine dispersing chewable tablet	Keppra tablet QL
levetiracetam ER QL	Keppra XR tablet QL
levetiracetam solution QL	Klonopin QL
levetiracetam tablet QL	Lamictal dispersing chewable tablet
Nayzilam AE, QL	Lamictal ODT
oxcarbazepine tablet QL	Lamictal ODT start kit/dose pack
oxcarbazepine suspension	Lamictal tablet
phenobarbital elixir CC	Lamictal tablet start kit/dose pack
phenobarbital tablet CC	Lamictal XR tablet QL
phenytoin suspension, chewable tablet	Lamictal XR start kit/dose pack
phenytoin sodium ER capsule	lamotrigine ER tablet QL
primidone	lamotrigine ODT
Roweepra QL	lamotrigine ODT start kit/dose pack
Sabril CC, QL	lamotrigine tablet start kit/dose pack
Tegretol suspension	levetiracetam tablet for oral suspension CC, QL
tiagabine QL	methsuximide
topiramate sprinkle capsule QL	Motpoly XR
topiramate tablet QL	Onfi QL
valproic acid	oxcarbazepine ER QL
Valtoco QL	Oxtellar XR QL
zonisamide capsule QL	perampanel tablet QL
	Phenytek
	rufinamide QL
	Spritam CC, QL
	subvenite oral suspension AE, QL

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Preferred Agents	Non-Preferred Agents
	subvenite tablet, dose pack
	Sympazan AE, CC, QL
	Tegretol tablet
	Tegretol XR
	Topamax sprinkle capsule QL
	Topamax tablet QL
	topiramate ER capsule QL
	topiramate ER sprinkle capsule QL
	topiramate solution
	Trileptal suspension
	Trileptal tablet QL
	Trokendi XR QL
	vigabatrin QL
	vigadrone QL
	Vigafyde CC, QL
	Vimpat QL
	Xcorpi tablet daily dose pack AE, CC, QL
	Xcorpi tablet AE, CC, QL
	Xcopri titration pack AE, CC
	Zarontin
	zonisamide suspension QL
	Ztalmy AE, CC, QL

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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CENTRAL NERVOUS SYSTEM: ANTIPSYCHOTICS: FIRST GENERATION (TYPICAL)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with ≥ 2 manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
amitriptyline/perphenazine tablet	Adasuve inhalation powder
chlorpromazine tablet	molindone tablet
chlorpromazine oral concentrate	pimozide
fluphenazine elixir	
fluphenazine oral concentrate	
fluphenazine tablet	
haloperidol oral concentrate	
haloperidol tablet	
loxapine capsule	
perphenazine tablet	
thioridazine tablet	
thiothixene capsule	
trifluoperazine tablet	

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CENTRAL NERVOUS SYSTEM: ANTIPSYCHOTICS: SECOND GENERATION (ATYPICAL) AND INJECTABLE

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval
aripiprazole tablets CC, QL asenapine CC, QL clozapine tablets CC, QL lurasidone CC, QL quetiapine CC, QL quetiapine ER CC, QL risperidone CC, QL ziprasidone capsules CC, QL Abilify Maintena AE, CC, QL Aristada ER AE, CC, QL Aristada Initio AE, CC, QL fluphenazine decanoate AE, CC, QL Geodon injection AE, CC, QL haloperidol decanoate AE, CC, QL haloperidol lactate AE, CC, QL Invega Sustenna AE, CC, QL olanzapine ODT, tablet CC, QL olanzapine vial AE, CC, QL Perseris ER AE, CC Risperdal Consta AE, CC, QL	• Diagnosis of any of the following conditions: ○ Dementias (ICD-10 Disease Groups F01, F02, F03, F06); ○ Dissociative and conversion disorders (ICD-10 Disease Group F44); ○ Episodic Mood Disorders (ICD-10 Disease Groups F30, F31, F39); ○ Huntington's disease (ICD-10 Disease Group G10); ○ Major depressive disorder (ICD-10 Disease Groups F32, F33); ○ Oppositional defiant disorder (ICD-10 = F91.3); ○ Pervasive developmental disorders (ICD-10 Disease Group F84); ○ Schizoaffective disorder (F25.9); ○ Schizophrenic Disorders (ICD-10 Disease Group F20; ICD-10 = F60.1); ○ Tic disorder (ICD-10 Disease Group F95); ○ Substance use disorders and related conditions (see below for list).
Abilify Asimtufii AE, CC, QL	• Patient has a diagnosis of bipolar disorder or schizophrenia **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe every 56 days
Invega Hafyera AE, CC, QL	• Patient is ≥ 18 years of age; **AND** • Patient has a confirmed diagnosis of schizophrenia; **AND** • Patient has received a minimum of 4 months of monthly injections with Invega Sustenna with adequate response and acceptable patient tolerance; **OR** • Patient has received a minimum of one 3-month injection of Invega Trinza with adequate response and acceptable patient tolerance. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe per 56 days
Invega Trinza AE, CC, QL	• Patient is ≥ 18 years of age; **AND** • Patient has a confirmed diagnosis of schizophrenia; **AND**

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to PA Criteria	Criteria for Approval
	• Patient has received a minimum of 4 months of monthly injections with Invega Sustenna with adequate response and acceptable patient tolerance. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe per 90 days

Uzedy AE, CC, QL	• Patient has a diagnosis of schizophrenia OR bipolar 1 disorder; **AND**
	• If used for bipolar I disorder, will be used for either:
	  ○ Maintenance monotherapy treatment; **OR**
	  ○ Maintenance therapy as adjunct to lithium or valproate.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 1 syringe per 30 days

Vraylar AE, CC, QL	**Age Limit:** ≥ 10 years: • Acute manic or mixed episodes associated with bipolar I disorder (ICD-10 Disease Group F31) **Age Limit:** ≥ 13 years: • Schizophrenic Disorders (ICD-10 Disease Group F20; ICD-10 = F60.1) **Age Limit:** ≥ 18 years: • Dementias (ICD-10 Disease Groups F01, F02, F03, F06); • Dissociative and conversion disorders (ICD-10 Disease Group F44); • Episodic Mood Disorders (ICD-10 Disease Groups F30, F39); • Huntington's disease (ICD-10 Disease Group G10); • Major depressive disorder (MDD) (ICD-10 Disease Groups F32, F33); ○ **Note:** If used as adjunctive therapy for MDD: documentation of current use of, or trial and failure of, contraindication, or intolerance to ≥ 1 antidepressant of adequate dose and duration (e.g., SSRI, SNRI, bupropion, mirtazapine). • Oppositional defiant disorder (ICD-10 = F91.3); • Pervasive developmental disorders (ICD-10 Disease Group F84); • Schizoaffective disorder (F25.9); • Tic disorder (ICD-10 Disease Group F95); • Substance use disorders and related conditions (see below for list). **Quantity Limit:** 1 per day

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	F60.1	Schizoid personality disorder
F01		Vascular dementia

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Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
F02		Dementia in other diseases classified elsewhere
F03		Unspecified dementia
F06		Other mental disorders due to known physiological condition
F20		Schizophrenia, schizotypal and delusional, and other non-mood psychotic disorders
	F25.9	Schizoaffective disorder, unspecified
F30		Manic episode
F31		Bipolar disorder
F32		Major depressive disorder, single episode
F33		Major depressive disorder, recurrent
F39		Unspecified mood [affective] disorders
F44		Dissociative and conversion disorders
F84		Pervasive developmental disorders
	F11.150	Opioid abuse with opioid-induced psychotic disorder with delusions
	F11.250	Opioid dependence with opioid-induced psychotic disorder with delusions
	F11.950	Opioid use, unspecified with opioid-induced psychotic disorder with delusions
	F12.150	Cannabis abuse with psychotic disorder with delusions
	F12.250	Cannabis dependence with psychotic disorder with delusions
	F12.950	Cannabis use, unspecified with psychotic disorder with delusions
	F13.150	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced psychotic disorder with delusions
	F13.250	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced psychotic disorder with delusions
	F13.950	Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic or anxiolytic-induced psychotic disorder with delusions
	F14.150	Cocaine abuse with cocaine-induced psychotic disorder with delusions
	F14.250	Cocaine dependence with cocaine-induced psychotic disorder with delusions
	F14.950	Cocaine use, unspecified with cocaine-induced psychotic disorder with delusions
	F15.150	Other stimulant abuse with stimulant-induced psychotic disorder with delusions

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Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	F15.250	Other stimulant dependence with stimulant-induced psychotic disorder with delusions
	F15.950	Other stimulant use, unspecified with stimulant-induced psychotic disorder with delusions
	F16.150	Hallucinogen abuse with hallucinogen-induced psychotic disorder with delusions
	F16.250	Hallucinogen dependence with hallucinogen-induced psychotic disorder with delusions
	F16.950	Hallucinogen use, unspecified with hallucinogen-induced psychotic disorder with delusions
	F18.150	Inhalant abuse with inhalant-induced psychotic disorder with delusions
	F18.250	Inhalant dependence with inhalant-induced psychotic disorder with delusions
	F18.950	Inhalant use, unspecified with inhalant-induced psychotic disorder with delusions
	F19.150	Other psychoactive substance abuse with psychoactive substance-induced psychotic disorder with delusions
	F19.250	Other psychoactive substance dependence with psychoactive substance-induced psychotic disorder with delusions
	F19.950	Other psychoactive substance use, unspecified with psychoactive substance-induced psychotic disorder with delusions
	F11.151	Opioid abuse with opioid-induced psychotic disorder with hallucinations
	F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
	F11.951	Opioid use, unspecified with opioid-induced psychotic disorder with hallucinations
	F12.151	Cannabis abuse with psychotic disorder with hallucinations
	F12.251	Cannabis dependence with psychotic disorder with hallucinations
	F12.951	Cannabis use, unspecified with psychotic disorder with hallucinations
	F13.151	Sedative, hypnotic or anxiolytic abuse with sedative, hypnotic or anxiolytic-induced psychotic disorder with hallucination
	F13.251	Sedative, hypnotic or anxiolytic dependence with sedative, hypnotic or anxiolytic-induced psychotic disorder with hallucination
	F13.951	Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic or anxiolytic-induced psychotic disorder with hallucination
	F14.151	Cocaine abuse with cocaine-induced psychotic disorder with hallucinations
	F14.251	Cocaine dependence with cocaine-induced psychotic disorder with hallucinations

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Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	F14.951	Cocaine use, unspecified with cocaine-induced psychotic disorder with hallucinations
	F15.151	Other stimulant abuse with stimulant-induced psychotic disorder with hallucinations
	F15.251	Other stimulant dependence with stimulant-induced psychotic disorder with hallucinations
	F15.951	Other stimulant use, unspecified with stimulant-induced psychotic disorder with hallucinations
	F16.151	Hallucinogen abuse with hallucinogen-induced psychotic disorder with hallucinations
	F16.251	Hallucinogen dependence with hallucinogen-induced psychotic disorder with hallucinations
	F16.951	Hallucinogen use, unspecified with hallucinogen-induced psychotic disorder with hallucinations
	F18.151	Inhalant abuse with inhalant-induced psychotic disorder with hallucinations
	F18.251	Inhalant dependence with inhalant-induced psychotic disorder with hallucinations
	F18.951	Inhalant use, unspecified with inhalant-induced psychotic disorder with hallucinations
	F19.151	Other psychoactive substance abuse with psychoactive substance-induced psychotic disorder with hallucinations
	F19.251	Other psychoactive substance dependence with psychoactive substance-induced psychotic disorder with hallucinations
	F19.951	Other psychoactive substance use, unspecified with psychoactive substance-induced psychotic disorder with hallucinations
	F11.159	Opioid abuse with opioid-induced psychotic disorder, unspecified
	F91.3	Oppositional defiant disorder
F95		Tic disorder
G10		Huntington’s disease

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 2-week** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Abilify MyCite CC, QL	• Trial and failure, intolerance, or contraindication to ≥ 1 long-acting antipsychotic. **Quantity Limit:** 1 per day

Bysanti AE, CC, QL	• Diagnosis of one of the following conditions:
	  ○ Schizophrenia; **OR**
	  ○ Bipolar I disorder with acute mania or mixed episodes; **AND**
	• ≥ 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of > 2 preferred antipsychotics.
	
	Age Limit: ≥ 18 years
	Quantity Limit:
	Tablets: 2 per day
	Titration packs: 1 per 365 days

Caplyta AE, CC, QL	**Bipolar I or II:** • Patient has a confirmed diagnosis of bipolar I or II disorder (bipolar depression); **AND** • Medication will be used as monotherapy or adjunctive therapy with lithium or valproate; **AND** • Trial and failure of ≥ 2 preferred antipsychotics. **Schizophrenia:** • Patient has a confirmed diagnosis of schizophrenia; **AND** • Trial and failure of ≥ 2 preferred antipsychotics. **MDD:** • Patient has a diagnosis of moderate to severe major depressive disorder (MDD); **AND** • Medication will be used as adjunctive therapy with an antidepressant; **AND** • Prescribed by, or in consultation with, a psychiatrist or psychiatric mental health nurse practitioner (PMHNP); **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred antidepressants; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• 6-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of aripiprazole or Vraylar. **Renewal Criteria (all indications):** • Attestation or documentation (e.g., progress note) of disease improvement and/or stabilization. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Cobenfy AE, CC, QL	• Diagnosis of schizophrenia; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to one preferred agent; **AND** • Prescriber attests that liver enzymes and bilirubin were measured prior to initiation; **AND** • Patient meets the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day

Lybalvi AE, CC, QL	• Patient has a diagnosis of schizophrenia OR bipolar I disorder; **AND**
	• If used for bipolar I disorder, will be used for either:
	  ○ acute treatment of manic or mixed episodes as monotherapy or as adjunct to lithium or valproate; **OR**
	  ○ maintenance monotherapy treatment; **AND**
	• Patient is NOT currently using opioids; **AND**
	• Patient is NOT undergoing acute opioid withdrawal; **AND**
	• Patient has a history of trial and therapeutic failure, allergy, contraindication, or intolerance of ≥ 1 preferred second-generation (atypical) antipsychotic.
	
	Renewal Criteria:
	• Patient must continue to meet the above criteria; **AND**
	• Patient must have disease improvement and/or stabilization
	
	Age Limit: ≥ 18 years
	Quantity Limit: 1 per day

Nuplazid AE, CC, QL	• Diagnosis of Parkinson's Disease; **AND** • Trial of dose adjustment or withdrawal of anti-Parkinson's medications prior to treatment with this agent, (ex; anticholinergics, amantadine, dopamine agents, COMT inhibitors, selegiline) because these are known to cause hallucinations. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day

Opipza CC, QL	• Diagnosis of any of the following conditions:
	  ○ Dementias (ICD-10 Disease Groups F01, F02, F03, F06);
	  ○ Dissociative and conversion disorders (ICD-10 Disease Group F44);

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Episodic Mood Disorders (ICD-10 Disease Groups F30, F31, F39); ○ Huntington's disease (ICD-10 Disease Group G10); ○ Major depressive disorder (ICD-10 Disease Groups F32, F33); ○ Oppositional defiant disorder (ICD-10 = F91.3); ○ Pervasive developmental disorders (ICD-10 Disease Group F84); ○ Schizoaffective disorder (F25.9); ○ Schizophrenic Disorders (ICD-10 Disease Group F20; ICD-10 = F60.1); ○ Tic disorder (ICD-10 Disease Group F95); ○ Substance use disorders and related conditions; **AND** • Patient has had at least a 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to both aripiprazole tablet **AND** aripiprazole oral solution. **Quantity Limit:** • 2 mg film: 2 per day • 5 mg & 10 mg film: 1 per day
olanzapine/fluoxetine capsule CC, QL Symbyax CC, QL	• Diagnosis of depressive episodes associated with bipolar disorder; **AND** • Trial and failure on one of the following: lithium, lamotrigine, bupropion, paroxetine. **OR** • Diagnosis of treatment-resistant depression; **AND** • Trial and failure on one of the following: selective serotonin reuptake inhibitor (SSRI), serotonin norepinephrine reuptake inhibitor (SNRI), new generation antidepressant, tricyclic antidepressant, monoamine oxidase inhibitor. **Quantity Limit:** 1 per day

6. THERAPEUTIC DUPLICATION/MULTIPLE AGENTS CRITERIA

Prior authorization when ≥ 3 atypical antipsychotics are used may be approved under the following conditions:

a. Approve for 1 year when it is continuation of current therapy and member is stable on 3 or more agents; **OR**

b. A maximum of two months to allow patients to taper to dual therapy (if one of the previous will be discontinued); **OR**

c. Additional agents may be added to existing dual therapy after a two-week trial at the maximum tolerated dose of each agent.

CURRENT PDL STATUS

ANTIPSYCHOTICS: SECOND GENERATION (ATYPICAL)

Preferred Agents	Non-Preferred Agents
aripiprazole tablet CC, QL	Abilify MyCite CC, QL
asenapine CC, QL	Abilify tablet QL
clozapine tablet CC, QL	aripiprazole ODT QL

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Preferred Agents	Non-Preferred Agents
lurasidone CC, QL	aripiprazole solution QL
olanzapine ODT CC, QL	Bysanti tablet AE, CC, QL
olanzapine tablet CC, QL	Bysanti dose pack AE, CC, QL
quetiapine tablet CC, QL	Caplyta AE, CC, QL
quetiapine ER tablet CC, QL	clozapine ODT QL
risperidone ODT CC, QL	Clozaril QL
risperidone solution CC, QL	Cobenfy AE, CC, QL
risperidone tablet CC, QL	Fanapt QL
Vraylar AE, CC, QL	Geodon capsule QL
ziprasidone capsule CC, QL	Invega ER QL
	Latuda QL
	Lybalvi AE, CC, QL
	Nuplazid AE, CC, QL
	olanzapine/fluoxetine CC, QL
	Opipza CC, QL
	paliperidone ER QL
	Rexulti tablet QL
	Risperdal solution QL
	Risperdal tablet QL
	Saphris QL
	Secuado QL
	Seroquel QL
	Seroquel XR QL
	Symbyax CC, QL
	Versacloz QL
	Zyprexa tablet QL
	Zyprexa Zydis QL

ANTIPSYCHOTICS: INJECTABLE

Preferred Agents	Non-Preferred Agents
Abilify Asimtufii AE, CC, QL	Erzofri AE, QL
Abilify Maintena AE, CC, QL	Haldol Decanoate ampule AE, QL
Aristada AE, CC, QL	risperidone ER vial AE, QL
Aristada Initio AE, CC, QL	Rykindo AE, QL
fluphenazine decanoate vial AE, CC, QL	ziprasidone mesylate vial AE, QL
Geodon vial AE, CC, QL	Zyprexa vial AE, QL
haloperidol decanoate ampule AE, CC, QL	Zyprexa Relprevv AE, QL
haloperidol decanoate vial AE, CC, QL	
haloperidol lactate syringe AE, CC, QL	
haloperidol lactate vial AE, CC, QL	
Invega Hafyera AE, CC, QL	
Invega Sustenna AE, CC, QL	
Invega Trinza AE, CC, QL	
olanzapine vial AE, CC, QL	
Perseris AE, CC	
Risperdal Consta AE, CC, QL	
Uzedy AE, CC, QL	

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CENTRAL NERVOUS SYSTEM: DOPAMINE RECEPTOR AGONISTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
pramipexole	bromocriptine
ropinirole	Mirapex ER
	Neupro
	pramipexole ER
	ropinirole ER

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CENTRAL NERVOUS SYSTEM: PARKINSON'S DISEASE (ANTIPARKINSON'S AGENTS)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 1-week** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Nourianz AE, CC, QL	• Diagnosis of Parkinson's disease (PD); **AND**
	• Receiving PD therapy with carbidopa/levodopa; **AND**
	• Experiencing "off" episodes with carbidopa/levodopa; **AND**
	• Trial and failure of at least 2 adjunctive therapies, such as:
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole);
	  ○ Monoamine oxidase-B inhibitors (e.g., selegiline);
	  ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); **AND**
	• NONE of the following contraindications:
	  ○ Severe hepatic impairment (Child-Pugh C); **OR**
	  ○ End-stage renal disease, including dialysis; **OR**
	  ○ Pregnant; **OR**
	  ○ Major psychiatric disorder.
	
	Renewal Criteria:
	• Patient has clinically meaningful response of treatment (e.g., patient shows a reduction in time of "off" episodes).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 1 per day

Ongentys AE, CC, QL	• Diagnosis of Parkinson's disease (PD); **AND** • Receiving PD therapy with carbidopa/levodopa; **AND** • Experiencing "off" episodes with carbidopa/levodopa for at least 2 hours per day; **AND** • Trial and failure of at least 2 adjunctive therapies, such as: ○ Dopamine agonists (e.g., pramipexole, ropinirole);

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Monoamine oxidase-B inhibitors (e.g., selegiline); ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); **AND** • NONE of the following contraindications: ○ Severe hepatic impairment (Child-Pugh C); **OR** ○ End-stage renal disease (creatinine clearance ≤ 15 ml/min); **OR** ○ Use with a monoamine oxidase-B (MAO-B) inhibitor. **Renewal Criteria** • Patient has clinically meaningful response of treatment (e.g., patient shows a reduction in time of "off" episodes) **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Vyalev AE, CC, QL	• Diagnosis of Parkinson's disease (PD); **AND** • Receiving PD therapy with carbidopa/levodopa; **AND** • Experiencing "off" episodes with carbidopa/levodopa for at least 2 hours per day; **AND** • Trial and failure of at least 2 adjunctive therapies, such as: ○ Dopamine agonists (e.g., pramipexole, ropinirole); ○ Monoamine oxidase-B inhibitors (e.g., selegiline); ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); **AND** • Patient will not take within two weeks of a non-selective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, isocarboxazid, tranylcypromine); **AND** • Patient meets the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Patient has clinically meaningful response of treatment (e.g., patient shows a reduction in time of "off" episodes). **Age Limit:** ≥ 18 years **Quantity Limit:** 2 vials (20 mL) per day
Xadago AE, CC, QL	• Diagnosis of Parkinson's disease (PD); **AND** • Receiving PD therapy with carbidopa/levodopa; **AND** • Experiencing "off" episodes with carbidopa/levodopa; **AND** • Does not have severe hepatic impairment (Child-Pugh Score > 9); **AND** • Not taking ANY the following medications: ○ Dextromethorphan; **OR** ○ MAOIs (e.g., or other drugs that are potent inhibitors of monoamine oxidase (e.g., linezolid); **OR** ○ Other serotonergic drugs (e.g., SNRIs, SSRIs, TCAs, St. John's wort, cyclobenzaprine); **OR** ○ Opioids (e.g., meperidine, methadone, propoxyphene, tramadol); **OR** ○ Sympathomimetic medications (e.g., methylphenidate, amphetamine). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day

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CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
amantadine	Azilect
benztropine tablet	carbidopa tablet
carbidopa/levodopa tablet	carbidopa/levodopa ER capsule
carbidopa/levodopa ER tablet	Crexont
carbidopa/levodopa ODT	Dhivy
carbidopa/levodopa/entacapone	Duopa
entacapone	Gocovri
selegiline	Inbrija
trihexyphenidyl	Nourianz AE, CC QL
	Ongentys AE, CC, QL
	Osmolex ER
	rasagiline
	Rytary
	Sinemet
	tolcapone
	Vyalev AE, CC, QL
	Xadago AE, CC, QL

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval

Austedo [AE, CC, QL]
Austedo XR tablet [CC, QL]
Austedo XR titration kit [CC]
	Huntington's Chorea:
	• Patient is diagnosed with chorea related to Huntington's disease; **AND**
	• Patient does NOT have the following conditions:
	  ○ Hepatic impairment or hepatic disease; **AND**
	  ○ History of, or current, untreated or inadequately treated depression; **OR**
	  ○ Suicidal ideation; **AND**
	• Patient has tried and failed tetrabenazine.
	
	Tardive Dyskinesia:
	• Diagnosis of tardive dyskinesia; **AND**
	• Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
	• Documentation or claims history of current or former chronic patient use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.).
	
	Renewal Criteria (all indications):
	• Patient continues to meet criteria defined for initial approval; **AND**
	• Documentation (e.g., progress note) of improvement in symptoms associated with respective condition (i.e., tardive dyskinesia or Huntington's chorea).

Ingrezza [AE, CC, QL]	**Huntington's Chorea:**
	• Patient is diagnosed with chorea related to Huntington's disease; **AND**
	• Patient does NOT have the following conditions:
	  ○ History of, or current, untreated or inadequately treated depression; **OR**
	  ○ Suicidal ideation; **AND**
	• Patient is NOT concurrently using any of the following:
	  ○ Monoamine oxidase (MAO) inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) within 14 days; **OR**
	  ○ Strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); **OR**
	  ○ Another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine); **AND**
	• Patient has tried and failed tetrabenazine.

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Agent(s) Subject to PA Criteria	Criteria for Approval

	Tardive Dyskinesia:
	• Diagnosis of tardive dyskinesia (TD); **AND**
	• Prescribed by or in consultation with a neurologist or psychiatrist (or other mental health provider), provided patient has reasonable access; **AND**
	• Documentation or claims history of current or former chronic patient use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.); **AND**
	• Patient is NOT concurrently using any of the following:
	  ○ Monoamine oxidase (MAO) inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) within 14 days; **OR**
	  ○ Strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); **OR**
	  ○ Another VMAT2 inhibitor (e.g., tetrabenazine, valbenazine).
	
	Renewal Criteria (all indications):
	• Patient continues to meet criteria defined for initial approval; **AND**
	• Documentation (e.g., progress note) of improvement in symptoms associated with respective condition (i.e., tardive dyskinesia or Huntington's chorea).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 1 per day

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Austedo tablet AE, CC, QL	Xenazine
Austedo XR CC, QL	

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Preferred Agents	Non-Preferred Agents
Austedo XR titration kit CC	
Ingrezza AE, CC, QL	
tetrabenazine	

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with ≥ 2 manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

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Agent(s) Subject to PA Criteria	Criteria for Approval

Auvelity AE, CC, QL	**Major Depressive Disorder:**
	• Diagnosis of major depressive disorder (MDD); **AND**
	• Patient is not pregnant, breastfeeding, or planning to become pregnant; **AND**
	• Patient as tried and failed, unless allergic, contraindicated or intolerant to 2 preferred agents in any sub-class: **OR**
	• Patient has suicidal ideations with severe depression based on an objective measure [e.g., Patient Health Questionnair-9 (PHQ-9), Hamilton Rating Scale for Depression (HDRS), Montgomery-Asberg Depression Rating Scale (MADRS), Clinically Useful Depression Outcome Scale (CUDOS), or Quick Inventory of Depressive Symptomatology – Self Report 16 Item (QIDS-SR16).
	
	Agitation Associated with Dementia:
	• Diagnosis of dementia due to Alzheimer's disease; **AND**
	• Prescriber submits documentation patient has presence of clinically significant agitation such as:
	  ○ Physical aggression (e.g. throwing objects, biting, hitting self, destroying property); **OR**
	  ○ Verbal aggression (e.g. yelling, speaking in an excessively loud voice, using profanity, screaming, shouting); **OR**
	  ○ Excessive motor activity (e.g. pacing, rocking, gesturing, restlessness).
	
	Renewal Criteria:
	
	Major Depressive Disorder:
	• Patient must continue to meet the above criteria; **AND**
	• Patient must have disease improvement and/or stabilization of disease.
	
	Agitation Associated with Dementia:
	• Prescriber must submit clinical documentation demonstrating disease improvement and/or stabilization of disease.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 2 per day

Raldesy AE, CC	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Diagnosis of major depressive disorder (MDD); **AND**
	• Prescribed by, or in consultation with, psychiatrist, neurologist, or another qualified healthcare provider experienced in treating depression or related conditions; **AND**
	• Patient meets at least ONE of the following criteria:
	  ○ Unable to tolerate, swallow, or absorb oral tablet trazodone; **OR**
	  ○ Tried and failed two preferred agents, one being trazodone IR; **AND**
	• Patient must meet the minimum age recommended by the package insert for the provided indication.
	
	Renewal Criteria:

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Agent(s) Subject to PA Criteria	Criteria for Approval
	• Patient has experienced disease improvement and/or stabilization such as improvement in depressive symptoms, as assessed by the prescriber; **AND** • Patient continues to require an oral solution. **Age Limit:** ≥ 18 years

Spravato AE, CC, QL
 	
*****Only covered via the pharmacy benefit.*****
	Approval Duration: 4 weeks initial; 1 year renewal (treatment resistant depression only)
	
	Treatment-resistant depression:
	• Diagnosis of depression considered treatment resistant as evidenced by BOTH of the following:
	  ○ Trial and failure (defined as < 50% reduction in symptom severity using any validated depression rating scale) of ≥ 2 antidepressants from different classes for a duration of ≥ 6 weeks each at generally accepted doses in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced; **AND**
	  ○ Trial and failure of antidepressant augmentation therapy for a duration of ≥ 6 weeks in the current depressive episode with ≥ 1 of the following, unless contraindicated or clinically significant adverse effects are experienced:
	  ▪ An atypical antipsychotic; **OR**
	  ▪ Lithium; **OR**
	  ▪ An antidepressant from a different class; **AND**
	• Prescribed by, or in consultation with, a psychiatrist or psychiatric mental health nurse practitioner (PMHNP); **AND**
	• Prescriber has performed baseline depression assessment using any validated rating scale; **AND**
	• If female of childbearing potential, NOT pregnant or planning to become pregnant, **AND**
	• Prescriber attests that:
	  ○ An accessible treatment center certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program has been identified; **AND**
	  ○ Dosing schedule has been reviewed with patient; **AND**
	  ○ Patient understands and is committed to dosing schedule and requirements (e.g., office visits, transportation).
	
	Major depressive disorder with acute suicidal ideations:
	• Diagnosis of MDD with acute suicidal ideation or behavior; **AND**
	• Used in conjunction with another oral antidepressant medication (not to be used as monotherapy); **AND**
	• Prescribed by, or in consultation with, a psychiatrist or psychiatric mental health nurse practitioner (PMHNP); **AND**
	• Prescriber has performed baseline depression assessment using any validated rating scale; **AND**
	• If female of childbearing potential, NOT pregnant or planning to become pregnant, **AND**
	• Prescriber attests that:
	  ○ An accessible treatment center certified in the Spravato Risk Evaluation and Mitigation Strategies (REMS) program has been identified; **AND**

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Agent(s) Subject to PA Criteria	Criteria for Approval
	○ Dosing schedule has been reviewed with patient; **AND** ○ Patient understands and is committed to dosing schedule and requirements (e.g., office visits, transportation). **Renewal Criteria (not applicable when used for acute suicidal ideation):** **Treatment-resistant depression:** • Continue to meet initial approval criteria for treatment resistant depression; **AND** • Prescriber attestation that patient has been compliant with doses/appointments; **AND** • Prescriber provides documentation of disease improvement or stabilization as evidenced by improvement on a validated depression rating scale. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 kit (56 or 84 mg) per week; overrides allowed for twice weekly)
Zurzuvae AE, CC, QL	**Approval Duration**: 6 months • Diagnosis of postpartum depression (PPD); **AND** • Symptom onset in the third trimester or within 4 weeks postpartum; **AND** • Prescribed by, or consultation with, a psychiatrist, an obstetrician-gynecologist (OB-GYN), or other specialist in the treatment of PPD; **AND** • Within one year of giving birth; **AND** • Member has not received prior treatment with Zurzuvae for the current pregnancy. **Age Limit:** ≥ 18 years **Quantity Limit:** one 14-day treatment course per pregnancy (re-treatment within the same pregnancy is not permitted)

CURRENT PDL STATUS

ANTIDEPRESSANTS: OTHER

Preferred Agents	Non-Preferred Agents
bupropion	Auvelity AE, CC, QL
bupropion SR	bupropion XL 450 mg tablet
bupropion XL 150 mg, 300 mg tablet	Forfivo XL
mirtazapine ODT, tablet	nefazodone
trazodone (except 25 mg and 75 mg tablets)	Raldesy AE, CC
	Remeron
	Spravato AE, CC, QL
	trazodone 25 mg and 75 mg tablets
	Trintellix
	Viibryd
	vilazodone
	Wellbutrin SR
	Wellbutrin XL
	Zurzuvae AE, CC, QL

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ANTIDEPRESSANTS: SNRIS

Preferred Agents	Non-Preferred Agents
desvenlafaxine succinate ER tablet	desvenlafaxine ER base tablet
venlafaxine	Effexor XR
venlafaxine ER	Fetzima
	Pristiq
	venlafaxine besylate ER tablet

ANTIDEPRESSANTS: SSRIS

Preferred Agents	Non-Preferred Agents
citalopram tablet, 10 mg/5 mL solution	Celexa
escitalopram tablet	citalopram capsule, 20 mg/10 mL solution
fluoxetine capsule, solution	escitalopram capsule, solution
paroxetine tablet	fluoxetine 90 mg DR capsule QL
sertraline oral concentrate, tablet	fluoxetine tablet
	fluvoxamine
	fluvoxamine ER
	Lexapro
	paroxetine mesylate
	paroxetine CR/ER
	paroxetine suspension
	Paxil
	Paxil CR
	Pexeva
	Prozac
	sertraline capsule
	Zoloft

ANTIDEPRESSANTS: TRICYCLICS

Preferred Agents	Non-Preferred Agents
amitriptyline	amoxapine
clomipramine capsule	Anafranil
desipramine	imipramine pamoate
doxepin capsule, oral concentrate	Norpramin
imipramine tablet	nortriptyline solution
nortriptyline capsule	Pamelor
	protriptyline
	trimipramine

ANTIDEPRESSANTS: MAOIs

Preferred Agents	Non-Preferred Agents
	Emsam
	Marplan
	Nardil
	phenelzine
	tranylcypromine

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CENTRAL NERVOUS SYSTEM: ANTI-MIGRAINE AGENTS, TRIPTANS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Onzetra Xsail CC, QL Tosymra CC, QL Zembrace SymTouch CC, QL	• Trial and failure of a corresponding generic sumatriptan formulation (e.g., nasal spray, injection).

6. QUANTITY LIMIT CRITERIA

One-time approval when all of the following circumstances are true

a. NOT using triptans in combination with an MAOI (e.g., Parnate, Marplan, or Nardil); **AND**

b. Patient must **NOT** have a history of ischemic heart disease; **AND**

c. Prescriber has counseled the member about the negatives (e.g., causes additional migraines) of daily use and/or overuse of triptans and will attempt to taper the quantity of triptan medication used monthly; **AND**

d. Current use of any oral or injectable prophylactic agent, such as (though not limited to):

- Antiepileptic drugs (AEDs): divalproex sodium, sodium valproate, topiramate
- Beta Blockers: metoprolol, propranolol, timolol, atenolol, nadolol
- Antidepressants: amitriptyline, venlafaxine
- NSAIDs: fenoprofen, ibuprofen, ketoprofen, naproxen

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- CGRP inhibitor: Ajovy, Emgality 120 mg/mL
- Botulinum toxin: Botox

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
rizatriptan ODT QL	almotriptan tablet QL
rizatriptan tablet QL	eletriptan tablet QL
sumatriptan spray QL	Frova tablet QL
sumatriptan tablet QL	frovatriptan tablet QL
sumatriptan vial QL	Imitrex cartridge QL
	Imitrex pen QL
	Imitrex tablet QL
	Maxalt-MLT ODT QL
	Maxalt tablet QL
	naratriptan tablet QL
	Onzetra Xsail CC, QL
	Relpax tablet QL
	sumatriptan cartridge QL
	sumatriptan injector QL
	sumatriptan/naproxen tablet QL
	Symbravo QL
	Tosymra spray
	Zembrace SymTouch CC, QL
	zolmitriptan ODT QL
	zolmitriptan spray QL
	zolmitriptan tablet QL
	Zomig spray QL
	Zomig tablet QL

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CENTRAL NERVOUS SYSTEM: ANTI-MIGRAINE AGENTS, CGRP INHIBITORS

GUIDELINES FOR USE

CGRP medications are limited to two brand switches per class (acute and preventative) per year.
CGRP medications are limited to one for acute and preventive migraine concurrently.

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

<table>
<tr><th>Agent(s) Subject to Criteria</th><th>Criteria for Approval</th></tr>
<tr><td>Aimovig AE, CC, QL
Emgality 120 mg/mL AE, CC, QL</td><td>Approval Duration: 3 months initial; 1 year renewal

• Diagnosis of migraine with or without aura; AND
• Patient has tried and failed a ≥ 1-month trial (at maximally tolerated doses) of two medications listed below from the 2012 American Academy of Neurology/American Headache Society guidelines. At least ONE medication must be level A or B recommendation, unless ALL are contraindicated:

<table>
<tr><th>Level A</th><th>Level B</th><th>Level C</th></tr>
<tr><td>• divalproex sodium
• sodium valproate
• topiramate
• metoprolol
• propranolol
• timolol</td><td>• amitriptyline
• venlafaxine
• atenolol
• nadolol</td><td>• clonidine
• guanfacine
• lisinopril
• candesartan
• carbamazepine
• cyproheptadine
• nebivolol
• pindolol</td></tr>
</table>

Renewal Criteria:
• Patient has an overall improvement in function with therapy.

Age Limit: ≥ 18 years</td></tr>
<tr><td>Ajovy AE, CC, QL</td><td>Approval Duration: 3 months initial; 1 year renewal

• Patient is 6 to 17 years of age or older and weighs 45 kg or more:
  ○ Diagnosis of episodic migraine; AND
  ○ If patient is 12 years or older, patient has a 2-month trial and failure of topiramate, unless contraindicated or clinically significant adverse effects are experienced; OR
• Patient is 18 years of age or older:
  ○ Diagnosis of migraine with or without aura; AND
  ○ Patient has tried and failed a ≥ 1-month trial (at maximally tolerated doses) of two medications listed below from the 2012 American Academy of Neurology/American Headache Society guidelines. At least ONE medication must be level</td></tr>
</table>

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Agent(s) Subject to Criteria	Criteria for Approval
	A or B recommendation, unless **ALL** are contraindicated: Level A: divalproex sodium; sodium valproate; topiramate; metoprolol; propranolol; timolol Level B: amitriptyline; venlafaxine; atenolol; nadolol Level C: clonidine; guanfacine; lisinopril; candesartan; carbamazepine; cyproheptadine; nebivolol; pindolol **Renewal Criteria:** • Patient has an overall improvement in function with therapy. **Age Limit:** Episodic migraine: ≥ 6 years Migraine with or without aura: ≥ 18 years **Quantity Limit:** 1 autoinjector/syringe per 28 days
Nurtec ODT AE, CC, QL	**Acute treatment of migraine:** • Diagnosis of migraine, with or without aura; **AND** • Trial and failure, or contraindication to, 2 triptans. **Renewal Criteria:** • Attestation or documentation of resolution in headache pain or reduction in headache severity, as assessed by prescriber. **Age Limit:** ≥ 18 years **Quantity Limit:** 18 tablets per 30 days
Qulipta AE, CC, QL Nurtec ODT AE, CC, QL *(for prevention of episodic migraine)*	**Approval Duration:** 3 months initial; 1 year renewal **Episodic migraine:** • Patient has diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria; **AND** • Patient has tried and failed a ≥ 1-month trial of a preferred injectable CGRP agent (i.e., Aimovig, Ajovy, Emgality 120 mg/mL); **AND** • Patient has experienced ≥ 4 migraine days per month; **AND** • Patient has not experienced > 15 headache days per month during the prior 6 months; **AND** • Medication overuse has been ruled out. **Chronic Migraine:** • Patient has diagnosis of migraine with or without aura based on International Classification of Headache Disorders (ICHD-III) diagnostic criteria; **AND** • Patient has tried and failed a ≥ 1-month trial of a preferred injectable CGRP agent (i.e. Aimovig, Ajovy, Emgality 120 mg/mL); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Patient has experienced ≥ 8 migraine days per month during the last 3 months; **AND** • Patient has experienced ≥ 15 headache days per month during the prior 3 months; **AND** • Medication overuse has been ruled out. **Renewal Criteria:** • Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches. **Age Limit:** ≥ 18 years **Quantity Limit:** **Quilipta** • **30mg tablet and 60mg tablet:** 1 per day • **10mg tablet:** 2 per day **Nurtec ODT** • 18 tablets per 30 days
Ubrelvy AE, CC, QL	• Diagnosis of migraine, with or without aura; **AND** • Trial and failure, or contraindication to, 2 triptans (e.g., sumatriptan). **Renewal Criteria:** • Attestation or documentation of resolution in headache pain or reduction in headache severity, as assessed by prescriber. **Age Limit:** ≥ 18 years **Quantity Limit:** • 50 mg tablet: 10 tablets (1 package) per 30 days • 100 mg tablet: 16 tablets (1 package) per 30 days • One-time fill of 20 tablets (2 packages) per 30 days allowed with prior authorization: current use of any oral or injectable prophylactic agent listed below.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

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5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Emgality 100 mg/mL AE, CC, QL	**Approval Duration**: 3 months initial; 1 year renewal • Diagnosis of **episodic** cluster headache as evidenced by a history of ≥ 2 cluster periods lasting from ≥ 7 days to ≤ 1 year each and separated by ≥ 3 months; **AND** • Prescribed by, or in consultation with, a neurologist or headache/pain specialist; **AND** • NOT to be used in combination with any other injectable CGRP (e.g., Ajovy) or botulinum toxin (e.g., Botox). **Renewal Criteria:** • Patient has an overall improvement in function with therapy compared with previous cluster periods; **AND** • Member has not received more than 12 months of consecutive treatment OR it has been at least 3 months since last treatment with Emgality 100 mg/mL. **Age Limit:** ≥ 18 years **Quantity Limit:** 300 mg (3 mL) per 30 days
Zavzpret AE, CC, QL	• Patient has a diagnosis of migraine with or without aura; **AND** • Prescriber attestation will NOT be used for preventive treatment of migraine or for chronic migraine; **AND** • Patient must have tried and failed or have a contraindication or intolerance to 2 triptans; **AND** • Patient must have tried and failed or have a contraindication or intolerance to 1 preferred CGRP antagonist. **Renewal Criteria** • Patient must continue to meet the above criteria; **AND** • Patient must demonstrate symptom improvement (e.g., resolution in headache pain or reduction in headache severity), as assessed by the prescriber. **Age Limit:** ≥ 18 years **Quantity Limit:** 8 nasal spray devices per 30 days

6. QUANTITY LIMIT CRITERIA FOR NURTEC ODT AND UBRELVY

Current use of any oral or injectable prophylactic agent, such as (though not limited to):

a. Antiepileptic drugs (AEDs): divalproex sodium, sodium valproate, topiramate
b. Beta Blockers: metoprolol, propranolol, timolol, atenolol, nadolol
c. Antidepressants: amitriptyline, venlafaxine
d. NSAIDs: fenoprofen, ibuprofen, ketoprofen, naproxen
e. CGRP inhibitor: Ajovy, Emgality 120 mg/mL
f. Botulinum toxin: Botox

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CURRENT PDL STATUS

ACUTE TREATMENT

Preferred Agents	Non-Preferred Agents
Nurtec ODT AE, CC, QL	Zavzpret AE, CC, QL
Ubrelvy AE, CC, QL	

PROPHYLAXIS, INJECTABLE

Preferred Agents	Non-Preferred Agents
Aimovig AE, CC, QL	Emgality 100 mg/mL AE, CC, QL
Ajovy AE, CC, QL	
Emgality 120 mg/mL AE, CC, QL	

PROPHYLAXIS, ORAL

Preferred Agents	Non-Preferred Agents
Nurtec ODT AE, CC, QL	
Qulipta AE, CC, QL	

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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CENTRAL NERVOUS SYSTEM: STIMULANTS AND RELATED AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval
atomoxetine CC, QL clonidine ER CC, QL dexmethylphenidate CC, QL dexmethylphenidate ER CC, QL dextroamphetamine sulfate tablet 5mg, 10mg, 15mg CC, QL dextroamphetamine/amphetamine CC, QL dextroamphetamine/amphetamine ER CC, QL guanfacine ER CC, QL Methylin solution CC, QL methylphenidate solution CC, QL methylphenidate ER tablets 10 mg & 20 mg CC, QL (generic Metadate ER) methylphenidate ER tablet 18 mg, 27 mg, 36 mg, 54 mg CC, QL (generic Concerta) methylphenidate tablets CC, QL mixed amphetamine salts tablets CC, QL	• Diagnosis of: ○ Add/ADHD (ICD-10 Disease Group F90); **OR** ○ Narcolepsy (ICD-10 Codes G47.419, G47.411, G47.421, G47.429); **OR** ○ Sleep apnea (ICD-10 Code G47.30); **OR** ○ Circadian rhythm (shift work) sleep disorder (ICD-10 Codes G47.20, G47.21, G47.22, G47.23, G47.24, G47.25, G47.26, G47.27, G47.29); **OR** ○ Idiopathic hypersomnia (ICD-10 Codes G47.11, G47.12)
Qelbree CC, QL	• Diagnosis of ADHD (ICD-10 Disease Group F90); **AND** • Trial and failure of at least one other preferred agent.
Vyvanse capsule, chewable tablet CC, QL lisdexamfetamine capsule, chewable tablet CC, QL	Diagnosis of: ▪ ADD/ADHD (ICD-10 Disease Group F90); **OR** ▪ Narcolepsy (ICD-10 Codes G47.419, G47.411, G47.421, G47.429); **OR** ▪ Sleep apnea (ICD-10 Code G47.30); **OR** ▪ Circadian rhythm (shift work) sleep disorder (ICD-10 Codes G47.20, G47.21, G47.22, G47.23, G47.24, G47.25, G47.26, G47.27, G47.29); **OR** Patient has a diagnosis of moderate to severe binge eating disorder based on DSM V diagnostic criteria; **AND** ▪ Prescriber attests or provides documentation that a comprehensive evaluation has been performed, including, physical exam and any necessary labs; **AND** ▪ The patient been counseled on the benefits of cognitive behavioral therapy (CBT) and referred if appropriate. **Renewal Criteria:**

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to PA Criteria	Criteria for Approval
	• Documentation of disease response [e.g., reduction in the number of binge-eating days per week, improvement of the Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating (Y-BOCS-BE) total score]. **Quantity Limit:** 1 per day

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
F90		Attention-deficit hyperactivity disorders
	G47.411	Narcolepsy with cataplexy
	G47.419	Narcolepsy without cataplexy
	G47.421	Narcolepsy in conditions classified elsewhere with cataplexy
	G47.429	Narcolepsy in conditions classified elsewhere without cataplexy
	G47.30	Sleep apnea, unspecified
	G47.20	Circadian rhythm sleep disorder, unspecified type
	G47.21	Circadian rhythm sleep disorder, delayed sleep phase type
	G47.22	Circadian rhythm sleep disorder, advanced sleep phase type
	G47.23	Circadian rhythm sleep disorder, irregular sleep wake type
	G47.24	Circadian rhythm sleep disorder, free running type
	G47.25	Circadian rhythm sleep disorder, jet lag type
	G47.26	Circadian rhythm sleep disorder, shift work type
	G47.27	Circadian rhythm sleep disorder in conditions classified elsewhere
	G47.29	Other circadian rhythm sleep disorder
	G47.11	Idiopathic hypersomnia with long sleep time
	G47.12	Idiopathic hypersomnia without long sleep time

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

Preferred with PA (PDP) criteria must be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Adzenys XR-ODT AE, CC, QL
amphetamine ER ODT AE, CC, QL
	• Diagnosis of:
	  ○ Attention Deficit Disorder (ADD)/ Attention-deficit hyperactivity disorder (ADHD) (ICD-10 Disease Group F90); **OR**
	  ○ Narcolepsy (ICD-10 Codes G47.419, G47.411, G47.421, G47.429); **OR**
	  ○ Sleep apnea (ICD-10 Code G47.30); **OR**
	  ○ Circadian rhythm (shift work) sleep disorder (ICD-10 Codes G47.20, G47.21, G47.22, G47.23, G47.24, G47.25, G47.26, G47.27, G47.29); **OR**
	  ○ Idiopathic hypersomnia (ICD-10 Codes G47.11, G47.12); **AND**
	• One of the following:
	  ○ Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to TWO preferred agents; **OR**
	  ○ Patient has a swallowing disorder and cannot be given tablets or capsules.
	
	Age Limit: ≥ 6 years
	Quantity Limit: 1 per day

Arynta AE, CC, QL	**Approval Duration:** 1 year (initial and renewal)
	
	• Diagnosis of ONE of the following:
	  ○ Attention Deficit Disorder (ADD/Attention-deficit/hyperactivity disorder (ADHD [ICD-10 Disease Group F90]; **OR**
	  ○ Moderate to severe binge eating disorder (BED) based on DSM V diagnostic criteria; **AND**
	• Prescriber attests or provides documentation that a comprehensive evaluation has been performed, including physical exam and any necessary labs; **AND**
	• The patient has been counseled on the benefits of cognitive behavioral therapy (CBT) and referred if appropriate; **AND**
	• One of the following:

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to TWO preferred agents; **OR** ○ Patient has a swallowing disorder and cannot be given tablets or capsules. **Renewal Criteria:** • Documentation of disease response [e.g., reduction in the number of binge-eating days per week, improvement of the Yale-Brown Obsessive Compulsive Scale Modified for Binge Eating (Y-BOCS-BE) total score]. **Age Limit:** ≥ 6 years **Quantity Limit:** 7mL per day
Xelstrym CC, QL Daytrana patch CC, QL methylphenidate patch CC. QL	• Diagnosis of: ○ Attention Deficit Disorder (ADD)/ Attention-deficit hyperactivity disorder (ADHD) (ICD-10 Disease Group F90); **OR** ○ Narcolepsy (ICD-10 Codes G47.419, G47.411, G47.421, G47.429); **OR** ○ Sleep apnea (ICD-10 Code G47.30); **OR** ○ Circadian rhythm (shift work) sleep disorder (ICD-10 Codes G47.20, G47.21, G47.22, G47.23, G47.24, G47.25, G47.26, G47.27, G47.29); **OR** ○ Idiopathic hypersomnia (ICD-10 Codes G47.11, G47.12); **AND** • One of the following: ○ Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ONE preferred agent; **OR** ○ Inability to swallow or tolerate medications. **Quantity Limit:** 1 per day
methylphenidate chewable tablet CC, QL	Diagnosis of: ▪ Attention Deficit Disorder (ADD)/ Attention-deficit hyperactivity disorder (ADHD) (ICD-10 Disease Group F90); **OR** ▪ Narcolepsy (ICD-10 Codes G47.419, G47.411, G47.421, G47.429); **OR** ▪ Sleep apnea (ICD-10 Code G47.30); **OR** ▪ Circadian rhythm (shift work) sleep disorder (ICD-10 Codes G47.20, G47.21, G47.22, G47.23, G47.24, G47.25, G47.26, G47.27, G47.29); **OR** ▪ Idiopathic hypersomnia (ICD-10 Codes G47.11, G47.12); **AND** One of the following: ▪ Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ONE preferred agent; **OR** ▪ Inability to swallow tablets or use the oral solution. **Quantity Limit:** 3 per day

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Agent(s) Subject to Criteria	Criteria for Approval
ProCentra solution CC, QL dextroamphetamine solution CC, QL	Diagnosis of: ▪ Attention Deficit Disorder (ADD)/ Attention-deficit hyperactivity disorder (ADHD) (ICD-10 Disease Group F90); **OR** ▪ Narcolepsy (ICD-10 Codes G47.419, G47.411, G47.421, G47.429); **OR** ▪ Sleep apnea (ICD-10 Code G47.30); **OR** ▪ Circadian rhythm (shift work) sleep disorder (ICD-10 Codes G47.20, G47.21, G47.22, G47.23, G47.24, G47.25, G47.26, G47.27, G47.29); **OR** ▪ Idiopathic hypersomnia (ICD-10 Codes G47.11, G47.12); **AND** One of the following: ▪ Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ONE preferred agent; **OR** ▪ Inability to swallow tablets or capsules whole. **Quantity Limit:** 60mL per day
Intuniv ER tablet CC, QL	Diagnosis of: ▪ Attention Deficit Disorder (ADD)/ Attention-deficit hyperactivity disorder (ADHD) (ICD-10 Disease Group F90); **OR** ▪ Narcolepsy (ICD-10 Codes G47.419, G47.411, G47.421, G47.429); **OR** ▪ Sleep apnea (ICD-10 Code G47.30); **OR** ▪ Circadian rhythm (shift work) sleep disorder (ICD-10 Codes G47.20, G47.21, G47.22, G47.23, G47.24, G47.25, G47.26, G47.27, G47.29); **OR** ▪ Idiopathic hypersomnia (ICD-10 Codes G47.11, G47.12); **AND** • BMN criteria. **Quantity Limit:** 1 per day

6. THERAPEUTIC DUPLICATION

Patients are limited to **one** long-acting and **one** short-acting CNS stimulant at a time within the quantity/dosing limits. Overrides may be approved:

For the date of service when patients are switching from one agent to another.

For 1 year when the member requires two different strengths of one medication because the prescribed dosage cannot be achieved otherwise (e.g., Concerta 18 mg and Concerta 27 mg taken together once daily).

A clinical pharmacist may approve with clinical justification when:

- Prescriber requests more than one long-acting or more than one short-acting;
- Prescriber is splitting the dosage of a long-acting agent for the patient (e.g., Concerta 18 mg AM and Concerta 27 mg at 4:00 PM).

NOTES:

- Intuniv (guanfacine ER) and Kapvay (clonidine ER) are exempt from this edit.
- Strattera (atomoxetine) is included in this edit.

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CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
atomoxetine capsule CC, QL	Adderall QL
clonidine ER tablet CC, QL	Adderall XR QL
dexmethylphenidate ER CC, QL	Adzenys XR-ODT AE, CC, QL
dexmethylphenidate IR CC, QL	amphetamine ER ODT AE, CC, QL
dextroamphetamine tablet 5 mg, 10 mg, 15 mg CC, QL	amphetamine sulfate tablet QL
dextroamphetamine/amphetamine ER (generic Adderall XR) CC, QL	Aptensio XR QL
dextroamphetamine/amphetamine IR CC, QL	Arynta AE, CC, QL
guanfacine ER CC, QL	atomoxetine solution QL
Jornay PM AE, QL	Atoncy QL
lisdexamfetamine CC, QL	Azstarys QL
Methylin CC, QL	Concerta QL
methylphenidate solution CC, QL	Cotempla XR-ODT AE, QL
methylphenidate IR tablet CC, QL	Daytrana CC, QL
methylphenidate ER tablet 10 mg, 20 mg CC, QL (generic Metadate ER)	Desoxyn QL
methylphenidate ER tablet 18 mg, 27 mg, 36 mg, 54 mg CC, QL (generic Concerta)	Dexedrine QL
Qelbree ER CC, QL	dextroamphetamine ER QL
Vyvanse CC, QL	dextroamphetamine solution CC, QL
	dextroamphetamine tablet 2.5 mg, 7.5 mg, 20 mg, 30 mg QL
	Dyanavel XR AE, QL
	Evekeo QL
	Focalin QL
	Focalin XR QL
	Intuniv ER CC, QL
	methamphetamine tablet QL
	methylphenidate CD QL
	methylphenidate ER capsule QL
	methylphenidate ER ODT AE, QL
	methylphenidate ER tablet 63 mg, 72 mg tablet QL (generic Relexxii)
	methylphenidate ER sprinkle QL
	methylphenidate LA QL
	methylphenidate ER OROS QL
	methylphenidate chewable tablet CC, QL
	methylphenidate patch CC, QL
	Mydayis ER AE, QL
	Onyda XR AE, QL
	ProCentra CC, QL
	QuilliChew ER AE, QL
	Quillivant XR QL
	Relexxii QL
	Ritalin QL
	Xelstrym CC, QL
	Zenzedi QL

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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CENTRAL NERVOUS SYSTEM: NARCOLEPSY AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval
armodafinil tablet CC, QL modafinil tablet CC, QL	Diagnosis of: ▪ Narcolepsy (ICD-10 Codes G47.419, G47.411, G47.421, G47.429); **OR** ▪ Sleep apnea (ICD-10 Code G47.30); **OR** ▪ Shift work sleep disorder (ICD-10 Codes G47.20, G47.21, G47.22, G47.23, G47.24, G47.25, G47.26, G47.27, G47.29); **OR** ▪ Idiopathic hypersomnia (ICD-10 Codes G47.11, G47.12).

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	G47.411	Narcolepsy with cataplexy
	G47.419	Narcolepsy without cataplexy
	G47.421	Narcolepsy in conditions classified elsewhere with cataplexy
	G47.429	Narcolepsy in conditions classified elsewhere without cataplexy
	G47.30	Sleep apnea, unspecified
	G47.20	Circadian rhythm sleep disorder, unspecified type
	G47.21	Circadian rhythm sleep disorder, delayed sleep phase type
	G47.22	Circadian rhythm sleep disorder, advanced sleep phase type
	G47.23	Circadian rhythm sleep disorder, irregular sleep wake type
	G47.24	Circadian rhythm sleep disorder, free running type
	G47.25	Circadian rhythm sleep disorder, jet lag type
	G47.26	Circadian rhythm sleep disorder, shift work type
	G47.27	Circadian rhythm sleep disorder in conditions classified elsewhere
	G47.29	Other circadian rhythm sleep disorder
	G47.11	Idiopathic hypersomnia with long sleep time

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	G47.12	Idiopathic hypersomnia without long sleep time

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

Preferred with PA (PDP) criteria must be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Sunosi CC, QL	• Prescriber is a neurologist, sleep medicine, or other specialist in the treatment of narcolepsy; **AND**
	• Prescriber attestation or documentation that member's blood pressure is adequately controlled (≤ 140/90 mmHg); **AND**
	• Trial and failure/intolerance of, or contraindication to, ≥ 1 narcolepsy agent (e.g., modafinil); **AND**
	• Diagnosis of excessive daytime sleepiness associated with narcolepsy; **AND**
	  ○ Trial and failure of ≥ 1 stimulant (e.g., amphetamine); **OR**
	• Diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA); **AND**
	  ○ Member is using constant positive airway pressure (CPAP).
	
	Quantity Limit: 1 per day

Wakix CC, QL	• Prescriber is a neurologist, sleep medicine, or other specialist in the treatment of narcolepsy; **AND** • Diagnosis of cataplexy and/or excessive daytime sleepiness associated with narcolepsy; **AND** • Documentation of a multiple sleep latency test (MSLT) confirming narcolepsy; **AND** • Trial and failure/intolerance of, contraindication to, ≥ 1 narcolepsy agent (e.g., modafinil); trial can be waived if member has a history of substance abuse; **AND** • Trial and failure/intolerance of, contraindication to, of ≥ 1 stimulant (e.g., amphetamine); trial can be waived if member has a history of substance abuse; **OR** • Trial and failure/intolerance of, contraindication to, of ≥ 1 antidepressant (e.g., imipramine, citalopram) for cataplexy

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Agent(s) Subject to Criteria	Criteria for Approval
	symptoms. **Quantity Limit:** 2 per day
Xyrem CC, QL	Prescriber is a neurologist, sleep medicine, or other specialist in the treatment of narcolepsy; **AND** Diagnosis of cataplexy and/or excessive daytime sleepiness associated with narcolepsy; **AND** • Documentation of a multiple sleep latency test (MSLT) confirming narcolepsy; **AND** • Trial and failure/intolerance of, contraindication to, ≥ 1 narcolepsy agent (e.g., modafinil); **AND** • Trial and failure/intolerance of, contraindication to, of ≥ 1 stimulant (e.g., amphetamine) for excessive daytime sleepiness symptoms; **OR** • Trial and failure/intolerance of, contraindication to, of ≥ 1 antidepressant (e.g., imipramine, citalopram) for cataplexy symptoms; **AND** • If requesting Xywav: failure of Xyrem due to intolerance or adverse outcome (e.g., hypernatremia) suspected to be caused by high sodium content of Xyrem. **Quantity Limit:** 18 mL per day
Xywav CC, QL	**Cataplexy and excessive daytime sleepiness associated with narcolepsy:** • Prescriber is a neurologist, sleep medicine, or other specialist in the treatment of narcolepsy; **AND** • Diagnosis of cataplexy and/or excessive daytime sleepiness associated with narcolepsy; **AND** • Documentation of a multiple sleep latency test (MSLT) confirming narcolepsy; **AND** • Trial and failure/intolerance of, contraindication to, ≥ 1 narcolepsy agent (e.g., modafinil); **AND** • Trial and failure/intolerance of, contraindication to, of ≥ 1 stimulant (e.g., amphetamine) for excessive daytime sleepiness symptoms; **OR** • Trial and failure/intolerance of, contraindication to, of ≥ 1 antidepressant (e.g., imipramine, citalopram) for cataplexy symptoms; **AND** • If requesting Xywav: failure of Xyrem due to intolerance or adverse outcome (e.g., hypernatremia) suspected to be caused by high sodium content of Xyrem. **Idiopathic Hypersomnia:** • Prescriber is a neurologist, sleep medicine, or other specialist in the treatment of sleep disorders; **AND** • Patient is at least 18 years of age; **AND** • Diagnosis of idiopathic hypersomnia; **AND** • Documentation of a multiple sleep latency test (MSLT) confirming idiopathic hypersomnia; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Other causes of sleep disorder have been ruled out; **AND** • Trial and failure/intolerance of, contraindication to modafinil; **AND** • Trial and failure/intolerance of, contraindication to, of ≥ 1 stimulant (e.g., amphetamine) for excessive daytime sleepiness symptoms; **AND** • The requested dose does not exceed FDA approved dosing for diagnosis. **Quantity Limit:** 18 mL per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
armodafinil tablet CC, QL	Nuvigil tablet CC, QL
modafinil tablet CC, QL	Provigil tablet CC, QL
	sodium oxybate solution CC, QL
	Sunosi tablet CC, QL
	Wakix tablet CC, QL
	Xyrem solution CC, QL
	Xywav solution CC, QL

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CENTRAL NERVOUS SYSTEM: NEUROPATHIC AND MISCELLANEOUS PAIN AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent in the same sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
duloxetine DR 80 mg, 90 mg, 120mg CC	**Generalized Anxiety Disorder (GAD):** • Patient has a confirmed diagnosis of generalized anxiety disorder (GAD); **AND** • Trial and failure of all preferred delayed-release capsule strengths (20mg, 30mg, and 60mg) or allergy, contraindication (including potential drug-drug interactions), or intolerance to those preferred delayed-release capsule strengths; **AND** • Provider has submitted clinical rationale why other dosage forms and/or strengths cannot be used. **Major Depressive Disorder (MDD):** • Patient has a confirmed diagnosis of major depressive disorder (MDD); **AND** • Trial and failure of all preferred delayed-release capsule strengths (20mg, 30mg, and 60mg) or allergy, contraindication (including potential drug-drug interactions), or intolerance to those preferred delayed-release capsule strengths; **AND** • Provider has submitted clinical rationale why other dosage forms and/or strengths cannot be used. **Renewal Criteria (all indications):** • Attestation or documentation (e.g., progress note) that the member has demonstrated clinical benefit from therapy and/or stabilization and continues to require the requested duloxetine delayed-release capsule strength.

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to Criteria	Criteria for Approval
Gabarone CC, QL	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to gabapentin capsule AND gabapentin oral solution; **AND** • Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with at least 2 manufacturers (if available and covered) of gabapentin capsule AND gabapentin oral solution.
ZTlido CC, QL	• Diagnosis of post-herpetic neuralgia; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to BOTH of the following: o lidocaine 5% patch o capsaicin (OTC). **Quantity Limit:** 3 per day

CURRENT PDL STATUS

NEUROPATHIC PAIN

Preferred Agents	Non-Preferred Agents
duloxetine DR capsule 20 mg, 30 mg, 60 mg	Drizalma Sprinkle capsule
gabapentin capsule (except 200 mg) QL	duloxetine DR capsule 40 mg
gabapentin solution QL	duloxetine DR capsule 80 mg, 90 mg, 120mg CC
gabapentin tablet QL	gabapentin capsule 200 mg QL
Lidocaine patch QL	gabapentin ER tablet
pregabalin capsule QL	Gabarone tablet CC, QL
pregabalin solution QL	Gralise tablet
Relgaabi (except 200 mg)	Horizant tablet
	Lyrica capsule QL
	Lyrica solution QL
	Lyrica CR tablet QL
	milnacipran tablet QL
	milnacipran dose pack QL
	Neurontin capsule QL
	Neurontin solution QL
	Neurontin tablet QL
	pregabalin ER tablet QL
	Relgaabi capsule 200 mg QL
	Savella tablet dose pack QL
	Savella tablet QL
	ZTlido patch CC, QL

MISCELLANEOUS PAIN AGENTS

Preferred Agents	Non-Preferred Agents
Journavx* tablet QL	

*Not considered a preferred agent for purposes of meeting step therapy requirements for non-preferred agents in this class.

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CENTRAL NERVOUS SYSTEM: SEDATIVE HYPNOTICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. MAXIMUM DURATION (MD) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

temazepam 15, 30 mg MD, QL
zolpidem MD, QL
Ambien MD, QL
Ambien CR MD, QL
Belsomra MD, QL
Dayvigo MD, QL
Doral MD, QL
doxepin QL (generic Silenor)
Edluar CC, MD, QL
estazolam MD, QL
eszopiclone MD, QL
flurazepam MD, QL
Halcion MD, QL
Quviviq AE,CC, MD, QL
ramelteon CC, MD, QL
Restoril MD, QL
Rozerem CC, MD, QL
Silenor QL
temazepam 7.5, 22.5 mg MD, QL
triazolam MD, QL
zaleplon MD, QL
zolpidem ER MD, QL
zolpidem SL MD, QL
	Approval Duration: 6 months
	
	• Patient has been evaluated for signs and symptoms of abuse, dependency, misuse, or overuse of controlled substances including KASPER monitoring; **AND**
	• Patient has had a trial (at least 3 weeks) of non-pharmacological therapies (e.g., stimulus control, sleep restriction, sleep hygiene measures, and relaxation therapy); **AND**
	• Patient has a diagnosis of severe or refractory insomnia; **AND/OR**
	• Patient has a comorbid condition (e.g., psychiatric disorder, chronic pain) which causes and/or exacerbates insomnia; **AND/OR**
	• Patient requires use of a sedative hypnotic medication to maintain compliance with nighttime breathing apparatus (e.g., CPAP); **OR**
	• A Clinical Pharmacist may approve the request if there is another valid medical reason why the recipient requires long-term use of the requested medication.
	• Approval of requests beyond 60 days should be limited to non-benzodiazepine agents (e.g., eszopiclone, suvorexant, zaleplon, zolpidem) wherever possible due to the higher potential for abuse, dependency, and withdrawal associated with benzodiazepines.
	• Benzodiazepine sedative hypnotics (e.g., estazolam, flurazepam, temazepam, triazolam) should only be approved for long-term use when:
	  ○ Patient has tried and failed a non-benzodiazepine sedative hypnotic (e.g., eszopiclone, suvorexant, zaleplon, zolpidem) or is unable to use these agents due to allergy or contraindication which does not apply to benzodiazepine sedative hypnotics; **AND**
	  ○ Patient meets all other above criteria for exceeding the duration limit.

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires a 14-day trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Edluar CC, MD, QL	• Diagnosis of dysphagia; **OR** • Trial and failure of 2 sedative hypnotics, ONE of which must be zolpidem.
Hetlioz CC, QL tasimelteon CC, QL	• Diagnosis of Non-24-hour sleep-wake disorder (“non-24”) in adults; **OR** • Used for the treatment of nighttime sleep disturbances in a patient age ≥ 3 years that has been diagnosed with Smith-Magenis syndrome (SMS).
Igalmi AE, CC, QL	• Patient has agitation associated with a confirmed diagnosis of schizophrenia or bipolar disorder, defined as meeting DSM-5 criteria for schizophrenia, schizoaffective, or schizophreniform disorder or bipolar I or II disorder; **AND** • Agitation is NOT due to acute intoxication; **AND** • Prescriber attestation that patient will be monitored by a healthcare provider, including an assessment of vital signs and alertness to prevent falls and syncope; **AND** • Patient is NOT taking medications known to prolong the QT interval; **AND** • Prescriber attestation that patient has been advised to avoid activities requiring mental alertness for at least 8 hours following administration; **AND** • 14-day trial and therapeutic failure, allergy, contraindication (including potential drug- drug interactions with other medications), or intolerance of 2 preferred agents (may include any preferred benzodiazepine or antipsychotic). **Renewal Criteria:** • Patient must continue to meet the above criteria; **AND** • Prescriber attestation of response (patient not requiring alternative agents following treatment of mild to moderate agitation); **AND** • Prescriber attestation that the patient has been monitored and has not experienced any treatment-restricting adverse effects

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Agent(s) Subject to Criteria	Criteria for Approval
	(e.g., syncope, orthostatic hypotension, fall, QT prolongation, symptomatic bradycardia). **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day
Quviviq AE, CC, MD, QL	• 14-day trial and therapeutic failure, allergy, contraindication (including potential drug- drug interactions with other medications), or intolerance of 1 preferred agent. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Rozerem CC, MD, QL	• NPD criteria. ○ Trial of preferred agents can be waived if there is a history of substance abuse. **Quantity Limit:** 1 per day
temazepam 7.5 mg, 22.5 mg MD, QL	• Trial and failure of 15 mg dose; **OR** • Prescriber requests 7.5 mg starting dose. **Quantity Limit:** 1 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
eszopiclone tablet MD, QL	Ambien CR tablet MD, QL
ramelteon tablet MD, QL	Ambien tablet MD, QL
temazepam 15 mg, 30 mg capsule MD, QL	Belsomra tablet MD, QL
zolpidem ER tablet MD, QL	Dayvigo tablet MD, QL
	Doral tablet MD, QL
	doxepin tablet QL
	Edluar SL tablet CC, MD, QL
	estazolam tablet MD, QL
	flurazepam capsule MD, QL
	Halcion tablet MD, QL
	Hetlioz capsule CC, QL
	Hetlioz LQ suspension CC, QL
	Igalmi film AE, CC, QL
	quazepam tablet MD, QL
	Quviviq tablet AE, CC, MD, QL
	Restoril capsule MD, QL
	Rozerem tablet CC, MD, QL
	tasimelteon capsule CC, QL
	temazepam 7.5 mg, 22.5 mg capsule MD, QL
	triazolam tablet MD, QL
	zaleplon capsule MD, QL
	zolpidem capsule MD, QL
	zolpidem SL tablet MD, QL

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CENTRAL NERVOUS SYSTEM: SKELETAL MUSCLE RELAXANTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 1-week** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
dantrolene CC, QL	• NPD criteria; **OR** • Prescribed for prophylaxis against malignant hyperthermia.

Amrix MD, QL
carisoprodol MD, QL
carisoprodol compound MD, QL
Fexmid MD, QL
Soma MD, QL
	• Limited to 21 days of therapy per rolling 30 days; UNLESS
	• Patient has a diagnosis of the following conditions:
	  ○ Lumbago with sciatica; **OR**
	  ○ Radiculopathy; **OR**
	  ○ Cervical disc disorder; **OR**
	  ○ Intervertebral disc disorders with radiculopathy; **OR**
	  ○ Prescribed by or in consult with neurology, neurosurgery, or orthopedic specialist for another chronic condition.

Zanaflex 2mg, 4mg, 6mg capsules CC, QL tizanidine 2mg, 4mg, 6mg capsules CC, QL	• At least 1-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to generic tizanidine tablets at the equivalent dose.
Zanaflex 8mg capsule CC, QL tizanidine 8mg capsule CC, QL	• At least 1-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to generic tizanidine tablets; **AND** • Provider has submitted clinical rationale why other dosage forms and/or strengths cannot be used. **Quantity Limit:** 4 per day

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Agent(s) Subject to Criteria	Criteria for Approval
Tonmya AE, CC, QL	• Patient has a diagnosis of fibromyalgia; **AND** • At least 4-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 2 preferred agents, one of which must be generic cyclobenzaprine tablets; **AND** • Provider has submitted clinical rationale why other dosage forms and/or strengths of generic cyclobenzaprine cannot be used. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
baclofen 5 mg, 10 mg, 20 mg tablet	Amrix ER MD, QL
cyclobenzaprine QL	Atmeksi AE, QL
methocarbamol 500 mg, 750 mg tablet	baclofen 15 mg tablet, solution QL, suspension QL
orphenadrine ER	carisoprodol tablet MD, QL
tizanidine tablet	carisoprodol/ASA MD, QL
	chlorzoxazone QL
	cyclobenzaprine ER QL
	Dantrium QL
	dantrolene CC, QL
	Fexmid MD, QL
	Fleqsuvy QL
	Lorzone QL
	Lyvispah QL
	metaxalone QL
	methocarbamol 1000 mg tablet
	Norgesic
	Norgesic Forte tablet
	Ontralfy AE, QL
	orphenadrine/ASA/caffeine
	orphengesic forte
	Ozobax QL
	Ozobax DS QL
	Soma MD, QL
	Tanlor tablet
	tizanidine capsule CC, QL
	Tonmya AE, CC, QL
	Zanaflex capsule CC, QL
	Zanaflex tablet

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CENTRAL NERVOUS SYSTEM: TOBACCO CESSATION

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Chantix AE, QL	• Age ≥ 18 years old.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
bupropion SR tablet QL	
Chantix tablet dose pack AE, QL	
Chantix tablet AE, QL	
nicotine gum QL	
nicotine lozenge QL	
nicotine lozenge mini QL	
nicotine patch QL	
Nicotrol nasal spray QL	
Varenicline dose pack AE, QL	
Varenicline tablet AE, QL	

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SPINAL MUSCULAR ATROPHY

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Evrysdi oral solution CC
Evrysdi oral tablet CC, QL
 	
*****All PA requests must be sent to MedImpact for review.*****
	Infantile-onset (Type 1) Spinal Muscular Atrophy (SMA):
	• Prescribed by or in consultant with a pediatric neurologist or other specialist in the diagnosis and treatment of spinal muscular atrophy (SMA); **AND**
	• Diagnosis of spinal muscular atrophy (SMA) Type 1; **AND**
	• Genetic test results (i.e., laboratory results) confirming SMA:
	  ○ Homozygous deletion or mutation of the survival motor neuron 1 (SMN1) gene; **OR**
	  ○ Compound heterozygous mutation of the SMN1 gene; **AND**
	  ○ At least two copies of the SMN2 gene; **AND**
	• Patient does not require permanent ventilation (defined as requiring a tracheostomy or more than 21 consecutive days of either non-invasive ventilation (≥ 16 hours per day) or intubation, in the absence of an acute reversible event); **AND**
	• Prescriber conducts and submits documentation of an assessment of baseline motor function using at least one of the following:
	  ○ Hammersmith Infant Neurologic Exam-Part 2 (HINE-2)
	  ○ Hammersmith Functional Motor Scale Expanded (HFMSE)
	  ○ Upper Limb Module (ULM) score
	  ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); **AND**
	• Not to be used in combination with Spinraza (nusinersen)**; AND**
	• Patient has not received treatment with Zolgensma (onasemnogene abeparvovec-xioi).
	
	Later-onset SMA:
	• Prescribed by or in consultation with a neurologist or other specialist in the diagnosis and treatment of spinal muscular atrophy (SMA); **AND**
	• Diagnosis of spinal muscular atrophy (SMA) Type 2 or 3; **AND**
	• Prescriber attestation/opinion that patient is non-ambulatory (e.g., requires wheelchair, not able to walk unassisted, etc.); **OR**
	• Prescriber attestation/opinion that patient is experiencing a decline in motor function/failure to achieve motor milestones; **AND**
	• Prescriber conducts and submits documentation of an assessment of baseline motor function using at least one of the following:
	  ○ Hammersmith Infant Neurologic Exam-Part 2 (HINE-2)
	  ○ Hammersmith Functional Motor Scale Expanded (HFMSE)
	  ○ Upper Limb Module (ULM) score
	  ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Not to be used in combination with Spinraza (nusinersen)**; AND** • Patient has not received treatment with Zolgensma (onasemnogene abeparvovec-xioi). **Renewal criteria (all requests):** • Individual does not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease; **AND** • Repeat motor function testing must be performed at every 12 month interval and must show additional motor improvement from the previous demonstrated motor improvement or that the patient demonstrates clinically significant improvements in SMA associated symptoms (such as a lack of disease progression, stabilization, or decreased decline in motor function, as compared to the natural history trajectory of the disease) evident by the comparative assessment of baseline motor function measurements using one of the following assessments: o Hammersmith Infant Neurologic Exam-Part 2 (HINE-2) must demonstrate: ▪ An improvement or maintenance of previous improvement of at least 2 points (or maximal score) increase in ability to kick; **OR** ▪ An improvement or maintenance of previous improvement of at least 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.) excluding voluntary grasp; **AND** ▪ The patient exhibited improvement, or maintenance of previous improvement in more HINE-2 motor milestones than worsening, from pretreatment baseline (net positive improvement); **OR** ▪ Has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk, etc.). o Hammersmith Functional Motor Scale Expanded (HFMSE) must demonstrate: ▪ An improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline; **OR** ▪ Has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk, etc.). o Upper Limb Module (ULM) score must demonstrate: ▪ An improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline; **OR** ▪ Has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk, etc.). o Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) must demonstrate: ▪ An improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline; **OR** ▪ Has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk, etc.).

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Agent(s) Subject to Criteria	Criteria for Approval
	• Not to be used in combination with Spinraza (nusinersen); **AND** • Patient has not received treatment with Zolgensma (onasemnogene abeparvovec-xioi).

Itvisma [AE, CC]
 	
*****All PA requests must be sent to MedImpact for review.*****
	Approval Duration: Date of service; once per lifetime
	
	• Prescribed by or in consultation with a neurologist or other specialist experienced in the diagnosis and treatment of spinal muscular atrophy (SMA); **AND**
	• Must have SMA diagnosis confirmed by submission of medical records (e.g., chart notes, laboratory values, genetic testing) demonstrating:
	  ○ A mutation or deletion of genes in chromosome 5q resulting in one of the following:
	  ▪ Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13); **OR**
	  ▪ Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1 exon 7 {allele 1} and mutation of SMN1 {allele 2}); **AND**
	
	• Patient is ≥ 2 years of age at the time of treatment; **AND**
	• Has not received prior treatment with onasemnogene abeparvovec gene replacement therapy (e.g., Zolgensma); **AND**
	• Baseline anti–AAV9 antibody titer is ≤1:50 as measured by a validated assay (e.g., ELISA), with documentation of results; **AND**
	• Does not have advanced SMA characterized by any of the following:
	  ○ Permanent invasive ventilation or chronic noninvasive ventilatory support (e.g., ≥16 hours/day) not expected to improve; **OR**
	  ○ Complete paralysis of all extremities with no residual motor function; **AND**
	• Patient is clinically stable at the time of planned dosing, with no active or recent serious infection and no clinical signs or symptoms of infection on the day of injection; **AND**
	• Baseline laboratory assessments obtained prior to ITVISMA administration, including:
	  • Liver function tests (e.g., ALT, AST, total bilirubin); **AND**
	  • Creatinine and complete blood count (including hemoglobin and platelet count); **AND**
	  • Baseline anti AAV9 antibody test; **AND**
	• Must be administered as a one-time intrathecal injection via lumbar puncture by an appropriate specialist or trained healthcare professional, with access to appropriate monitoring and supportive care; **AND**
	• Must be used with systemic corticosteroids (e.g., oral prednisolone/prednisone 1 mg/kg/day or equivalent) beginning 1 day prior to Itvisma and continued for at least 30 days, followed by a taper and ongoing monitoring as clinically indicated; **AND**
	• Provider attests that immunizations are up to date, with consideration of timing of live vaccines relative to corticosteroid

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Agent(s) Subject to Criteria	Criteria for Approval
	use, and appropriate prophylaxis against respiratory infections (e.g., influenza, RSV) has been addressed; **AND** • Not to be used in combination with another SMN1 gene replacement therapy (no repeat or sequential AAV9-based SMN1 gene therapy including IV onasemnogene abeparvovec [Zolgensma]); **AND** • Not to be used in combination with Spinraza (nusinersen); **AND** • Not to be used in combination with Evrysdi (risdiplam). **Age Limit:** ≥ 2 years

Spinraza CC
 	
*****All PA requests must be sent to MedImpact for review.*****
	Approval Duration: 6 months initial; 1 year renewal
	
	• Prescribed by or in consultant with a pediatric neurologist or other specialist in the diagnosis and treatment of spinal muscular atrophy (SMA); **AND**
	• Clinical documentation (e.g., progress notes) supporting diagnosis of Spinal Muscular Atrophy (SMA) type I, II, or III **AND**
	• Diagnosis/genetic testing results (official laboratory results) confirming 5q SMA:
	  ○ Homozygous deletion or mutation of the survival motor neuron 1 (SMN1) gene; **OR**
	  ○ Compound heterozygous mutation of the SMN1 gene; **AND**
	  ○ At least two copies of the SMN2 gene; **AND**
	• Patient is NOT maintained on permanent assisted ventilation in the absence of an acute, reversible event prompting the respiratory support; defined as:
	  ○ Tracheostomy or ventilator support for ≥ 16 hours per day for > 21 continuous days; **OR**
	  ○ Use of non-invasive ventilation beyond sleep > 12 hours in a 24 hour period. **AND**
	• Prescriber agrees to assess and monitor the following laboratory values throughout treatment:
	  ○ Complete blood count (CBC); **AND**
	  ○ Quantitative spot urine protein testing; **AND**
	  ○ Prothrombin Time (PT) or Activated Partial Thromboplastin Time (aPTT)
	• Prescriber conducts, and submits documentation of, an assessment of baseline motor function using at least one of the following:
	  ○ Hammersmith Infant Neurologic Exam-Part 2 (HINE-2)
	  ○ Hammersmith Functional Motor Scale Expanded (HFMSE)
	  ○ Upper Limb Module (ULM) score
	  ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND)
	• Not to be used in combination with Evrysdi (risidiplam); **AND**
	• Patient has not received treatment with Zolgensma (onasemnogen abeparvovec-xioi).
	
	Renewal Criteria (must meet all requirements):
	• All initial approval requirements continue to be met; **AND**
	• Individual does not require use of permanent assisted ventilation as a result of advanced SMA disease; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• The patient shall be considered a Responder to therapy by showing an improvement (rather than progression or lack of improvement) in motor function in accordance with the assessments outlined below (HINE-2, HFMSE, ULM, and/or CHOP-INTEND) after the initial 5 loading doses; **AND** • Repeat motor function testing must be performed at every 6 month interval and must show additional motor improvement from the previous demonstrated motor improvement or that the patient demonstrates clinically significant improvements in SMA associated symptoms (such as a lack of disease progression, stabilization, or decreased decline in motor function, as compared to the natural history trajectory of the disease) evident by the comparative assessment of baseline motor function measurements using one of the following assessments: ○ Hammersmith Infant Neurologic Exam-Part 2 (HINE-2) must demonstrate: ▪ An improvement or maintenance of previous improvement of at least 2 points (or maximal score) increase in ability to kick; **OR** ▪ An improvement or maintenance of previous improvement of at least 1-point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.) excluding voluntary grasp; **AND** ▪ The patient exhibited improvement, or maintenance of previous improvement in more HINE-2 motor milestones than worsening, from pretreatment baseline (net positive improvement); **OR** ▪ Has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk, etc.). ○ Hammersmith Functional Motor Scale Expanded (HFMSE) must demonstrate: ▪ An improvement or maintenance of previous improvement of at least a 3-point increase in score from pretreatment baseline; **OR** ▪ Has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk, etc.). ○ Upper Limb Module (ULM) score must demonstrate: ▪ An improvement or maintenance of previous improvement of at least a 2-point increase in score from pretreatment baseline; **OR** ▪ Has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk, etc.). ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) must demonstrate: ▪ An improvement or maintenance of previous improvement of at least a 4-point increase in score from pretreatment baseline; **OR** ▪ Has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk, etc.). • Provider must provide clinical documentation (chart/progress notes) from the most recent office visit and evaluation; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Not to be used in combination with Evrysdi (risdiplam); **AND** • Patient has not received treatment with Zolgensma (onasemnogene abeparvovec-xioi). **Low Dose Regimen** (12 mg): • Loading: 4 doses of 12 mg — one dose every 14 days × 3 doses, then a 4th dose 30 days after the 3rd dose. • Maintenance: 12 mg once every 4 months starting 4 months after the final loading dose. • Approval window: 5 doses in ~5 months. **High Dose Regimen** (50 mg / 28 mg): • Loading: 2 doses of 50 mg — 1st dose on day 0, 2nd dose on day 14. • Maintenance: 28 mg once every 4 months starting 4 months after the final loading dose. • Approval window: The loading phase requires only 2 doses over ~2 weeks, followed by the first maintenance dose at approximately day 134 (~4.5 months after the 2nd loading dose).

Zolgensma CC
 	
*****All PA requests must be sent to MedImpact for review.*****
	Approval Duration: Date of service; once per lifetime
	
	• Prescribed by or in consultation with a pediatric neurologist or other specialist in the diagnosis and treatment of spinal muscular atrophy (SMA); **AND**
	• Must have SMA confirmed by submission of medical records (e.g., chart notes, laboratory values):
	  ○ A mutation or deletion of genes in chromosome 5q resulting in one of the following:
	  - Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13); **OR**
	  - Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1 exon 7 {allele 1} and mutation of SMN1 {allele 2}); **AND**
	• Patient meets one of the following:
	  ○ Symptomatic SMA diagnosed by or in consultation with a neurologist with disease expertise; **OR**
	  ○ SMA diagnosis confirmed by newborn screening; **AND**
	  ○ 4 copies or less of the SMN2 gene; **AND**
	• Not have advanced SMA (e.g., permanent ventilation support; complete limb paralysis); **AND**
	• Not have pre-existing hepatic insufficiency; **AND**
	• Baseline anti-AAV9 antibody titer of ≤ 1:50 (as measured by ELISA); **AND**
	• Must be used with systemic corticosteroids (e.g., 1 mg/kg/day oral prednisone or equivalent) as directed; **AND**
	• Therapy to be administered prior to recipient's 2nd birthday; **AND**
	• Not to be used in combination with Spinraza (nusinersen); **AND**
	• Not to be used in combination with Evrysdi (risdiplam).

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2. NON-PREFERRED (NPD) CRITERIA

Not applicable.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Evrysdi oral solution CC	
Evrysdi oral tablet CC, QL	
Itvisma vial AE, CC	
Spinraza vial CC	
Zolgensma kit CC	

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ANALGESICS: NARCOTICS, LONG-ACTING

GUIDELINES FOR USE

Approval Duration: 6 months (1 year for active cancer, sickle cell anemia or hospice/palliative care)

1. PREFERRED WITH PA (PDP) CRITERIA (ALSO APPLIES TO NON-PREFERRED AGENTS)

Agent(s) Subject to Criteria	Criteria for Approval

Butrans [CC, QL]
fentanyl transdermal 12, 25, 50, 75, 100 mcg [CC, QL]
morphine sulfate ER (generic MS Contin) [CC, QL]
OxyContin ER tablet [CC, QL]
tramadol ER (generic Ultram ER)[AE, CC, QL]
	• Opioid Class Criteria for Initial Approval must be met; **AND**
	• Patient has severe pain requiring daily, around-the-clock, long-term pain management as evidenced by:
	  ○ Pain lasting > 3 consecutive months; **AND**
	  ○ Trial and failure within the past 90 days of 1 non-opioid analgesic (i.e., NSAIDs, APAP) at maximum tolerated doses without pain relief and/or functional improvement; **AND**
	  ○ Trial and failure within the past 90 days of at least 1 short-acting opioid analgesic at maximum tolerated doses without adequate relief of pain.
	• Additional criteria as applicable:
	  ○ Class Criteria for Naloxone Prescribing
	  ○ Class Criteria for High Morphine Milligram Equivalent (MME) Requests – Over 90 MME per Day
	  ○ Class Criteria for Approval of Very High MME Requests – Over 200 MME per Day
	  ○ Class Criteria for Opioids and Benzodiazepines

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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2. OPIOID CLASS CRITERIA

a. Refer to ANALGESICS (CLINICAL CRITERIA FOR SHORT-ACTING AND LONG-ACTING OPIOIDS) section.

3. OPIOID LONG-ACTING DUPLICATE THERAPY CRITERIA

a. Prescriber has discontinued the second long-acting opioid; **OR**

b. Prescriber has a plan to taper off one of the long-acting opioids; **OR**

c. Prescriber provided medical justification for continuation.

4. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

Preferred with PA (PDP) Criteria must be met.

5. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic.

6. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

7. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
methadone CC	• Approve for 30 days only in infants up to 1 year of age who are discharged from the hospital on a methadone taper for neonatal abstinence syndrome (NAS); **OR** • If used for pain, all of the following criteria apply: ○ Opioid Class Criteria for Initial Approval must be met; **AND** ○ Prescriber is a pain management specialist or prescriber has proof of consultation with a pain management specialist; **AND** ○ Severe pain requiring daily, around-the-clock, long-term pain management, defined as: ▪ Pain lasting > 6 consecutive months; **AND** ▪ Trial and failure of one non-opioid analgesic (i.e., NSAIDs, APAP) at maximum tolerated doses without adequate relief of pain; **AND** ▪ Trial and failure of one short-acting opioid analgesic at maximum tolerated doses without adequate relief of pain; **AND** ○ Trial and failure of two preferred long-acting opioids; **AND** ○ Patient does not have a history of drug or alcohol abuse/dependence or addiction (drug and alcohol toxicology screen results dated within the past month must be submitted with the PA request); **AND** ○ If the patient is female between the ages of 18 and 45 years of age, prescriber must attest to the fact that patient

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Agent(s) Subject to Criteria	Criteria for Approval
	has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); **AND** ○ Patient is not presently taking any other long-acting opioids. **Note:** Methadone will not be approved for drug addiction as a pharmacy benefit.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Butrans CC, QL	Belbucca AE, QL
fentanyl patch 12, 25, 50, 75, 100 mcg CC, QL	buprenorphine patch QL
morphine sulfate ER tablet CC, QL	ConZip ER capsule AE, QL
OxyContin ER tablet CC, QL	Diskets
tramadol ER tablet (generic Ultram ER) AE, CC, QL	fentanyl patch 37.5, 62.5, 87.5 mcg QL
	hydrocodone ER capsule QL
	hydrocodone ER tablet QL
	hydromorphone ER tablet QL
	Hysingla ER tablet QL
	methadone dispersible tablet CC
	methadone intensol oral concentrate CC
	methadone oral concentrate CC
	methadone solution
	methadone tablet
	methadose oral concentrate
	methadose tablet
	morphine sulfate ER capsule QL
	MS Contin ER tablet QL
	oxycodone ER tablet QL
	oxymorphone ER tablet QL
	tapentadol ER tablet AE, QL
	tramadol ER capsule AE, QL
	tramadol ER tablet (generic Ryzolt) AE, QL

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ANALGESICS: NARCOTICS, SHORT-ACTING

GUIDELINES FOR USE

Approval Duration: 1 month, 3 months, or 6 months based on full opioid criteria (1 year for active cancer, sickle cell anemia or hospice/palliative care)

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

codeine/APAP AE, CC, MD, QL
endocet CC, MD, QL
hydrocodone/APAP CC, MD, QL
hydrocodone/ibuprofen CC, MD, QL
hydromorphone tablets CC, MD, QL
morphine concentrate CC, MD
morphine solution, tablets CC, MD, QL
oxycodone solution, tablets CC, MD, QL
oxycodone/APAP tablets CC, MD, QL
tramadol 50 mg AE, CC, MD, QL
tramadol/APAP AE, MD, QL
	Codeine- and tramadol-containing products: Minimum age of 18 years
	
	PA required when:
	• The claim is for > 7-day supply for members ≥ 18 years old; **OR**
	• The claim is for > 3-day supply for members < 18 years old; **OR**
	• The claim brings the cumulative supply of short-acting opioids in the past 90 days to > 14 days; **OR**
	• Product is ≥ 30 morphine milligram equivalents (MME) in a single dosing unit (e.g., hydromorphone 8 mg tablet) or a concentrated liquid (e.g., morphine sulfate 20 mg/mL).
	
	30-day approval:
	• Only 1 short-acting opioid will be used at a time; **AND**
	• Trial and failure of, or contraindication to, at least 1 non-opioid pain medication (e.g., APAP, NSAIDs); **OR**
	• Medication is prescribed by a treating physician within 14 days of:
	  ○ A major surgery, any operative or invasive procedure or a delivery; **OR**
	  ○ A significant trauma, being any acute blunt, blast, or penetrating bodily injury that has a risk of death, physical disability, or impairment; **OR**
	  ○ Other clinical justification as to why treatment with opioids should extend beyond 14 days and provide a diagnosis more specific than pain.
	• If the request is for a high strength or concentrated dosage form, the prescriber must submit rationale why lower strength or less-concentrated products cannot be used.
	• Additional criteria as applicable:
	  ○ Class Criteria for Naloxone Prescribing
	  ○ Class Criteria for High Morphine Milligram Equivalent (MME) Requests – Over 90 MME per Day; **OR**
	  ○ Class Criteria for Approval of Very High MME Requests – Over 200 MME per Day
	  ○ Class Criteria for Opioids and Benzodiazepines
	
	3- or 6-month approval:
	• Opioid Class Criteria for Initial Approval must be met; **AND**
	• Prescriber must submit a diagnosis more specific than pain; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Trial and failure of, or contraindication to, at least 1 non-opioid pain medication (e.g., APAP, NSAIDs) within the past 6 months; **OR**
	• Medication is prescribed by a treating physician within 30 days of:
	  ○ A major surgery, any operative or invasive procedure or a delivery; **OR**
	  ○ A significant trauma, being any acute blunt, blast, or penetrating bodily injury that has a risk of death, physical disability, or impairment; **OR**
	  ○ Other clinical justification as to why treatment with opioids should extend beyond 30 days.
	• If short-term pain management is expected/indicated, approve for 3 months; **OR**
	• If long-term (e.g., > 3 months) pain management is expected/indicated OR patient is currently taking a long-acting narcotic; approve for 6 months.
	• If the request is for a high strength or concentrated dosage form, the prescriber must submit rationale why lower strength or less-concentrated products cannot be used.
	• Additional clinical justification will be required for doses that exceed quantity limits (e.g., 90 MME).
	• Additional criteria as applicable:
	  ○ Class Criteria for Naloxone Prescribing
	  ○ Class Criteria for High Morphine Milligram Equivalent (MME) Requests – Over 90 MME per Day; **OR**
	  ○ Class Criteria for Approval of Very High MME Requests – Over 200 MME per Day
	  ○ Class Criteria for Opioids and Benzodiazepines

2. OPIOID CLASS CRITERIA

Refer to ANALGESICS (CLINICAL CRITERIA FOR SHORT-ACTING AND LONG-ACTING OPIOIDS) section.

3. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 1-week** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

Preferred with PA (PDP) Criteria must be met.

4. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

5. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

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6. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Ascomp with codeine AE, CC, QL butalbital/APAP/caffeine/codeine CC, QL butalbital/ASA/caffeine/codeine AE, CC, QL butalbital compound/codeine AE, CC, QL	**Approval Duration:** 1 year • Diagnosis of one of the following headache disorders: ○ Muscular headache; **OR** ○ Tension-type headache; **OR** ○ Migraine. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day (30 per 30 days) - Not meant for daily use: up to 6 per headache day; 5 headache days per month

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
codeine/APAP solution AE, CC, MD, QL	APAP/caffeine/dihydrocodeine capsule MD, QL
codeine/APAP tablet AE, CC, MD, QL	ASA/butalbital/caffeine/codeine capsule AE, CC, QL
hydrocodone/APAP solution CC, MD, QL	Ascomp with codeine capsule AE, CC, QL
hydrocodone/APAP tablet CC, MD, QL	butalbital/APAP/caffeine/codeine capsule AE, CC, QL
hydrocodone/ibuprofen tablet CC, MD, QL	butalbital/codeine capsule AE, CC, QL
hydromorphone tablet CC, MD, QL	codeine tablet AE, MD, QL
morphine concentrate CC, MD	Dilaudid liquid MD, QL
morphine solution CC, MD, QL	Dilaudid tablet MD, QL
morphine syringe 10 mg/0.5 mL CC, MD	Fioricet with codeine capsule AE, CC, QL
morphine tablet CC, MD, QL	hydromorphone liquid MD, QL
oxycodone solution CC, MD, QL	hydromorphone suppository MD, QL
oxycodone tablet CC, MD, QL	levorphanol tablet MD, QL
oxycodone/APAP tablet CC, MD, QL	meperidine solution MD, QL
tramadol 50 mg tablet AE, CC, MD, QL	meperidine tablet MD, QL
tramadol/APAP tablet AE, MD, QL	morphine suppository MD, QL
	morphine syringe 20 mg/mL MD
	Nalocet tablet MD, QL
	oxycodone capsule MD, QL
	oxycodone concentrate MD, QL
	oxycodone oral syringe MD, QL
	oxycodone/APAP solution MD, QL
	oxymorphone tablet MD, QL
	Percocet tablet MD, QL
	Prolate solution MD, QL
	Prolate tablet MD, QL
	Qdolo AE, MD, QL
	Roxicodone tablet MD, QL
	Roxybond tablet MD, QL
	Seglentis tablet AE, MD, QL
	tapentadol solution AE
	tapentadol tablet AE
	tramadol 25 mg tablet AE, MD, QL
	tramadol 75 mg tablet AE, MD, QL
	tramadol 100 mg tablet AE, MD, QL
	tramadol solution AE, MD, QL

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ANALGESICS: CLINICAL CRITERIA FOR SHORT-ACTING AND LONG-ACTING OPIOIDS

GUIDELINES FOR USE

Approval Duration: Varies
(1 year for active cancer, sickle cell anemia or hospice/palliative care)

NOTE: Class criteria will be waived for members receiving hospice/palliative/end-of-life care or have a diagnosis of active cancer or sickle cell anemia.

1. CLASS CRITERIA FOR INITIAL APPROVAL

Exception apply to short-acting opioids for acute pain; additional criteria may also apply to specific formulation).

a. Prescriber has evaluated the member for risk of diversion, harm, or misuse:

i. Prescriber attests that KASPER report for the past 12 months has been reviewed; **AND**

ii. Prescriber submits urine drug screen (UDS) results dated within the past 30 days for ALL new chronic opioid (e.g., beyond 45 days of treatment) requests UNLESS the member is in a long-term care or skilled nursing facility. Note: UDS is not required for acute prescribing; **AND**

iii. If UDS is positive for illicit or unexpected substances, prescriber attests that naloxone was or will be prescribed; **AND**

b. Prescriber submits an assessment of baseline pain and function using an objective measure; **AND**

c. Prescriber attestation or documentation that non-opioid therapies (e.g., exercise therapy, cognitive behavioral therapy, NSAIDs, etc.) have been tried and/or are being used and optimized as appropriate; **AND**

d. For females of child-bearing age, prescriber attests that the member has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); **AND**

e. Patient does NOT have respiratory depression, acute or severe bronchial asthma, or hypercarbia; **AND**

f. Patient does NOT have known or suspected GI obstruction (e.g., paralytic ileus); **AND**

g. Up to 1 long-acting opioid and 1 short-acting opioid may be used at a time.

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2. CLASS CRITERIA FOR HIGH MORPHINE MILLIGRAM EQUIVALENT (MME) REQUESTS – OVER 90 MME PER DAY

a. Additional criteria shall apply for NEW requests where the cumulative opioid dose across all prescriptions is > 90 morphine milligram equivalents (MME):

i. Note: Buprenorphine products (for opioid addiction treatment or pain) are not assigned an MME value and will not be included in the calculation.

ii. Prescriber is, or has proof of consultation with, a Pain Management Specialist OR specialist in an appropriate discipline (e.g., orthopedist, neurologist, spine specialist, etc.) for evaluation of the source of pain and/or treatment of any underlying conditions; **AND**

iii. Prescriber must submit clinical justification for exceeding 90 MME/day; **AND**

iv. Prescriber attests that a naloxone prescription and associated counseling on its use was or will be offered to the member.

3. CLASS CRITERIA FOR APPROVAL OF VERY HIGH MME REQUESTS – OVER 200 MME PER DAY

a. Additional criteria shall apply any requests where the cumulative opioid dose across all prescriptions is > 200 MME/day:

i. Note: Buprenorphine products (for opioid addiction treatment or pain) are not assigned an MME value and will not be included in the calculation.

ii. Prescriber is, or has proof of consultation with, a Pain Management Specialist; **AND**

iii. Prescriber submits clinical justification for exceeding 200 MME/day; **AND**

iv. Prescriber submits documentation (e.g., progress notes) showing attempts and/or plans to taper below 200 MME/day as well as other non-opioid components (e.g., NSAIDs, physical therapy, etc.) of the treatment plan; **AND**

v. Prescriber attests that a naloxone prescription and associated counseling on its use was or will be given to the member.

4. CLASS CRITERIA FOR OPIOIDS AND BENZODIAZEPINES

a. Additional criteria shall apply when opioids are prescribed concurrently with benzodiazepines and/or KASPER report shows a benzodiazepine prescription in the past 12 months:

i. Prescriber must submit clinical justification for the concurrent use of benzodiazepines and opioids; **AND**

ii. Prescriber attests that the member and/or caregiver(s) has been or will be counseled about the increased risks of slowed or difficult breathing and/or excessive sedation, and the associated signs and symptoms; **AND**

iii. Prescriber attests that a naloxone prescription and associated counseling on its use was or will be given to the member.

5. CLASS CRITERIA FOR OPIOIDS AND BUPRENORPHINE

a. Prescriber verifies knowledge of the patient's relapse and agrees to increase psychosocial counseling **AND** prescriber provides the dates of planned counseling sessions; **OR**

b. Opioid(s) is being used short-term (≤ 30 days) for an acute injury leading to acute pain.

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Note: Requests for 2 different strengths are considered a therapy duplication and may be overridden if total mg/day does not exceed established limits or quantity limits for each specific strength.

6. CLASS CRITERIA FOR NALOXONE PRESCRIBING

a. Prescriber attests that a naloxone prescription and associated counseling on its use was or will be offered to the member when any of the following are true (e.g., found on KASPER report, medication list, or diagnosis list):

i. Opioid(s) is/are concurrently prescribed with a skeletal muscle relaxant (e.g., cyclobenzaprine); **OR**

ii. Opioid(s) is/are concurrently prescribed with a sedative hypnotic (e.g., zolpidem); **OR**

iii. Opioid(s) is/are concurrently prescribed with gabapentin or pregabalin; **OR**

iv. Member has a history of opioid or other controlled substance overdose; **OR**

v. Member has a history of substance use disorder (SUD).

7. OPIOID RENEWAL CRITERIA

a. Prescriber must submit proof of monitoring for evidence of diversion, harm, and misuse:

i. Attest that KASPER report has been checked within the past 3 months: **AND**

ii. If the member is not in a long-term care or skilled nursing facility, require prescriber to document risk assessment and provide most recent UDS results dated within:

a) One year if considered “low risk”; **OR**

b) Six months if considered “moderate risk”; **OR**

c) Three months if considered “high risk”; **AND**

iii. Prescriber explanation is required if UDS is positive for illicit or unexpected substances; **AND**

iv. If UDS is positive for illicit or unexpected substances, prescriber attests that naloxone was or will be prescribed.

b. Prescriber must submit an assessment of current pain and function using an objective measure; **AND**

c. Recipient should demonstrate a 30% improvement from baseline to continue current dose or documentation (e.g., progress note) that includes the rationale for continued opioid therapy at the current dose; **AND**

d. Prescriber must report whether patient has required use of opioid rescue medication (e.g., naloxone) or has been hospitalized or otherwise treated for opioid or other controlled substance overdose in the past 6 months; **AND**

i. If member has opioid overdose or use of naloxone within the past 6 months, the prescriber must submit documentation (e.g., progress notes) a plan for preventing future overdoses (e.g., dose reduction of opioid or opioid potentiator[s]; discontinuation of opioid potentiator[s]).

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ANALGESICS: NARCOTICS, FENTANYL CITRATE PRODUCTS

GUIDELINES FOR USE

Approval Duration: 6 months

Prior Approval for the medications of this edit must be obtained by the prescriber's office ONLY.

Prescribers/prescriber's agents or LTC facility-based prescribers/prescriber's agents must initiate the following prior authorization requests. Pharmacies/LTC pharmacies and their staff are not permitted to initiate these requests. For members flagged with an LTC eligibility segment, the prescriber signature prior authorization requirements MUST be satisfied by a FACILITY-BASED prescriber/prescriber agent (for faxed requests).

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable.

2. NON-PREFERRED (NPD) CRITERIA

a. Diagnosis of cancer pain unresponsive to any other therapy; **AND**

b. Patients must be receiving, and be tolerant to, opioid therapy; **AND**

c. Patients must have tried opioid doses greater than or equal to either Morphine 60 mg daily or Fentanyl Patches 50 mcg/hour for at least one week.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure, contraindication, or intolerance to the generic equivalent agent before obtaining approval for the branded agent. These requests must be submitted on the Brand Medically Necessary Form.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents – PA Required	Non-Preferred Agents – PA Required
None	fentanyl citrate lozenge CC, QL
	fentanyl citrate tablet CC, QL

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ANALGESICS: NARCOTIC AGONISTS/ANTAGONISTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure of appropriate duration, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in the Analgesics: Narcotics, Short-Acting class.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
None	butorphanol nasal spray
	pentazocine/naloxone tablet QL

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ANALGESICS: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to **ALL** unique chemical entities in the preferred agents indicated for the patient's condition, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Duexis CC ibuprofen/famotidine CC Vimovo CC, QL naproxen/esomeprazole CC, QL	• NPD Criteria above; **OR** • Trial and failure (e.g., poor adherence) of individual, generic non-NSAID components (famotidine or esomeprazole, as applicable).

diclofenac epolamine patch CC
diclofenac 2% solution pump CC
diclofenac 1.5% topical solution CC
Flector CC
ketorolac nasal spray CC
Licart CC
Pennsaid 2% pump CC
Sprix CC
	• NPD Criteria above; **OR**
	• Trial and failure of diclofenac 1% topical gel; **AND**
	  ○ Contraindication to oral NSAIDs; **OR**
	  ○ Unable to tolerate, swallow, or absorb oral NSAIDs.

celecoxib 400 mg QL	Allow up to 17 capsules in 8 days when high dose regimen is needed for acute gout: 800 mg orally immediately, followed by 400 mg 12 hours later and then 400 mg every 12 hours for 7 days.

Orudis (ketoprofen 75 mg capsule) CC, QL
ketoprofen capsule CC, QL
	Approval Duration: 3 months
	• Diagnosis of one of the following conditions:
	  ○ Rheumatoid arthritis; **OR**
	  ○ Osteoarthritis; **OR**
	  ○ Pain; **OR**
	  ○ Primary dysmenorrhea; **AND**
	  ○ NPD Criteria above; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• ≥ 3-day trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents; **AND**
	• ≥ 3-day trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to one of the following:
	  ○ ketoprofen capsule; **OR**
	  ○ ketoprofen ER capsule; **AND**
	• Provider has submitted clinical rationale why other dosage forms and/or strengths cannot be used.
	
	Quantity Limit: 4 per day

Vyscoxa CC, QL	• Patient has ONE of the following diagnoses:
	  ○ Osteoarthritis; **OR**
	  ○ Rheumatoid Arthritis; **OR**
	  ○ Ankylosing Spondylitis; **OR**
	  ○ Juvenile Rheumatoid Arthritis; **AND**
	• NPD Criteria above; **AND**
	• Unable to swallow whole, or consume crushed generic tablets; **AND**
	
	Quantity Limit: 40 mL per day

Zybic AE, CC, QL	• Patient has ONE of the following diagnoses:
	  ○ Osteoarthritis; **OR**
	  ○ Rheumatoid Arthritis; **OR**
	  ○ Juvenile Rheumatoid Arthritis; **AND**
	• NPD criteria above; **AND**
	• Unable to swallow whole, or consume crushed generic tablets; **AND**
	• Provider has submitted clinical rationale why other dosage forms and/or strengths of generic meloxicam cannot be used.
	
	Age Limit: ≥ 2 years
	Quantity Limit: 10 mL per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
celecoxib capsule QL	Arthrotec
diclofenac sodium topical gel 1%	Celebrex QL
diclofenac sodium DR/EC tablets	Daypro tablet
Ibu tablet	diclofenac epolamine patch CC
ibuprofen suspension	diclofenac potassium capsule
ibuprofen tablet (except 300 mg)	diclofenac potassium powder pack
indomethacin capsule	diclofenac potassium tablet
indomethacin ER capsule	diclofenac 1.5% topical solution CC
ketorolac tablet	diclofenac sodium SR/ER tablet
meloxicam tablet	diclofenac 2% solution pump CC
nabumetone tablet	diclofenac sodium/misoprostol
naproxen sodium tablet	diflunisal tablet
naproxen tablet	Dolobid tablet QL

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Preferred Agents	Non-Preferred Agents
piroxicam capsule	Duexis tablet CC
sulindac tablet	EC-Naprosyn tablet
	EC-naproxen tablet
	Elyxyb solution CC, AE, QL
	etodolac capsule
	etodolac tablet
	etodolac ER tablet
	Feldene capsule
	fenoprofen capsule
	fenoprofen tablet
	Fenopron capsule
	Flector patch CC
	flurbiprofen tablet
	ibuprofen 300 mg tablet
	ibuprofen/famotidine tablet
	indomethacin suppository
	indomethacin suspension QL
	ketoprofen ER capsule
	ketoprofen capsule
	ketoprofen capsule 75 mg CC, QL
	ketorolac nasal spray CC
	Kiprofen capsule
	Licart patch CC
	Lofena tablet
	meclofenamate capsule
	mefenamic acid capsule
	meloxicam capsule CC, QL
	Nalfon tablet
	Naprelan CR tablet
	Naprosyn suspension
	naproxen DR tablet
	naproxen suspension
	naproxen sodium CR/ER tablet
	naproxen/esomeprazole DR tablet CC, QL
	Orudis capsule CC, QL
	oxaprozin tablet
	Pennsaid CC
	Relafen tablet
	Relafen DS tablet
	Tolectin 600 tablet QL
	Tolectin DS capsule CC, QL
	tolmetin capsule QL
	tolmetin tablet QL
	Vimovo CC, QL
	Vyscoxa suspension CC, QL
	Zybic suspension AE, CC, QL

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ANALGESICS: OPIATE DEPENDENCE TREATMENTS

GUIDELINES FOR USE

Approval Duration: Date of Service Only

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Not applicable.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

6. THERAPEUTIC DUPLICATION

a. Buprenorphine-containing products will deny for therapeutic duplication when:

i. There is a claim for any opioid in the past 30 days; **OR**

ii. There is a claim for another buprenorphine-containing product in the past 90 days.

b. Only the buprenorphine prescriber's office can request these overrides; they will be made aware of the narcotic in history.

c. Date-of-Service (DOS) approvals can be granted when ONE of the following apply:

i. The prescriber verifies knowledge of the patient's relapse and agrees to increase psychosocial counseling. Please obtain dates of planned counseling sessions. If no planned sessions, do not approve, **OR**

ii. The narcotic analgesic is being used short-term (30 days or less) for an acute injury leading to acute pain.

iii. Requests for 2 different strengths are considered a therapy duplication. Pharmacist may override if total mg/day does not exceed established limits or exceed quantity limits for each specific strength.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Brixadi	None
Buprenorphine SL tablet QL	

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Preferred Agents	Non-Preferred Agents
buprenorphine/naloxone SL film QL	
buprenorphine/naloxone SL tablet QL	
lofexidine tablet QL	
Lucemyra tablet QL	
naltrexone tablet	
Sublocade ER syringe QL	
Suboxone film QL	
Vivitrol ER suspension	
Zubsolv SL tablet QL	

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ANTI-INFECTIVE: ORAL ANTIFUNGALS

GUIDELINES FOR USE

Approval Duration: 6 months, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

itraconazole capsule CC, QL	• Prescribed for the treatment or prophylaxis (in an immunocompromised patient) of systemic fungal infection (e.g., aspergillosis, esophageal candidiasis, histoplasmosis); **OR**
	• Diagnosis of onychomycosis, tinea, or other superficial fungal infection; **AND**
	• Trial and failure of intolerance or contraindication to, ≥ 1 of the following agents:
	  ○ Topical antifungal (e.g., clotrimazole, ketoconazole)
	  ○ Oral griseofulvin
	  ○ Oral terbinafine
	
	Quantity Limit: 4 per day

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure of an appropriate duration, allergy, contraindication (including potential drug-drug interactions with other medications), intolerance, or evidence of organism resistance to generic itraconazole (for systemic infection) **OR** 2 preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Vivjoa CC, QL	**Approval Duration:** 1 year • Patient has diagnosis of recurrent vulvovaginal candidiasis with ≥ 3 episodes of vulvovaginal candidiasis in ≤ 12-month period; **AND** • Patient is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy); **AND** • Patient is not pregnant; **AND** • Patient is not lactating; **AND** • Patient has tried and failed or has a contraindication or intolerance to maintenance antifungal therapy with oral fluconazole for 6 months.

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Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limit: 18 tablets per treatment course

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
clotrimazole troche	Cresemba
fluconazole suspension, tablet	Diflucan
griseofulvin suspension	flucytosine
itraconazole capsule CC, QL	fulvicin P-G AE, QL
ketoconazole	griseofulvin microsize tablet, ultramicrosize tablet
nystatin suspension, tablets	itraconazole solution
terbinafine	Noxafil
	Oravig
	posaconazole
	Sporanox QL
	Tolsura
	Vfend
	Vivjoa CC, QL
	voriconazole QL

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ANTI-INFECTIVE: ORAL ANTIVIRALS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent from the same sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Xofluza AE, CC, QL	• Confirmed or suspected diagnosis of acute, uncomplicated, outpatient influenza; **AND**
	• Patient is symptomatic for ≤ 48 hours; **OR**
	• Prescribed for post-exposure prevention of influenza after contact with an individual diagnosed with influenza; **AND**
	• Allergy, contraindication, intolerance, or other reason a preferred influenza antiviral cannot be used; **AND**
	• Patient is NOT:
	  ○ Taking concurrent neuraminidase inhibitors (e.g., Tamiflu, Relenza); **OR**
	  ○ Taking polyvalent cation-containing laxatives, antacids, or oral supplements (e.g., calcium, iron, magnesium, selenium, or zinc); **OR**
	  ○ Pregnant; **OR**
	  ○ Hospitalized.
	
	Age Limit: ≥ 5 years
	Quantity Limit: 2 tablets (1 dose) per fill

CURRENT PDL STATUS

ANTIVIRALS: HERPES

Preferred Agents	Non-Preferred Agents
acyclovir	Valtrex
famciclovir	Zovirax oral suspension

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Preferred Agents	Non-Preferred Agents
valacyclovir	

ANTIVIRALS: INFLUENZA

Preferred Agents	Non-Preferred Agents
oseltamivir QL	Flumadine
	Relenza
	rimantadine
	Tamiflu QL
	Xofluza AE, CC, QL

ANTIVIRALS: COVID-19

Preferred Agents	Non-Preferred Agents
Paxlovid	

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ANTI-INFECTIVE: ORAL ANTIBIOTICS

GUIDELINES FOR USE

Approval Duration: Date of Service, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
vancomycin capsule, solution CC	• Diagnosis of *clostridium difficile*-associated diarrhea (ICD-10 = A04.7); **OR** • Diagnosis of *Staphylococcal* enterocolitis.
linezolid tablet CC, MD, QL	• Completion of a course of therapy begun during a hospital or healthcare facility stay; **OR** • Diagnosis of methicillin-resistant staph aureus (MRSA), vancomycin-resistant enterococcus (VRE); **AND** • Prescriber attestation that the choice of therapy is based on culture and sensitivity testing; **OR** • Trial and failure of another first-line antibiotic in a patient at high risk for complications. **Maximum Duration:** 28 days **Quantity Limit:** 2 per day • **NOTE:** linezolid suspension may be approved when the above criteria are met AND the member is unable to swallow linezolid tablets.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure of an appropriate course of therapy, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Dificid tablet, suspension CC, QL fidaxomicin tablet CC, QL	**Approval Duration:** Date of Service (total 10-day course of therapy) • Patient age ≥ 6 months; **AND** • Diagnosis of pseudomembranous colitis due to C. difficile infection; **AND** • Trial and failure of vancomycin.

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Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limits: • Oral tablets: 2 per day (400mg) • 40mg/mL suspension: 10mL per day (400mg)
Firvanq CC	• Diagnosis of *clostridium difficile*-associated diarrhea (ICD-10 = A04.7); **OR** • Diagnosis of *Staphylococcal* enterocolitis.
metronidazole 125 mg tablet CC	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to metronidazole 250mg tablet **AND** metronidazole 500mg tablet.

Solosec AE, CC, QL	• Female patient with diagnosis of bacterial vaginosis (BV); **AND**
	  ○ No in vitro resistance to nitroimidazole derivatives (metronidazole, tinidazole, secnidazole) or prior failure of metronidazole or tinidazole for the current course of infection; **AND**
	  ○ Trial and failure of, or contraindication to, at least one preferred non-nitroimidazole (e.g., clindamycin); **OR**
	• Female patient with diagnosis of trichomoniasis caused by Trichomonas vaginalis; **AND**
	  ○ No in vitro resistance to nitroimidazole derivatives (metronidazole, tinidazole, secnidazole) or prior failure of metronidazole or tinidazole for the current course of infection; **AND**
	  ○ History of unacceptable/toxic side effects (not including hypersensitivity reactions) to at least two preferred medications not requiring prior approval.
	
	Age Limit: ≥ 12 years
	Quantity Limit: 1 packet per fill

Nuzyra AE, CC, QL	• Diagnosis of community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infection (ABSSSI) caused by susceptible microorganism(s)*; **AND** • If female of childbearing potential, patient is NOT pregnant; **AND** • Patient is not a candidate (based on culture and sensitivity data) or has failed treatment with ≥ 2 preferred antibiotics from 2 different classes; **AND** • Patient has NOT failed a tetracycline unless susceptibility results demonstrate that pathogen is NOT susceptible to other tetracyclines but is susceptible to omadacycline; **AND** • If continuing an inpatient/hospital treatment course, prescriber attests that it would be clinically inappropriate to deescalate therapy or use alternative therapy based on susceptibility results or lack of susceptibility results in conjunction with clinical picture; **AND** • Total treatment duration will not exceed 14 days per course. **Age Limit:** ≥ 18 years **Quantity Limit**: 2 per day; override by call center for loading dose

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Agent(s) Subject to Criteria	Criteria for Approval
	*CABP susceptible microorganisms include: *Chalmydophila pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumoniae, Mycoplasma pneumoniae, Staphylococcus aureus* (methicillin-susceptible isolates; MSSA)*, Streptococcus pneumoniae*. ABSSSI susceptible microorganisms include: *Enterobacter cloacae, Enterococcus faecalis, Klebsiella pneumoniae, Staphylococcus aureus* (methicillin-susceptible and -resistant isolates; MSSA and MRSA)*, Streptococcus lugdunensis, Streptococcus anginosus group* (includes S. anginosus, S. intermedius, and S. constellatus)*, Streptococcus pyogenes*.

Vowst AE, CC, QL	**Approval Duration:** 30 days (Limit to 1 fill per approval)
	
	• Diagnosis of recurrent Clostridioides difficile infection (CDI); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist or infectious disease specialist; **AND**
	• Patient has completed at least 3 full courses of antibiotic treatment with two or more of the following guideline recommended agents:
	  ○ Vancomycin oral
	  ○ Dificid
	  ○ Metronidazole oral; **AND**
	• Treatment with Vowst will be initiated between 48 and 96 hours of completion of the most recent course of antibiotics; **AND**
	• At least 8 hours prior to the first dose of Vowst, the patient will receive an appropriate bowel cleansing regimen (e.g., magnesium citrate or polyethylene glycol).
	
	Renewal Criteria:
	• Diagnosis of recurrent Clostridioides difficile infection (CDI); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist or infectious disease specialist; **AND**
	• Patient had treatment failure defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst AND a positive stool test for C. difficile; **AND**
	• Patient has not previously received more than 1 treatment course of Vowst; **AND**
	• Previous course of Vowst was at least 12 days ago but no more than 8 weeks ago.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 12 capsules over 3 days

CURRENT PDL STATUS

ANTIBIOTICS: CEPHALOSPORINS

Preferred Agents	Non-Preferred Agents
cefaclor capsule	cefaclor ER tablet
cefadroxil capsule, suspension	cefaclor suspension
cefadroxil suspension (<12 years of age)	cefadroxil suspension (>12 years of age)

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Preferred Agents	Non-Preferred Agents
cefdinir capsule, suspension	cefadroxil tablet
cefprozil suspension, tablet	cefixime capsule, tablet, suspension
cefuroxime axetil tablet	cefpodoxime suspension, tablet
cephalexin capsule, suspension	cephalexin tablet
	Suprax capsule, chewable tablet, suspension

ANTIBIOTICS: GASTROINTESTINAL

Preferred Agents	Non-Preferred Agents
metronidazole 250 mg, 500 mg tablet	Aemcolo
neomycin	Dificid suspension, tablet CC, QL
tinidazole	fidaxomicin CC, QL
vancomycin capsule, solution CC	Firvanq CC
	Flagyl
	Likmez
	metronidazole capsule
	metronidazole 125 mg tablet CC
	nitazoxanide
	Solosec AE, CC, QL
	Vancocin
	Vowst AE, CC, QL

ANTIBIOTICS: MACROLIDES

Preferred Agents	Non-Preferred Agents
azithromycin	clarithromycin ER
clarithromycin	E.E.S 400 Filmtab
E.E.S. granules for suspension 200 mg	EryPed
erythromycin base tablet DR 250 mg, 500 mg	Ery-Tab DR 333 mg tablet
erythromycin ethylsuccinate suspension	Erythrocin
Ery-Tab DR 250 mg, 500 mg tablet	erythromycin base capsule DR
	erythromycin base tablet
	erythromycin base tablet DR 333 mg
	erythromycin ethylsuccinate 400 mg tablet
	erythromycin filmtab
	Zithromax

ANTIBIOTICS: OXAZOLIDINONES

Preferred Agents	Non-Preferred Agents
linezolid suspension QL, MD	Sivextro QL
linezolid tablet CC, QL, MD	Zyvox suspension QL, MD
	Zyvox tablet QL, MD

ANTIBIOTICS: PENICILLINS

Preferred Agents	Non-Preferred Agents
amoxicillin	amoxicillin/clavulanate ER
amoxicillin/clavulanate chewable table, suspension, tablet	Augmentin
Ampicillin capsule	Augmentin XR
Dicloxacillin capsule	
penicillin V potassium tablet, suspension	

ANTIBIOTICS: QUINOLONES

Preferred Agents	Non-Preferred Agents
ciprofloxacin tablet	Baxdela AE, QL
levofloxacin tablet	ciprofloxacin suspension

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Preferred Agents	Non-Preferred Agents
	Cipro
	levofloxacin solution
	moxifloxacin
	ofloxacin

ANTIBIOTICS: SULFONAMIDES, FOLATE ANTAGONIST

Preferred Agents	Non-Preferred Agents
sulfamethoxazole/trimethoprim	Bactrim
Sulfatrim suspension	Bactrim DS
trimethoprim	sulfadiazine

ANTIBIOTICS: TETRACYCLINES

Preferred Agents	Non-Preferred Agents
demeclocycline tablet	Doryx tablet
doxycycline hyclate 50 mg, 100 mg capsule	Doryx MPC tablet
doxycycline hyclate tablet	doxycycline hyclate 75 mg capsule
doxycycline monohydrate 50 mg, 100 mg capsule	doxycycline hyclate DR tablet
doxycycline monohydrate suspension	doxycycline IR-DR capsule
doxycycline monohydrate tablet	doxycycline monohydrate 75 mg, 150 mg capsule
minocycline capsule	minocycline tablet
tetracycline capsule	minocycline ER tablet
	Morgidox capsule
	Morgidox Kit
	Nuzyra tablet AE, CC, QL
	Oracea capsule
	tetracycline tablet

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ANTI-INFECTIVE: VAGINAL ANTIBIOTICS

GUIDELINES FOR USE

Approval Duration: Date of Service

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial of appropriate duration and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Cleocin Ovule	Cleocin cream
clindamycin vaginal 2% cream	Clindesse vaginal cream
metronidazole vaginal 0.75% gel	Vandazole gel
Nuvessa gel	Xaciato gel

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ANTIRETROVIRALS: HUMAN IMMUNODEFICIENCY VIRUS/ACQUIRED IMMUNODEFICIENCY SYNDROME (HIV/AIDS)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Rukobia AE, CC, QL	• Diagnosis of human immunodeficiency virus (HIV); **AND** • Prescribed by, or in consultation with, an infectious disease specialist or HIV specialist (AAHIVS); **AND** • Previous treatment with at least 3 drug classes (nucleoside reverse transcriptase inhibitors [NRTI], non-nucleoside reverse transcriptase inhibitors [NNRTI], or protease inhibitor [PI]); **AND** • Documentation (e.g., progress note, lab report) of baseline viral load ≥ 400 copies/mL on current antiretroviral regimen; **AND** • Used in combination with highly active antiretroviral therapy (HAART); **AND** • Not used in combination with strong cytochrome P450 (CYP)3A inducers. **Renewal Criteria:** • Documentation (e.g., progress note, lab report) of a decrease in viral load from pretreatment baseline. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day
Sunlenca tablet AE, CC, QL	• Diagnosis of human immunodeficiency virus type 1 (HIV-1) infection; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Prescribed by, or in consultation with, an infectious disease specialist or HIV specialist (AAHIVS); **AND** • Patient is heavily treatment-experienced with multidrug resistance HIV-1 infection (has documented resistance to ≥ 2 antiretroviral [ARV] medications from each of at least 3 of the 4 main classes: nucleoside reverse-transcriptase inhibitors [NRTIs], non–nucleoside reverse-transcriptase inhibitors [NNRTIs], protease inhibitors [PIs], and integrase strand-transfer inhibitors [INSTI]); **AND** • Patient has ≤ 2 fully active ARVs remaining from the 4 main classes that can be effectively combined; **AND** • Documentation (e.g., progress note, lab report) of baseline viral load ≥ 400 copies/mL on current antiretroviral regimen; **AND** • Patient has no history of treatment failure or known or suspected resistance to lenacapavir; **AND** • Patient will be taking with other antiretrovirals (optimized background regimen); **AND** • Not used in combination with strong cytochrome CYP3A inducers. **Renewal Criteria:** • Patient has been adherent to their ARV treatment regimen; **AND** • Patient has not experienced virologic failure of lenacapavir and has documented clinical improvement and/or stabilization (e.g., disease response as indicated by a decrease in viral load from pretreatment baseline; increased or stabilized CD4+ counts). **Age Limit:** ≥ 18 years **Quantity Limit:** 300 mg tablets: 5 tablets per fill

Vocabria AE, CC, QL	**Pre-Exposure Prophylaxis:**
	• Prescribed for pre-exposure prophylaxis (PrEP) of HIV; **AND**
	• Prescriber submits prior authorization request; **AND**
	• Used as an oral lead-in for Apretude (cabotegravir extended release injectable suspension) or for oral therapy for patients who will miss a planned injection of Apretude
	• Prescriber attests that:
	  ○ Patient is considered high-risk for HIV infection; **AND**
	  ○ Risk-reduction and medication adherence counseling were performed; **AND**
	  ○ Negative HIV-1 test immediately prior to initiating.
	
	Treatment of HIV Infection:
	• Patient has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection; **AND**
	• Patient is virologically suppressed with HIV-RNA < 50 copies/mL and is on a stable antiretroviral regimen; **AND**
	• Patient has no history of treatment failure or known or suspected resistance to cabotegravir or rilpivirine; **AND**
	• Patient will take rilpivirine concomitantly for 28 days; **AND**
	• Patient will be using cabotegravir as:
	  ○ Oral lead-in to assess tolerability of cabotegravir prior to administration of the injectable extended-release formulations of cabotegravir/rilpivirine; **OR**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Oral therapy for patients who plan to miss a dose of their cabotegravir/rilpivirine injection; **AND** • Patient will NOT receive concomitant therapy with ANY of the following medications that can result in significant decreases of cabotegravir and/or rilpivirine; **AND** ○ Carbamazepine ○ Oxcarbazepine ○ Phenobarbital ○ Phenytoin ○ Rifabutin ○ Rifampin ○ Rifapentine ○ Dexamethasone (more than a single-dose treatment) ○ St. John's wort; **AND** • Prescribed by or in consultation with an infectious disease specialist or HIV specialist. **Age Limit:** ≥ 12 years **Quantity Limit:** 1 per day
Yeztugo tablet AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal **Pre-Exposure Prophylaxis:** • Prescribed for HIV-1 PrEP ○ Day 1 / Day 2 initiation along with injection; **OR** ○ Temporary oral bridging; **OR** ○ Supplemental oral dosing when needed for coverage with concomitant CYP3A inducers; **AND** • Documentation that patient's weight is ≥35 kg; **AND** • Prior authorization request is submitted by the prescriber; **AND** • Prescriber attests that patient is considered high-risk for HIV infection; **AND** • Prescriber attests that risk-reduction and medication adherence counseling were performed; **AND** • Documentation of negative HIV-1 status immediately prior to initiating Yeztugo using an FDA-approved method. If an antigen/antibody test is used, results should be confirmed with an RNA assay, even if available after the first dose; **AND** • The requested dose does not exceed the FDA-approved dose for this indication. **Renewal Criteria:** • Patient continues to meet the above criteria; **AND** • The requested dose does not exceed the FDA-approved dose for this indication. **Age Limit:** ≥16 years **Quantity Limit:** 4 tablets per fill; 8 tablets per year
Yeztugo injection AE, CC	**Approval Duration:** 6 months initial; 1 year renewal • Prescribed for pre-exposure prophylaxis (PrEP) of HIV ○ For Day 1/Day 2 Initiation along with tablets; **OR** ○ For ongoing maintenance therapy, **AND** • Documentation that patient's weight is ≥35 kg; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Prior authorization request is submitted by the prescriber; **AND** • Prescriber attests that patient is considered high-risk for HIV infection; **AND** • Prescriber attests that risk-reduction and medication adherence counseling were performed; **AND** • Documentation of negative HIV-1 test immediately prior to each Yeztugo injection, including Day1/Day 2 initiation (with tablets) and all maintenance doses to confirm HIV-negative status using an FDA-approved method. If an antigen/antibody test is used, results should be confirmed with an RNA assay, even if available after the first dose; **AND** • The requested dose does not exceed the FDA-approved dose for this indication **Renewal Criteria:** • Patient continues to meet the above criteria; **AND** • The requested dose does not exceed the FDA-approved dose for this indication. **Age Limit:** ≥16 years

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
abacavir QL	Aptivus
	Bixlenvo QL
abacavir-lamivudine	Complera QL
atazanvir QL	darunavir
Biktarvy QL	efavirenz/lamivudine/tenofovir disoproxil fumarate (generic Symfi, Symfi Lo) QL
Cimduo QL	emtricitabine QL
Delstrigo QL	Epivir QL
Descovy QL	etravirine
Dovato QL	fosamprenavir
Edurant, Edurant Ped	Fuzeon
efavirenz	Idvynso QL
efavirenz/emtricitabine/tenofovir disoproxil fumarate (generic Atripla) QL	Kaletra
emtricitabine/tenofovir disoproxil fumarate (generic Truvada) QL	maraviroc
emtricitabine/rilpivirine/tenofovir disoproxil fumarate (generic Complera) QL	nevirapine QL
Emtriva QL	nevirapine ER QL
Evotaz QL	Norvir
Genvoya QL	Prezcobix QL
Intelence	Retrovir
Isentress	Reyataz QL
Juluca QL	rilpivirine
lamivudine QL	Rukobia AE, CC, QL
lamivudine-zidovudine	stavudine QL
lopinavir-ritonavir	Sunlenca AE, CC, QL
Odefsey QL	Tivicay PD
Pifeltro QL	Triumeq PD
Prezista	Truvada CC, QL
ritonavir	Viracept

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Preferred Agents	Non-Preferred Agents
Selzentry	Viread tablet QL, powder packet
Stribild QL	Vocabria AE, CC, QL
Symfi QL	Yeztugo tablet QL, vial
Symtuza QL	Ziagen QL
tenofovir disoproxil fumarate QL	zidovudine capsule
Tivicay QL	
Triumeq QL	
Tybost	
zidovudine syrup, tablet	

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HEPATITIS B AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Vemlidy AE, CC, QL	• Diagnosis of hepatitis B virus infection; **AND** • Prescribed by, or in consultation with, a hepatology/ gastroenterology, infectious disease, transplant or other appropriate specialist; **AND** • Patient does NOT have decompensated cirrhosis (Child-Pugh B or C); **AND** • Trial and failure of, intolerance, or contraindication to, entecavir or (tenofovir disoproxil fumarate); **AND** • NOT concurrently taking any P-gp inducers (e.g., oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, or St. John's wort); **AND** • If HIV-1 positive, NOT using Vemlidy as monotherapy. **Age Limit:** ≥ 6 years and weight ≥ 25 kg **Quantity Limit:** 1 per day (allow 2 per day for drug interactions)

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Epivir-HBV solution	Adefovir tablet
lamivudine HBV tablet	Baraclude solution, tablet
	Hepsera tablet
	Vemlidy tablet AE, CC, QL

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HEPATITIS C AGENTS: INTERFERONS AND RIBAVIRINS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
PEGASYS syringe, vial CC, QL	• Prescribed by a gastroenterologist, hepatologist, or infectious disease specialist for the treatment of chronic hepatitis C.
ribavirin CC	• Prescribed in combination with interferon or direct-acting antiviral for the treatment of chronic hepatitis C; **AND** • Criteria for the accompanying product have been met.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent in the same sub-class.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable

CURRENT PDL STATUS

HEPATITIS C: INTERFERONS

Preferred Agents	Non-Preferred Agents
PEGASYS syringe, vial CC, QL	

HEPATITIS C: RIBAVIRINS

Preferred Agents	Non-Preferred Agents
ribavirin capsule, tablet CC	

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HEPATITIS C AGENTS: DIRECT-ACTING ANTIVIRALS

GUIDELINES FOR USE

Approval Duration: Course of Therapy

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Mavyret [CC, QL] sofosbuvir/velpatasvir [CC, QL]	• Simplified HCV Treatment Criteria below are met; **OR** • HCV Direct-Acting Antiviral Class Criteria (Non-Simplified) below are met; **AND** • If applicable, Additional Criteria for Patients Previously Treated with a Direct-Acting Antiviral below are met.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires clinical justification (e.g., allergy, contraindication, potential drug-drug interactions with other medications, or intolerance) as to why **Mavyret or sofosbuvir/velpatasvir** cannot be used or are not indicated. **HCV Direct-Acting Antiviral Class Criteria (Non-Simplified) must be met.**

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. TREATMENT CRITERIA

Treatment Criteria Category	Criteria for Approval

Simplified HCV Treatment Criteria (treatment-naïve, non-cirrhotic, uncomplicated cases)	**Approval Duration**: Mavyret – 12 weeks;
	sofosbuvir/velpatasvir – 16 weeks
	
	• Diagnosis of chronic hepatitis C virus (HCV) infection; **AND**
	• Prescribed regimen is either of the following:
	  ○ Mavyret 12 weeks; **OR**
	  ○ sofosbuvir/velpatasvir for 16 weeks; **AND**
	• Documentation (e.g., progress note, prior authorization form questions) of the following clinical data confirming simplified treatment eligibility:
	  ○ Date of Hepatitis C diagnosis or earliest record of HCV infection; **AND**
	  ○ Recent (within 3 months) qualitative or quantitative HCV RNA level (HCV viral load); **AND**
	  ○ NOT pregnant; **AND**
	  ○ NOT previously treated for HCV; **AND**

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Treatment Criteria Category	Criteria for Approval
	○ NOT cirrhotic based on FIB-4 score < 3.25 (https://www.heaptitisc.uw.edu/page/clinical-calculators/fib-4); **AND** ○ Human immunodeficiency virus (HIV) **negative; AND** ○ Hepatitis B surface antigen (HBsAg) **negative; AND** ○ No history of liver transplant or hepatocellular carcinoma.
HCV Direct-Acting Antiviral Class Criteria (non-simplified)	**Approval Duration**: Full course of treatment (varies by product and clinical factors) Diagnosis of acute or chronic hepatitis C virus (HCV) infection; **AND** Prescribed treatment regimen is included in the requested drug's package insert and/or supported by current HCV guidelines for the patient's age/weight, and other clinical data requested below; **AND** Prescribed by, a gastroenterologist, hepatologist, infectious disease (including HIV specialist, AAHIVP), or transplant specialist OR prescriber completed/participates in an HCV academic/mentorship training program or network (e.g., KHAMP, ECHO); **AND** Documentation (e.g., progress note, prior authorization form questions) of the following clinical data: ○ Date of acute or chronic HCV diagnosis or earliest record of HCV infection; **AND** ○ Recent (within 3 months) qualitative or quantitative HCV RNA level (HCV viral load); **AND** ○ HCV genotype, including subtype and resistance mutations (if known); **AND** ○ If pregnant, prescriber attests that the benefits of HCV treatment outweigh potential risks to the fetus; **AND** ○ If applicable, prior HCV treatment regimen(s); **AND** ○ If cirrhotic, assessment of liver disease severity using the Child-Pugh score; **AND** ○ Human immunodeficiency virus (HIV) status; **AND** ○ Hepatitis B surface antigen (HBsAg) status; **AND** ○ If applicable, any history of liver transplant or hepatocellular carcinoma.
Additional Criteria for Patients Previously Treated with a Direct-Acting Antiviral	• Prescriber must answer the following questions: ○ Is retreatment necessary due to treatment failure or reinfection? ○ Was the patient compliant (e.g., few to no missed doses) with previous DAA therapy? If not, why? ○ Were there any additional factors that led to DAA treatment failure? If so, describe these factors and how they have been addressed or are no longer relevant. ○ Patient must be evaluated for alcohol and substance abuse using a validated screening tool; **AND** ○ If the patient has a recent history (within the past 6 months) of alcohol or substance abuse, the following is required: ○ Documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment; **AND** ○ Documentation that the patient is not actively participating in illicit substance use or alcohol abuse with confirmatory laboratory testing (e.g., urine drug screen); **AND**

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Treatment Criteria Category	Criteria for Approval
	• Provider attests that they believe: ○ Patient is willing and able to comply with the requirements of the proposed retreatment plan; **AND** ○ Any factors that may have led to noncompliance with previous treatment(s) have been addressed; **AND** ○ Patient has received education regarding risk behaviors (e.g., IV drug use) associated with HCV infection.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Mavyret AE, CC, QL	Epclusa AE, CC, QL
sofosbuvir/velpatasvir AE, CC, QL	Harvoni AE, CC, QL
	ledipasvir/sofosbuvir AE, CC, QL
	Sovaldi AE, CC, QL
	Viekira Pak AE, CC, QL
	Vosevi AE, CC, QL
	Zepatier AE, CC, QL

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DIABETES: INSULINS AND RELATED AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Admelog vial and Solostar CC	• Trial and failure of ≥ 2 preferred insulins; **AND** • Clinical rationale (e.g., intolerance to an inactive ingredient) that a preferred product cannot be used.
Fiasp vial, pump cartridge, and FlexTouch CC Lyumjev pen, Tempo Pen, vial CC	• Trial and failure of ≥ 2 preferred insulins; **AND** • Clinical rationale (e.g., intolerance to an inactive ingredient) that a preferred product cannot be used.
Symlin AE, CC	• Prescribed by, or in consultation with, an endocrinologist or other diabetes specialist; **AND** • Trial and failure of ≥ 1 rapid-acting insulin. **Age Limit:** ≥ 18 years
Basaglar KwikPen CC insulin glargine-yfgn pen and vial CC Semglee (yfgn) pen and vial CC	• Trial and failure of ≥ 2 preferred insulins, one of which must be insulin glargine or Lantus; **AND** • Clinical rationale (e.g., intolerance to an inactive ingredient) that a preferred product cannot be used.

CURRENT PDL STATUS

RAPID- AND SHORT-ACTING INSULINS

Preferred Agents	Non-Preferred Agents
Humulin R vial	Admelog and Admelog Solostar CC

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Preferred Agents	Non-Preferred Agents
Humulin R U-500 KwikPen, vial	Afrezza
insulin lispro Junior (Jr) KwikPen	Apidra Solostar, vial
insulin lispro pen, vial	Fiasp FlexTouch, pen, pumpcart, vial CC
Novolog cartridge, FlexPen, vial	Humalog 200 unit/mL KwikPen
	Humalog cartridge, KwikPen, vial
	Humalog Junior (Jr) KwikPen
	Humalog Tempo Pen
	Kirsty vial, pen
	Lyumjev pen, Tempo Pen, vial CC
	Merilog Solostar, vial
	Novolin R pen, vial
	Symlin AE, CC

INTERMEDIATE-ACTING INSULINS

Preferred Agents	Non-Preferred Agents
Humalog Mix 50/50 KwikPen	Humalog Mix 75/25 KwikPen, vial
Humulin 70/30 KwikPen, vial	Humulin N KwikPen
Humulin N vial	Novolin 70/30 pen, vial
insulin aspart/insulin aspart protamine pen, vial	Novolin N pen
insulin lispro/insulin lispro protamine KwikPen	Novolog Mix vial
insulin lispro protamine mix	
Novolin N vial	
Novolog Mix FlexPen	

LONG-ACTING INSULINS

Preferred Agents	Non-Preferred Agents
insulin glargine Solostar U100 (generic for Lantus Solostar)	Basaglar KwikPen, Tempo Pen CC
insulin glargine vial	insulin glargine Solostar and Max Solostar (generic Toujeo)
Lantus and Lantus Solostar	insulin glargine-yfgn pen, vial CC
Levemir FlexPen, FlexTouch, vial	Rezvoglar Kwikpen
	Semglee (yfgn) pen, vial CC
	Toujeo Solostar, Max Solostar
	Tresiba FlexTouch, vial

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DIABETES: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) RECEPTOR AGONISTS

GUIDELINES FOR USE

NOTE: GLP-1 medications are limited to two brand switches per year.

Approval Duration: 6 months

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Mounjaro AE, CC, QL
Ozempic pen AE, CC, QL
Trulicity CC, QL
Victoza CC, QL
	• Diagnosis of Type II Diabetes Mellitus (T2DM) confirmed with clinical documentation including:
	  ○ ICD-10 diagnosis of T2DM (chart notes within the past 12 months) ; **AND**
	  ▪ A1c lab value that correlates to a T2DM diagnosis (i.e., 6.5 or greater); **OR**
	  ▪ Historical A1c that correlates to a T2DM diagnosis (i.e. 6.5 or greater), **AND** A1C within the past 6 months; **AND**
	• No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); **AND**
	• Not used in combination with another GLP-1 receptor agonist OR DPP4 **UNLESS** the member is changing therapy; **AND**
	• The requested dose does not exceed the maximum FDA-approved dose for the treatment of diabetes mellitus.
	
	Renewal Criteria:
	• ICD-10 diagnosis of T2DM (chart notes within the past 12 months); **AND**
	• Clinical documentation must be submitted demonstrating an A1c value within the past 6 months; **AND**
	• The provider attests that the patient has been evaluated for safety (e.g. lacks treatment limiting adverse events) and demonstrates a positive response to therapy; **AND**
	• No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); **AND**
	• Not used in combination with another GLP-1 receptor agonist OR DPP4 **UNLESS** the member is changing therapy; **AND**
	• The requested dose does not exceed the maximum FDA-approved dose for treating diabetes mellitus.
	
	*Drugs used for anorexia, weight loss, or weight gain are excluded from coverage.

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires documentation of **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

Additional drug-specific criteria must also be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Ozempic tablet AE, CC, QL
Rybelsus AE, CC, QL
	• Diagnosis of Type II Diabetes Mellitus (T2DM) confirmed with clinical documentation including:
	  ○ ICD-10 diagnosis of T2DM (chart notes within the past 12 months); **AND**
	  ▪ A1c lab value that correlates to a T2DM diagnosis (i.e., 6.5% or greater); **OR**
	  ▪ Historical A1c that correlates to a T2DM diagnosis (i.e. 6.5% or greater), **AND** A1C within the past 6 months; **AND**
	• No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); **AND**
	• Not used in combination with another GLP-1 receptor agonist OR DPP4 **UNLESS** the member is changing therapy; **AND**
	• The requested dose does not exceed the maximum FDA-approved dose for the treatment of diabetes mellitus; **AND**
	• ≥ 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents, unless otherwise specified. (chart notes or claim history must confirm).
	
	Renewal Criteria:
	• ICD-10 diagnosis of T2DM (chart notes within the past 12 months); **AND**
	• Demonstrate ONE of the following:
	  ○ an A1c of less than or equal to 8% within the past 6 months; **OR**
	  ○ demonstration of improved A1c value; **OR**
	  ○ provider must submit clinical justification for continued therapy; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• The provider attests that the patient has been evaluated for safety (e.g. lacks treatment limiting adverse events) and demonstrates a positive response to therapy; **AND** • No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); **AND** • Not used in combination with another GLP-1 receptor agonist OR DPP4 **UNLESS** the member is changing therapy; **AND** • The requested dose does not exceed the maximum FDA-approved dose for treating diabetes mellitus. *Drugs used for anorexia, weight loss, or weight gain are excluded from coverage.

exenatide CC, QL
liraglutide CC, QL
	• Diagnosis of Type II Diabetes Mellitus (T2DM) confirmed with clinical documentation including:
	  ○ ICD-10 diagnosis of T2DM (chart notes within the past 12 months); **AND**
	  ▪ A1c lab value that correlates to a T2DM diagnosis (i.e., 6.5% or greater); **OR**
	  ▪ Historical A1c that correlates to a T2DM diagnosis (i.e. 6.5% or greater), AND A1C within the past 6 months; **AND**
	• No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); **AND**
	• Not used in combination with another GLP-1 receptor agonist OR DPP4 **UNLESS** the member is changing therapy; **AND**
	• The requested dose does not exceed the maximum FDA-approved dose for the treatment of diabetes mellitus; **AND**
	• ≥ 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents, unless otherwise specified (chart notes or claim history must confirm); **AND**
	• A known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation.
	
	Renewal Criteria:
	• ICD-10 diagnosis of T2DM (chart notes within the past 12 months); **AND**
	• Demonstrate **ONE** of the following:
	  ○ an A1c of less than or equal to 8% within the past 6 months; **OR**
	  ○ demonstration of improved A1c value; **OR**
	  ○ provider must submit clinical justification for continued therapy; **AND**
	• The provider attests that the patient has been evaluated for safety (e.g. lacks treatment limiting adverse events) and demonstrates a positive response to therapy; **AND**
	• No personal or family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); **AND**
	• Not used in combination with another GLP-1 receptor agonist OR DPP4 **UNLESS** the member is changing therapy; **AND**
	• The requested dose does not exceed the maximum FDA-approved dose for treating diabetes mellitus; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• A known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. *Drugs used for anorexia, weight loss, or weight gain are excluded from coverage.
Soliqua AE, CC, QL Xultophy AE, CC, QL	• Trial and failure (e.g., non-compliance, need to reduce injections) of a long-acting insulin (e.g. insulin glargine) and a GLP-1 agonist (e.g., Victoza) used concurrently; **AND** • Not used in combination with a DPP-4 inhibitors (such as Janumet or Tradjenta) **UNLESS** the member is changing therapy and the DPP-4 inhibitor medication will be discontinued. **Age Limit:** ≥ 18 years

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Mounjaro AE, CC, QL	exenatide CC, QL
Ozempic pen AE, CC, QL	liraglutide CC, QL
Trulicity CC, QL	Ozempic tablet AE, CC, QL
Victoza CC, QL	Rybelsus AE, CC, QL
	Soliqua AE, CC, QL
	Xultophy AE, CC, QL

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DIABETES: DIPEPTIDYL PEPTIDASE-4 (DPP-4) INHIBITORS

GUIDELINES FOR USE

NOTE: DPP-4 inhibitors are NOT allowed to be used concurrently with GLP-1 receptor agonists.

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Janumet CC, QL Januvia CC, QL Jentadueto CC, QL Jentadueto XR CC, QL Nesina CC, QL sitagliptin/metformin ER CC, QL Tradjenta CC, QL	• Diagnosis of Type II Diabetes Mellitus (without chronic kidney disease); **AND** ○ Trial and failure (e.g., A1c goal not met) of, intolerance, or contraindication to metformin; **OR** • Diagnosis of Type II Diabetes Mellitus (with chronic kidney disease (ICD-10 Group N18)); **AND** ○ Trial and failure of, intolerance, or contraindication to ≥ 1 SGLT2 inhibitor plus metformin. **AND** • Not used in combination with a GLP-1 receptor (such as Ozempic or Mounjaro) **UNLESS** the member is changing therapy and the GLP medication will be discontinued.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

Preferred with PA (PDP) criteria must be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Janumet XR CC, QL sitagliptin/metformin ER (generic Janumet XR) CC, QL sitagliptin/metformin IR (generic Janumet, Zituvimet) CC, QL Zituvimet CC, QL Zituvimet XR CC, QL	• Diagnosis of Type II Diabetes Mellitus (without chronic kidney disease); **AND** ○ Trial and failure (e.g., A1c goal not met) of, intolerance, or contraindication to metformin; **OR** • Diagnosis of Type II Diabetes Mellitus (with chronic kidney disease (ICD-10 Group N18)); **AND** ○ Trial and failure of, intolerance, or contraindication to ≥ 1 SGLT2 inhibitor plus metformin; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in Janumet or sitagliptin/metformin ER; **AND** • At least 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 1 preferred agent; **AND** • Not used in combination with a GLP-1 receptor (such as Ozempic or Mounjaro) **UNLESS** the member is changing therapy and the GLP medication will be discontinued.
Zituvio CC, QL *(brand only)*	• Diagnosis of Type II Diabetes Mellitus (without chronic kidney disease); **AND** ○ Trial and failure (e.g., A1c goal not met) of, intolerance, or contraindication to metformin; **OR** • Diagnosis of Type II Diabetes Mellitus (with chronic kidney disease (ICD-10 Group N18)); **AND** ○ Trial and failure of, intolerance, or contraindication to ≥ 1 SGLT2 inhibitor plus metformin; **AND** • Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in Januvia; **AND** • Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with at least 2 manufacturers (if available) of the corresponding generic; **AND** • At least 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 1 preferred agent; **AND** • Not used in combination with a GLP-1 receptor (such as Ozempic or Mounjaro) **UNLESS** the member is changing therapy and the GLP medication will be discontinued. **Quantity Limit:** 1 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Janumet CC, QL	alogliptin QL
Januvia CC, QL	alogliptin/metformin QL
Jentadueto CC, QL	alogliptin/pioglitazone QL
Jentadueto XR CC, QL	Brynovin QL
linagliptin/metformin QL	dapagliflozin/saxagliptin QL
Nesina CC, QL	Glyxambi QL
sitagliptin/metformin ER (generic Zituvimet XR) CC, QL	Janumet XR CC, QL
Tradjenta CC, QL	Kazano QL
	Oseni QL
	saxagliptin QL
	saxagliptin/metformin ER QL
	sitagliptin (generic Januvia, Zituvio) QL
	sitagliptin/metformin (generic Janumet, Zituvimet) CC, QL
	sitagliptin/metformin ER (generic Janumet XR) CC, QL
	Steglujan AE, QL
	Trijardy XR QL
	Zituvio CC, QL
	Zituvimet CC, QL
	Zituvimet XR CC, QL

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DIABETES: SODIUM-GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Synjardy CC, QL	• Diagnosis of Type 2 Diabetes Mellitus; **AND** ○ Diagnosis of chronic kidney disease (ICD-10 Group N18); **OR** ○ Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR** ○ Diagnosis of heart failure with reduced ejection fraction; **OR** ○ Trial and failure (e.g., A1c goal not met) of, intolerance or contraindication to metformin. **Quantity Limit:** 2 per day
dapagliflozin CC, QL Jardiance CC, QL	• Diagnosis of Type 2 Diabetes Mellitus; **AND** ○ Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR** ○ Trial and failure (e.g., A1c goal not met) of, intolerance, or contraindication to metformin; **OR** • Diagnosis of chronic kidney disease (ICD-10 Group N18); **OR** • Diagnosis of heart failure. **Quantity Limit:** 1 per day
Xigduo XR CC, QL	• Diagnosis of Type 2 Diabetes Mellitus; **AND** ○ Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR** ○ Trial and failure (e.g., A1c goal not met) of, intolerance or contraindication to metformin; **OR** • Diagnosis of heart failure with reduced ejection fraction.

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

Preferred with PA (PDP) criteria must be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Farxiga CC, QL	• NPD criteria; **AND**
	• Diagnosis of Type 2 Diabetes Mellitus; **AND**
	  ○ Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR**
	  ○ Trial and failure (e.g., A1c goal not met) of, intolerance, or contraindication to metformin; **OR**
	• Diagnosis of chronic kidney disease (ICD-10 Group N18); **OR**
	• Diagnosis of heart failure.
	
	Quantity Limit: 1 per day

Inpefa AE, CC, QL	• Diagnosis of Type 2 Diabetes Mellitus; **AND** • Diagnosis of chronic kidney disease; **AND** • Patient has other cardiovascular risk factors; **OR** • Diagnosis of heart failure; **AND** • Patient has had ≥ 3-month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 1 preferred agent. **Quantity Limit:** 1 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
dapagliflozin CC, QL	dapagliflozin/metformin ER QL
Jardiance CC, QL	Farxiga CC, QL
Synjardy CC, QL	Inpefa AE, CC, QL
Xigduo XR CC, QL	Invokamet CC, QL
	Invokamet XR QL
	Invokana CC, QL
	Segluromet AE, QL

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Preferred Agents	Non-Preferred Agents
	Steglatro AE, QL
	Synjardy XR QL

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DIABETES: ALPHA-GLUCOSIDASE INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with ≥ 2 manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
acarbose QL	miglitol QL
	Precose QL

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DIABETES: METFORMINS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents (e.g., metformin IR and metformin ER).

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
metformin solution CC Riomet CC	• Unable to swallow metformin or metformin ER tablets.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
glyburide/metformin	glipizide/metformin
metformin 500 mg, 850 mg, 1000 mg tablet	metformin ER tablet (generic Fortamet, Glumetza)
metformin ER tablet (generic Glucophage XR)	metformin solution CC
	metformin 625 mg, 750 mg tablet
	Riomet solution CC

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DIABETES: MEGLITINIDES

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
nateglinide QL	
repaglinide QL	

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DIABETES: SULFONYLUREAS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
glimepiride (except 3 mg)	glimepiride 3 mg tablet
glipizide (except 15 mg)	glipizide 15 mg tablet
glipizide ER	
glipizide XL	
glyburide	
glyburide micronized	

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DIABETES: THIAZOLIDINEDIONES (TZDS)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
pioglitazone QL	Actoplus Met QL
	Actos QL
	Duetact QL
	pioglitazone/glimepiride QL
	pioglitazone/metformin QL

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ENDOCRINE AND METABOLIC AGENTS: GLUCAGON AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Baqsimi CC	• Intramuscular (IM) glucagon was dispensed in the past 180 days; **OR** • Prescriber attestation that caregiver(s) or family member(s) would have or have had difficulty preparing and administering the IM injection in a correct and timely manner.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure **within the past 180 days**, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Baqsimi spray CC	diazoxide suspension
Gvoke autoinjector, syringe	Glucagon emergency kit
Proglycem suspension	Gvoke vial
Zegalogue	

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ENDOCRINE AND METABOLIC AGENTS: GROWTH HORMONES

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Genotropin CC Norditropin Flexpro CC	• Diagnosis (documented or reported) of one of the following conditions: ○ Hypofunction and other disorders of the pituitary gland (ICD-10 = E23.x); **OR** ○ Short stature due to endocrine disorder (ICD-10 = E34.3) or idiopathic short stature (ICD-10 = R62.52); **OR** ○ Post-procedural (iatrogenic) hypopituitarism (ICD-10 = E89.3); **OR** ○ Neoplasm of pituitary or craniopharyngeal duct (ICD-10 = C75.1, C75.2, D35.2, D35.3, D44.3, D44.4); **OR** ○ Turner's syndrome (ICD-10 = Q96); **OR** ○ Congenital malformation syndromes (e.g., Noonan syndrome, Prater-Willi syndrome) predominantly associated with short stature (ICD-10 = Q87.1); **OR** ○ End-stage renal disease (ICD-10 = N18.5, N18.6, N18.9); **OR** ○ Newborn light for gestational age (ICD-10 = P05.0y); **OR** ○ Cachexia (ICD-10 = R64). *x = a blank value or a number 1-7 that completes an ICD-10 code. ICD-10 Disease Group = E23* *y = value of 0-8 (based on member weight) that completes an ICD-10 code.* • For all diagnoses except HIV-associated wasting or cachexia (ICD-10: B22.2 or R64) and short bowel syndrome (ICD-10: K90.82), documentation or attestation of open epiphyses is required when appropriate.
Skytrofa AE, CC	**Growth Failure Secondary to Growth Hormone Deficiency (GHD):** • Pediatric patient is 1 year of age and older, and weighs at least 11.5 kg; **AND** • Patient has growth failure secondary to GHD; **AND** • Patient must have tried and failed 1 preferred short-acting growth hormone products due to frequency of administration or adherence; **AND** • For all diagnoses except HIV-associated wasting or cachexia (ICD-10: B22.2 or R64) and short bowel syndrome (ICD-10: K90.82), documentation or attestation of open epiphyses is required when appropriate. **Replacement of Growth Hormone:**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Adult patient is 18 years of age and older; **AND** • Patient requires replacement of endogenous growth hormone due to a documented diagnosis of GHD; **AND** • Patient must have tried and failed 1 preferred short-acting growth hormone products due to frequency of administration or adherence. **Renewal Criteria (all indications):** • Patient continues to meet the above criteria; **AND** • Patient has a positive response compared to pre-treatment baseline.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to **ALL** the different active ingredients of the preferred agents.

Preferred with PA (PDP) criteria must be met.

For all diagnoses except HIV-associated wasting or cachexia (ICD-10: B22.2 or R64) and short bowel syndrome (ICD-10: K90.82), documentation or attestation of open epiphyses is required when appropriate.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Ngenla [AE, CC]	• Diagnosis of growth hormone deficiency; **AND**
	• Pediatric patient must NOT have closed epiphyses if used for longitudinal growth promotion; **AND**
	• Patient does NOT have active malignancy; **AND**
	• Patient does NOT have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
	• Patient does NOT have Prader-Willi syndrome with ≥ 1 of the following:
	  ○ Severe obesity
	  ○ History of upper airway obstruction or sleep apnea
	  ○ Severe respiratory impairment
	  ○ Unidentified respiratory infection; **AND**
	• NPD criteria.
	
	Renewal Criteria:
	• Patient continues to meet the above criteria; **AND**
	• Patient has a positive response compared to pre-treatment baseline.
	
	Age Limit: ≥ 3 years

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Agent(s) Subject to Criteria	Criteria for Approval

Sogroya CC, QL	• Patient will be at least 2.5 years old at the start of treatment; **AND**
	• Diagnosis of ONE of the following**:**
	  ○ Growth hormone deficiency; **OR**
	  ○ Short stature born small for gestational age (SGA) with no catch-up growth by 2 years of age; **OR**
	  ○ Growth failure associated with Noonan Syndrome (NS); **OR**
	  ○ Idiopathic Short Stature (ISS); **AND**
	• Patient does NOT have a hypersensitivity to any somapacitan product or any of the excipients; **AND**
	• Pediatric patients must NOT have closed epiphyses if used for longitudinal growth promotion; **AND**
	• Patient does NOT have active malignancy; **AND**
	• Patient does NOT have active proliferative or severe non-proliferative diabetic retinopathy; **AND**
	• Patient does NOT have evidence of active intracranial tumor growth; withhold therapy if progression is detected (imaging only when clinically indicated); **AND**
	• Patient does NOT have Prader-Willi syndrome with > 1 of the following:
	  ○ Severe obesity
	  ○ History of upper airway obstruction or sleep apnea
	  ○ Severe respiratory impairment
	  ○ Unidentified respiratory infection; **AND**
	• NPD criteria.
	
	Renewal Criteria:
	• Patient continues to meet the above criteria; **AND**
	• Patient has a positive response compared to pre-treatment baseline.
	
	Quantity Limit: 4 pens per 28 days

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Genotropin cartridge, syringe CC	Humatrope cartridge
Norditropin FlexPro CC	Ngenla AE, CC
Skytrofa AE, CC	Nutropin AQ NuSpin
	Omnitrope cartridge, vial
	Serostim vial
	Sogroya CC, QL
	Zomacton vial

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ENDOCRINE AND METABOLIC AGENTS: GLUCOCORTICOIDS, ORAL (ORAL STEROIDS)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **ALL** unique chemical entities in the preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Tarpeyo DR capsule AE, CC, QL	**Approval Duration:** 10 months • Patient has a biopsy-confirmed diagnosis of primary immunoglobulin A nephropathy (IgAN); **AND** • Patient is at least 18 years of age; **AND** • Patient has an eGFR of 35–90 mL/min/1.73 m²; **AND** • Patient has persistent proteinuria defined as Urine Protein-to-Creatinine Ratio (UPCR) ≥0.8 g/g or proteinuria ≥1 g/day despite optimized supportive care; **AND** • Patient is receiving a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (ACE inhibitor or ARB) for at least 12 weeks, unless documented contraindication or intolerance; **AND** • Patient does not have nephrotic syndrome, other glomerulopathies, or recent treatment with systemic immunosuppressive medications; **AND** • Patient does not have severe hepatic impairment (Child-Pugh Class C) • Patient will avoid concomitant therapy with strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine); **AND** • Provider attests that patient has been counseled to avoid ingestion of grapefruit juice while on Tarpeyo therapy; **AND** • Provider attests that the patient will be monitored for signs of adrenal insufficiency during and after a 2-week taper at the end of Tarpeyo therapy (9 months of therapy); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Prescribed by or in consultation with a nephrologist. **Age Limit:** ≥ 3 years **Quantity Limit:** 16 mg once daily (four 4-mg capsules)

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
budesonide DR capsule QL	Alkindi Sprinkle capsule
budesonide EC capsule QL	Cortef tablet
dexamethasone elixir, solution, tablet	cortisone acetate tablet
hydrocortisone tablet	dexamethasone dose pack, Intensol drop
methylprednisolone dose pack, 4 mg, 32 mg tablet	dexlyt tablet
prednisolone solution	Hemady tablet
prednisolone sodium phosphate solution 5 mg/5 mL, 15 mg/5 mL, 25 mg/5 Ml	Khindivi solution AE
prednisone dose pack, solution, tablet	Medrol dose pack, tablet
	methylprednisolone 8 mg, 16 mg tablet
	Millipred dose pack, tablet
	prednisolone tablet, DR tablet
	prednisolone sodium phosphate ODT, solution 10 mg/5 mL, 20 mg/5 mL
	prednisone Intensol oral concentrate
	Rayos DR tablet
	Tarpeyo DR capsule AE, CC, QL

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ENDOCRINE AND METABOLIC AGENTS: PANCREATIC ENZYMES

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Creon capsule	Pertzye capsule
Viokace tablet	
Zenpep capsule	

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ENDOCRINE AND METABOLIC AGENTS: PROGESTINS FOR CACHEXIA

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agent
megestrol acetate 40 mg/mL suspension QL, tablet	megestrol acetate 625 mg/5 mL suspension

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ENDOCRINE AND METABOLIC AGENTS: ANDROGENIC AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. **PREFERRED WITH PA (PDP) CRITERIA**

   Not applicable. All preferred agents are preferred without PA.

2. **NON-PREFERRED (NPD) CRITERIA**

   Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. **BRAND MEDICALLY NECESSARY CRITERIA**

   Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

   Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. **DRUG-SPECIFIC CLINICAL CRITERIA**

   Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Androgel gel pump	Androgel gel packet
testosterone gel pump (generic Androgel)	Natesto nasal pump
	Testim gel
	testosterone gel (generic Testim, Vogelxo)
	testosterone gel packet (generic Androgel)
	testosterone gel pump (generic Axiron, Fortesta, Vogelxo)
	Testosterone solution
	Vogelxo gel, gel packet, gel pump

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ENDOCRINE AND METABOLIC AGENTS: BONE RESORPTION SUPPRESSION AND RELATED AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Forteo AE, CC, QL
Bonsity AE, CC, QL
	• Diagnosis one of the following:
	  ○ Female with postmenopausal osteoporosis, **OR**
	  ○ Male with primary or hypogonadal osteoporosis, **OR**
	  ○ Female or male with osteoporosis associated with systemic glucocorticoid therapy; **AND**
	• Documented hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ –2.5 standard deviations; **AND**
	• Patient is at a high risk for fractures; **AND**
	• Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone, bone metastases or skeletal malignancies, etc.); **AND**
	• Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) for 24 months or more (lifetime cumulative); **AND**
	• Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of the following:
	  ○ Oral or IV bisphosphonate drug (e.g., alendronate, ibandronate, or risedronate); **AND**
	  ○ raloxifene tablets (Evista); **OR**
	  calcitonin injections (Miacalcin).
	
	Renewal Criteria:
	• Documentation of disease response (e.g., absence of fractures); **AND**
	• Total length of therapy will not exceed 24 months (lifetime cumulative).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 20 mcg per day

Enoby AE, CC, QL
Jubbonti AE, CC, QL
	Osteoporosis:
	• Patient is male; **OR**
	• Patient is female and postmenopausal; **AND**
	• Diagnosis of osteoporosis, confirmed by ONE of the following:
	  ○ Documented lumbar spine or total hip T-score ≤ -2.5 standard deviations; **OR**
	  ○ Documented lumbar spine or total hip T-score of -1.0 to -2.5 and patient is at a high risk for fractures based on FRAX score; **OR**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Documented lumbar spine or total hip T-score of -1.0 to -2.5 and patient has a fragility fracture of humerus, pelvis, or forearm; **AND** • Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of oral or IV bisphosphonate drugs (e.g., alendronate, ibandronate, or risedronate); **AND** • Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of denosumab therapy; **AND** • Prescriber attestation that the patient has been instructed to supplement with at least 1000 mg calcium and at least 400 IU vitamin D daily. **Bone Loss Related to Non-Metastatic Prostate Cancer:** • Diagnosis of non-metastatic prostate cancer; **AND** • Patient is receiving androgen deprivation therapy (ADT) with ONE of the following: ○ Luteinizing hormone-releasing hormone (LHRH) or gonadotropin releasing hormone (GnRH) agonist (e.g., Lupron); **OR** ○ Bilateral orchiectomy; **AND** • Diagnosis of secondary osteoporosis related to ADT, confirmed by ONE of the following: ○ Documented lumbar spine or total hip T-score ≤ -1.0 standard deviations; **OR** ○ History of fragility fracture; **AND** • Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of oral or IV bisphosphonate drugs (e.g., alendronate, ibandronate, or risedronate); **AND** • Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of denosumab therapy; **AND** • Prescriber attestation that the patient has been instructed to supplement with at least 1000 mg calcium and at least 400 IU vitamin D daily. **Bone Loss Related to Adjuvant Aromatase Inhibitor Therapy for Breast Cancer:** • Diagnosis of breast cancer; **AND** • Patient is receiving adjuvant aromatase inhibitor therapy (AIT) (e.g., anastrozole, exemestane, letrozole); **AND** • Diagnosis of secondary osteoporosis related to AIT, confirmed by ONE of the following: ○ Documented lumbar spine or total hip T-score ≤ -1.0 standard deviations; **OR** ○ History of fragility fracture; **AND** • Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of oral or IV bisphosphonate drugs (e.g., alendronate, ibandronate, or risedronate); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of denosumab therapy; **AND**
	• Prescriber attestation that the patient has been instructed to supplement with at least 1000 mg calcium and at least 400 IU vitamin D daily.
	
	Osteoporosis Associated with Systemic Glucocorticoid Therapy:
	• Patient is receiving ONE of the following:
	  ○ Glucocorticoid treatment of ≥ 7.5 mg per day of prednisone (or equivalent) and is expected to maintain treatment for at least 6 months; **OR**
	  ○ Glucocorticoid treatment of ≥ 30 mg per day; **OR**
	  ○ Cumulative glucocorticoid treatment of ≥ 5 g per year; **AND**
	• Diagnosis of secondary osteoporosis related to glucocorticoid therapy; **AND**
	• Patient is at a high risk for fracture, confirmed by ONE of the following:
	  ○ Documented lumbar spine or total hip T-score ≤ -2.5 standard deviations; **OR**
	  ○ Documented lumbar spine or total hip T-score of -1.0 to -2.5 and patient is at a high risk for fractures based on FRAX score; **OR**
	  ○ Documented lumbar spine or total hip T-score of -1.0 to -2.5 and patient has a fragility fracture of humerus, pelvis, or forearm; **AND**
	• Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of oral or IV bisphosphonate drugs (e.g., alendronate, ibandronate, or risedronate); **AND**
	• Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of denosumab therapy; **AND**
	• Prescriber attestation that the patient has been instructed to supplement with at least 1000 mg calcium and at least 400 IU vitamin D daily.
	
	Renewal Criteria (all indications):
	• Patient must continue to meet initial approval criteria; **AND**
	• Documentation of positive disease response to therapy (e.g., improved or stabilized BMD, absence of fractures).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 60 mg every 6 months

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 12-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Prolia AE, CC, QL
Bildyos AE, CC, QL
Bosaya AE, CC, QL
Conexxence AE, CC, QL
Osvyrti AE, CC, QL
Stoboclo AE, CC, QL
	Osteoporosis:
	• Patient is male; **OR**
	• Patient is female and postmenopausal; **AND**
	• Diagnosis of osteoporosis, confirmed by ONE of the following:
	  ○ Documented lumbar spine or total hip T-score ≤ -2.5 standard deviations;
	  ○ Documented lumbar spine or total hip T-score of -1.0 to -2.5 and patient is at a high risk for fractures based on FRAX score;
	  ○ Documented lumbar spine or total hip T-score of -1.0 to -2.5 and patient has a fragility fracture of humerus, pelvis, or forearm; **AND**
	• Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of oral or IV bisphosphonate drugs (e.g., alendronate, ibandronate, or risedronate); **AND**
	• Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of denosumab therapy; **AND**
	• Prescriber attestation that the patient has been instructed to supplement with at least 1000 mg calcium and at least 400 IU vitamin D daily; **AND**
	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Ebony or Jubbonti.
	
	Bone Loss Related to Non-Metastatic Prostate Cancer:
	• Diagnosis of non-metastatic prostate cancer; **AND**
	• Patient is receiving androgen deprivation therapy (ADT) with ONE of the following:
	  ○ Luteinizing hormone-releasing hormone (LHRH) or gonadotropin releasing hormone (GnRH) agonist (e.g., Lupron);
	  ○ Bilateral orchiectomy; **AND**
	• Diagnosis of secondary osteoporosis related to ADT, confirmed by ONE of the following:
	  ○ Documented lumbar spine or total hip T-score ≤ -1.0 standard deviations;

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Agent(s) Subject to Criteria	Criteria for Approval
	○ History of fragility fracture; **AND** • Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of oral or IV bisphosphonate drugs (e.g., alendronate, ibandronate, or risedronate); **AND** • Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of denosumab therapy; **AND** • Prescriber attestation that the patient has been instructed to supplement with at least 1000 mg calcium and at least 400 IU vitamin D daily; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Jubbonti. **Bone Loss Related to Adjuvant Aromatase Inhibitor Therapy for Breast Cancer:** • Diagnosis of breast cancer; **AND** • Patient is receiving adjuvant aromatase inhibitor therapy (AIT) (e.g. anastrozole, exemestane, letrozole); **AND** • Diagnosis of secondary osteoporosis related to AIT, confirmed by ONE of the following: ○ Documented lumbar spine or total hip T-score ≤ -1.0 standard deviations; ○ History of fragility fracture; **AND** • Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of oral or IV bisphosphonate drugs (e.g., alendronate, ibandronate, or risedronate); **AND** • Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of denosumab therapy; **AND** • Prescriber attestation that the patient has been instructed to supplement with at least 1000 mg calcium and at least 400 IU vitamin D daily; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Jubbonti. **Osteoporosis Associated with Systemic Glucocorticoid Therapy:** • Patient is receiving ONE of the following: ○ Glucocorticoid treatment of ≥ 7.5 mg per day of prednisone (or equivalent) and is expected to maintain treatment for at least 6 months; ○ Glucocorticoid treatment of ≥ 30 mg per day; ○ Cumulative glucocorticoid treatment of ≥ 5 g per year; **AND** • Diagnosis of secondary osteoporosis related to glucocorticoid therapy; **AND** • Patient is at a high risk for fracture, confirmed by ONE of the following: ○ Documented lumbar spine or total hip T-score ≤ -2.5 standard deviations;

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Documented lumbar spine or total hip T-score of -1.0 to -2.5 and patient is at a high risk for fractures based on FRAX score; ○ Documented lumbar spine or total hip T-score of -1.0 to -2.5 and patient has a fragility fracture of humerus, pelvis, or forearm; **AND** • Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of oral or IV bisphosphonate drugs (e.g., alendronate, ibandronate, or risedronate); **AND** • Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of denosumab therapy; **AND** • Prescriber attestation that the patient has been instructed to supplement with at least 1000 mg calcium and at least 400 IU vitamin D daily; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Jubbonti. **Renewal Criteria (all indications):** • Documentation of positive disease response to therapy (e.g., improved or stabilized BMD, absence of fractures). **Age Limit:** ≥ 18 years **Quantity Limit:** 60 mg every 6 months
Evenity AE, CC, QL	• Diagnosis of postmenopausal osteoporosis in a female patient; **AND** • Patient is at high risk for fracture, defined as meeting at least ONE of the following: ○ History of osteoporotic (fragility) fracture; **OR** ○ Multiple risk factors for fracture (e.g., very low T-score [≤ −2.5], advanced age, fall history, family history of hip fracture, FRAX 10-year probability of major osteoporotic fracture ≥ 20% or hip fracture ≥ 3%); **AND** • Step therapy: ○ Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of a preferred oral antiresorptive agent; ▪ The oral antiresorptive step may be waived if the patient is currently receiving or has recently completed denosumab therapy, and trial of an oral agent would pose unacceptable rebound fracture risk, OR if the patient has a documented contraindication or intolerance to all preferred oral agents; **AND** ○ Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of a preferred Injectable antiresorptive or anabolic agent; ▪ If a non-preferred formulation of teriparatide is used in place of preferred teriparatide products, patient must have documented allergy, intolerance, or contraindication to inactive ingredients in preferred teriparatide products (e.g., Bonsity or Forteo); AND

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Agent(s) Subject to Criteria	Criteria for Approval

	• Step therapy may be bypassed if the prescriber provides clinical documentation that the patient meets at least ONE of the following:
	  ○ Very high imminent fracture risk (e.g., recent hip or vertebral fracture within the preceding 12 months; **OR**
	  ○ Multiple vertebral fractures; **OR**
	  ○ T-score of ≤ −3.0 at any measured skeletal site; **AND**
	• Clinical rationale that delay of anabolic therapy to complete step therapy would place the patient at unacceptable risk of additional fractures; AND
	• Patient has no history of myocardial infarction or stroke within the previous 12 months; **AND**
	• Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of Evenity therapy; **AND**
	• Provider attestation that patient will be adequately supplemented with calcium and vitamin D during treatment; **AND**
	• Documented plan provided for transition to an antiresorptive agent (e.g., bisphosphonate or denosumab) upon completion of the Evenity course to maintain bone mineral density (BMD) gains; **AND**
	• Total length of therapy will not exceed 12 months (lifetime cumulative).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 2 syringes per 28 days

Tymlos [AE, CC, QL]	• Diagnosis of one of the following:
	  ○ Postmenopausal female with osteoporosis at high risk for fracture; **OR**
	  ○ Male with osteoporosis at high risk for fracture; **AND**
	• Patient is at high risk for fracture, defined as meeting at least ONE of the following:
	  ○ History of osteoporotic (fragility) fracture; **OR**
	  ○ Multiple risk factors for fracture (e.g., T-score ≤ −2.5, advanced age, fall history, family history of hip fracture, FRAX 10-year probability of major osteoporotic fracture ≥ 20% or hip fracture ≥ 3%); **AND**
	• Step Therapy:
	  ○ Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of a preferred oral antiresorptive agent:
	  ▪ The oral antiresorptive step may be waived if the patient is currently receiving or has recently completed denosumab therapy, and trial of an oral agent would pose unacceptable rebound fracture risk, OR if the patient has a documented contraindication or intolerance to all preferred oral agents; **AND**
	  ○ Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of a preferred Injectable antiresorptive or anabolic agent:
	  ▪ If a non-preferred formulation of teriparatide is used in place of preferred teriparatide products, patient must have documented allergy, intolerance, or

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Agent(s) Subject to Criteria	Criteria for Approval
	contraindication to inactive ingredients in preferred teriparatide products (e.g., Bonsity or Forteo); **AND** • Step therapy may be bypassed if the prescriber provides clinical documentation that the patient meets at least ONE of the following: ○ Very high imminent fracture risk (e.g., recent hip or vertebral fracture within the preceding 12 months; **OR** ○ Multiple vertebral fractures; **OR** ○ T-score of ≤ −3.0 at any measured skeletal site; **AND** ○ Clinical rationale that delay of anabolic therapy to complete step therapy would place the patient at unacceptable risk of additional fractures; **AND** • Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone, open epiphyses, bone metastases or skeletal malignancies, etc.); **AND** • Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide and/or teriparatide combined) for 24 months or more (lifetime cumulative); **AND** • Patient does not have pre-existing hypercalcemia or an underlying hypercalcemic disorder (e.g., primary hyperparathyroidism); **AND** • Provider attestation that any pre-existing hypocalcemia has been reviewed and corrected prior to initiation of Tymlos therapy; **AND** • Provider attestation that the patient will be adequately supplemented with calcium and vitamin D during treatment; **AND** • Documented plan provided for transition to an antiresorptive agent (e.g., bisphosphonate or denosumab) upon completion of the Tymlos course to maintain bone mineral density (BMD) gains. **Renewal Criteria:** • Documentation of disease response (e.g., absence of fractures, stable or improved BMD); **AND** • Total length of therapy will not exceed 24 months (lifetime cumulative). **Age Limit:** ≥ 18 years **Quantity Limit:** 1.56 mL per 30 days; maximum 12 fills per 12-month authorization period
teriparatide AE, CC, QL	• Diagnosis of one of the following: ○ Female with postmenopausal osteoporosis ○ Male with primary or hypogonadal osteoporosis ○ Female or male with osteoporosis associated with systemic glucocorticoid therapy; **AND** • Documented hip DXA (femoral neck or total hip) or lumbar spine T-score ≤ –2.5 (standard deviations); **AND** • Patient is at a high risk for fractures; **AND** • Patient is not at increased risk for osteosarcoma (e.g., Paget's disease of bone, bone metastases or skeletal malignancies, etc.); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Patient has not received therapy with parathyroid hormone analogs (e.g., abaloparatide, teriparatide) for 24 months or more (lifetime cumulative); **AND**
	• Documented allergy, intolerance, contraindication, or therapeutic failure to a minimum 12-month trial of the following:
	  ○ oral or IV bisphosphonate drug (e.g., alendronate, ibandronate, or risedronate), **AND**
	  ○ raloxifene tablets (Evista), **OR** calcitonin injections (Miacalcin); **AND**
	• Patient has a known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation.
	
	Renewal Criteria:
	• Documentation of disease response (e.g., absence of fractures); **AND**
	• Total length of therapy will not exceed 24 months (lifetime cumulative); **AND**
	• Patient has a known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 20 mcg per day

CURRENT PDL STATUS

Preferred ORAL and NASAL Agents	Non-Preferred ORAL and NASAL Agents
alendronate tablet QL	Actonel tablet QL
ibandronate tablet	alendronate oral solution QL
raloxifene tablet	Atelvia DR tablet QL
	Binosto tablet QL
	Boniva tablet QL
	calcitonin-salmon nasal spray, vial
	Evista tablet
	Fosamax tablet QL
	Fosamax Plus D tablet QL
	risedronate sodium tablet QL
	risedronate DR tablet QL

Preferred INJECTABLE Agents	Non-Preferred Agents
Bonsity AE, CC, QL	Bildyos AE, CC, QL
Enoby AE, CC, QL	Bosaya AE, CC, QL
Forteo AE, CC, QL	calcitonin-salmon vial
Jubbonti AE, CC, QL	Conexxence AE, CC, QL
	Evenity AE, CC, QL
	Miacalcin
	Osvyrti AE, CC, QL
	Prolia AE, CC, QL

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Preferred INJECTABLE Agents	Non-Preferred Agents
	Reclast solution
	Stoboclo AE, CC, QL
	teriparatide AE, CC, QL
	Tymlos AE, CC, QL
	zoledronic acid bag, bottle, vial

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ENDOCRINE AND METABOLIC AGENTS: UTERINE DISORDER TREATMENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent with the same indication for use.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Myfembree	
Oriahnn	
Orilissa	

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Rezurock [AE, CC, QL]	• Patient is post-allogenic stem cell transplants (generally 3 or more months); **AND** • Patient has diagnosis of chronic graft-versus-host disease (cGVHD); **AND** • Patient does not have histologic relapse of underlying cancer or post-transplant lymphoproliferative disease; **AND** • Patient has had a trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents; **AND** • Will be used in combination with stable doses of systemic therapies for GVHD which must include, but are not limited to, corticosteroids, calcineurin inhibitors (cyclosporine; tacrolimus), sirolimus, mycophenolate mofetil, methotrexate, or rituximab; **AND** • Belumosudil will not be used in combination with ibrutinib (subsequent therapy is allowed). **Renewal Criteria** • Patient continues to meet the above criteria; **AND** • Patient has not had unacceptable toxicity from the drug (e.g., grade 4 hepatotoxicity); **AND** • Patient has had a positive response to therapy. **Age Limit:** ≥ 12 years **Quantity Limit:** 1 per day

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Agent(s) Subject to Criteria	Criteria for Approval

Tavneos AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Patient has severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis; **AND**
	  ○ Patient has autoantibodies for proteinase 3 (PR3) or myeloperoxidase (MPO), as detected using indirect immunofluorescence (IIF) assay or antigen-specific enzyme linked immunosorbent assays (ELISAs); **OR**
	  ○ Disease is confirmed by tissue biopsy at the site of active disease; **AND**
	• Patient has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment; **AND**
	• Physician has assessed disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS]) and patient has a baseline score of ≥ 16 with 1 of the following:
	  ○ Patient has 1 major item; **OR**
	  ○ Patient has ≥ 3 non-major items; **OR**
	  ○ Patient has ≥ 2 renal items of proteinuria and hematuria; **AND**
	• Patient does NOT have an active infection, including clinically important localized infections; **AND**
	• Patient has failed on ≥ 1 of the following regimens:
	  ○ Patient has failed immunosuppressant therapy (e.g., cyclophosphamide, azathioprine, methotrexate, mycophenolate), unless contraindicated or intolerant; **OR**
	  ○ Patient has failed on anti-CD20 monoclonal antibody therapy (e.g., rituximab), unless contraindicated or intolerant; **AND**
	• Avacopan (Tavneos) will be used as adjunctive therapy in combination with standard therapy (e.g., corticosteroids, cyclophosphamide, azathioprine, mycophenolate, rituximab).
	
	Renewal Criteria:
	• Disease response from pre-treatment baseline as indicated by the following:
	  ○ Absence of new symptoms; **AND**
	  ○ Minimal use of glucocorticoids (e.g., < 5 mg of prednisone or equivalent); **AND**
	  ○ One or more of the following:
	  ▪ Decrease in relapses/flares and/or ANCA levels; **OR**
	  ▪ Improvement in organ manifestations (e.g., those with pulmonary renal syndrome should improve in PFTs, proteinuria, creatinine); **OR**
	  ▪ Remission (defined as a composite scoring index of 0 on the BVAS).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 6 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
azathioprine tablet	Astagraf XL capsule

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Preferred Agents	Non-Preferred Agents
CellCept suspension	CellCept capsule, tablet
cyclosporine capsule, modified capsule, modified solution	Envarsus XR tablet
Gengraf capsule, solution	everolimus tablet
mycophenolate mofetil capsule, tablet	Imuran tablet
mycophenolic acid tablet	mycophenolate mofetil suspension
tacrolimus capsule	Myfortic DR tablet
	Myhibbin suspension
	Neoral capsule, solution
	Prograf capsule, gran pack
	Rezurock tablet AE, CC, QL
	sirolimus solution, tablet
	Sandimmune capsule, solution
	Tavneos capsule AE, CC, QL
	tacrolimus XL capsule
	Zortress tablet

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IMMUNOLOGIC AND GENETIC: MULTIPLE SCLEROSIS AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Avonex CC, QL Betaseron CC, QL Copaxone 20 mg CC, QL dimethyl fumarate CC, QL fingolimod CC, QL	• Diagnosis of multiple sclerosis (ICD-10 Disease Group G35).
Kesimpta AE, CC, QL	• Initially prescribed by or in consultation with a neurologist or multiple sclerosis specialists; **AND** • Diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); **AND** • Patient has had an inadequate response to, or unable to tolerate, 1 or more preferred MS agent; **AND** • NOT have active Hepatitis B, or other clinically significant active infection; **AND** • Baseline serum immunoglobulin measurement has been or will be performed; **AND** • NOT used in combination with any other MS agent; **AND** • Patient does NOT have current systemic or clinically significant local infection. **Renewal Criteria:** • Documentation of response to therapy (e.g., progress note); **AND** • Documentation (e.g., lab results) of ongoing serum immunoglobulin monitoring.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 1-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

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5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

cladribine AE, CC, QL	**Approval Duration:** 35 days initial; one 35-day renewal
	
	• Initially prescribed by or in consultation with a neurologist or multiple sclerosis specialists; **AND**
	• Diagnosis of a relapsing form of multiple sclerosis (MS), relapsing-remitting MS (RRMS), or active secondary progressive MS (SPMS); **AND**
	• Patient has had an inadequate response to, or is unable to tolerate, 2 or more preferred MS agents; **AND**
	• Not used in combination with any other MS agent; **AND**
	• Patient does not meet any of the following conditions:
	  ○ Human immunodeficiency virus (HIV), hepatitis B or C, or tuberculosis (TB) infection;
	  ○ Current cancer or malignancy;
	  ○ Current systemic, or clinically significant local, infection;
	  ○ Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions;
	AND
	• Patient has had, or will have, ALL the following:
	  ○ Screening for hepatitis B/C, HIV, and TB infections; **AND**
	  ○ Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy; **AND**
	  ○ Baseline MRI ≤ 3 months before initiating the first treatment course; **AND**
	  ○ For women of childbearing potential, a negative pregnancy test and counseling on contraception use during therapy.
	
	Renewal Criteria:
	• At least 43 weeks has/will have elapsed since the end of the first treatment course; **AND**
	• Continue to meet initial approval criteria; **AND**
	• Documentation of response to therapy (e.g., progress note).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 10 per 28 days

Gilenya CC, QL	• Diagnosis of multiple sclerosis (ICD-10 Disease Group G35); • Patient has had an inadequate response to, or is unable to tolerate, 2 or more preferred MS agent; **AND** • Patient has had a trial and failure (e.g., allergy or intolerance to an inactive ingredient) with at least **TWO** manufacturers (if available) of the corresponding generic. **Quantity Limit:** 1 per day
Mavenclad AE, CC, QL	**Approval Duration:** 35 days initial; one 35-day renewal • Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with ≥ 2 manufacturers (if available and covered) of the corresponding generic Initially prescribed by or in consultation with a neurologist or multiple sclerosis specialists; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Diagnosis of a relapsing form of multiple sclerosis (MS), relapsing-remitting MS (RRMS), or active secondary progressive MS (SPMS); **AND**
	• Patient has had an inadequate response to, or is unable to tolerate, 2 or more preferred MS agents; **AND**
	• Not used in combination with any other MS agent; **AND**
	• Patient does not meet any of the following conditions:
	  ○ Human immunodeficiency virus (HIV), hepatitis B or C, or tuberculosis (TB) infection;
	  ○ Current cancer or malignancy;
	  ○ Current systemic, or clinically significant local, infection;
	  ○ Use of any other antineoplastic, immunosuppressive or immunomodulator drugs to treat other conditions;
	AND
	• Patient has had or will have all of the following:
	  ○ Screening for hepatitis B/C, HIV, and TB infections; **AND**
	  ○ Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy; **AND**
	  ○ Baseline MRI ≤ 3 months before initiating the first treatment course; **AND**
	  ○ For women of childbearing potential, a negative pregnancy test and counseling on contraception use during therapy.
	
	Renewal Criteria:
	• At least 43 weeks has/will have elapsed since the end of the first treatment course; **AND**
	• Continue to meet initial approval criteria; **AND**
	• Documentation of response to therapy (e.g., progress note).
	
	Age Limit: ≥ 18 years
	Quantity Limit: 10 per 28 days

Mayzent AE, CC, QL	• Initially prescribed by or in consultation with a neurologist or multiple sclerosis specialist; **AND**
	• Patient has a diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); **AND**
	• Patient has had an inadequate response to, or is unable to tolerate, 2 or more preferred MS agents; **AND**
	• NOT used in combination with another MS agent; **AND**
	• Patient does not meet any of the following conditions:
	  ○ Presence of contraindicated cardiovascular comorbidities (e.g., recent heart attack or stroke, heart failure);
	  ○ Current systemic or clinically significant local infection;
	  ○ Use of any other antineoplastic, immunosuppressive or immunomodulating drugs to treat other conditions;
	  ○ Prior use of alemtuzumab; **AND**
	• Patient has had or will have all of the following:
	  ○ CYP2C9 variant genotyping testing to guide dosing; **AND**
	  ○ Screening for clinically significant drug interactions; **AND**
	  ○ Baseline electrocardiogram (ECG), liver function tests (LFTs) and ophthalmic evaluation; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ If pre-existing non-contraindicated cardiac disease (e.g., arrhythmia), cardiology consultation and follow-up will be conducted prior to and during treatment; **AND** ○ Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy. **Renewal Criteria:** • Continue to meet initial approval criteria; **AND** • Documentation of response to therapy (e.g., progress note). **Age Limit:** ≥ 18 years
Ponvory AE, CC, QL	• Initially prescribed by or in consultation with a neurologist or multiple sclerosis specialists; **AND** • Patient has a diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); **AND** • Patient has had an inadequate response to, or is unable to tolerate, 2 or more preferred MS agents; **AND** • NOT used in combination with another MS agent; **AND** • Patient has a baseline heart rate (HR) ≥ 55 beats per minute (bpm); **AND** • If patient is of child-bearing potential, patient is taking effective contraception; **AND** • Patient does not meet any of the following conditions: ○ Presence of contraindicated cardiovascular comorbidities (e.g., recent heart attack or stroke, heart failure); ○ Presence of Mobitz Type II second- or third-degree atrioventricular (AV) block, sick sinus syndrome, or sinoatrial block (unless treated with a functioning pacemaker); ○ Current systemic or clinically significant local infection; ○ Moderate to severe hepatic impairment (Child-Pugh B or C); ○ Use of any other antineoplastic, immunosuppressive or immunomodulating drugs to treat other conditions; ○ Prior use of alemtuzumab; **AND** • Patient has had or will have all of the following: ○ Screening for clinically significant drug interactions; **AND** ○ Baseline electrocardiogram (ECG), liver function tests (LFTs) and ophthalmic evaluation; **AND** ○ Monitoring of respiratory function in patients with baseline respiratory conditions (e.g., pulmonary fibrosis, asthma, chronic obstructive pulmonary disease); **AND** ○ If pre-existing non-contraindicated cardiac disease (e.g., arrhythmia), cardiology consultation and follow-up will be conducted prior to and during treatment; **AND** ○ Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 weeks prior to beginning therapy. **Renewal Criteria:** • Continue to meet initial approval criteria; **AND** • Documentation of response to therapy (e.g., progress note).

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to Criteria	Criteria for Approval
	Age Limit: ≥ 18 years **Quantity Limit:** 1 per day
Rebif CC, QL	• Diagnosis of multiple sclerosis (ICD-10 Disease Group G35). **Quantity Limit:** 6 mL per 28 days
Zeposia AE, CC, QL	**Multiple Sclerosis:** • Initially prescribed by or in consultation with a neurologist or multiple sclerosis specialists; **AND** • Patient has a diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); **AND** • Patient has had an inadequate response to, or is unable to tolerate, 2 or more preferred MS agents; **AND** • NOT used in combination with another MS agent; **AND** • Patient does not meet any of the following conditions: o Presence of contraindicated cardiovascular comorbidities (e.g., recent heart attack or stroke, heart failure); o Current systemic or clinically significant local infection; o Use of any other antineoplastic, immunosuppressive or immunomodulating drugs to treat other conditions; o Prior use of alemtuzumab; **AND** • Patient has had or will have all of the following: o Screening for clinically significant drug interactions; **AND** o Baseline electrocardiogram (ECG), liver function tests (LFTs) and ophthalmic evaluation; **AND** o If pre-existing non-contraindicated cardiac disease (e.g., arrhythmia), cardiology consultation and follow-up will be conducted prior to and during treatment; **AND** o Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy. **MS Renewal Criteria:** • Continue to meet initial approval criteria; **AND** • Documentation of response to therapy (e.g., progress note). **Ulcerative Colitis:** **Approval Duration:** 6 months initial; 1 year renewal • Diagnosis of moderate to severely active ulcerative colitis (UC); **AND** • Prescribed by or in consultation with a gastroenterologist or other specialist in the treatment of UC; **AND** • Patient does not meet any of the following conditions: o Presence of contraindicated cardiovascular comorbidities (e.g., recent heart attack or stroke, heart failure); o Current systemic or clinically significant local infection; o Use of any other antineoplastic, immunosuppressive or immunomodulating drugs to treat other conditions; o Prior use of alemtuzumab; **AND** • Patient has had or will have all of the following: o CYP2C9 variant genotyping testing to guide dosing; **AND** o Screening for clinically significant drug interactions; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Baseline electrocardiogram (ECG), liver function tests (LFTs) and ophthalmic evaluation; **AND** ○ If pre-existing non-contraindicated cardiac disease (e.g., arrhythmia), cardiology consultation and follow-up will be conducted prior to and during treatment; **AND** ○ Testing for antibodies to the varicella zoster virus (VZV) OR have received immunization for VZV at least 4 to 6 weeks prior to beginning therapy; **AND** • Patient has trial and failure (at least 3 months) of ≥ 1 of the following conventional therapies: ○ Oral/rectal 5-aminosalicylic acid agents (e.g., balsalazide, Lialda, mesalamine, sulfasalazine); **OR** ○ Oral/rectal steroids (e.g., budesonide, hydrocortisone, prednisone); **OR** ○ Immunosuppressant (e.g., azathioprine, mercaptopurine); **OR** • Patient is deemed high-risk for intestinal complications or post-operative recurrence; **AND** • NOT used in combination with any other biologic agent; **AND** • Patient has had a ≥ 3-month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interaction), or intolerance to a preferred anti-TNF therapy indicated for ulcerative colitis. **UC Renewal Criteria:** • Documentation of response to therapy (e.g., progress note). **Quantity Limit:** 1 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Avonex CC, QL	Ampyra QL
Betaseron CC, QL	Aubagio QL
Copaxone 20 mg CC, QL	Bafiertam AE, QL
dalfampridine ER tablet QL	cladribine AE, CC, QL
dimethyl fumarate DR capsule CC, QL	Copaxone 40 mg QL
fingolimod capsule CC, QL	Extavia QL
Kesimpta AE, CC, QL	Gilenya CC, QL
teriflunomide tablet QL	glatiramer acetate QL
	Glatopa QL
	Mavenclad AE, CC, QL
	Mayzent AE, CC, QL
	Plegridy QL
	Ponvory AE, CC, QL
	Rebif CC, QL
	Tascenso ODT QL
	Tecfidera QL
	Vumerity AE, QL
	Zeposia AE, CC, QL

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IMMUNOLOGIC AND GENETIC: CYTOKINE AND CAM ANTAGONISTS

GUIDELINES FOR USE

Approval Duration: 6 months initial, 1 year renewal (unless otherwise specified)

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Enbrel CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria
Humira CC, QL Hadlima CC, QL Yuflyma CC, QL adalimumab-aaty CC, QL adalimumab-fkjp 40 mg CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Crohn's Disease (CD) Clinical Criteria • Hidradenitis Suppurativa (HS) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Non-radiographic axial spondylarthritis (nr-axSpA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria • Uveitis Clinical Criteria

Otezla CC, QL
Otezla XR CC, QL
	Approval Duration: 6 months initial; 1 year renewal
	
	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met:
	• Psoriatic Arthritis (PsA) Clinical Criteria
	
	Plaque Psoriasis:
	• Diagnosis of plaque psoriasis (mild, moderate, or severe); **AND**
	• Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of psoriasis; **AND**
	• Trial and failure (at least 3 months) of ≥ 1 conventional therapy:
	  ○ Disease-modifying anti-rheumatic drug (DMARD), such as methotrexate
	  ○ Immunosuppressant (e.g., cyclosporine)
	  ○ Oral retinoid (e.g., acitretin); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	
	Renewal Criteria (Plaque Psoriasis):
	• Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score.
	
	Behcet's Disease:
	• Prescribed for the treatment of oral ulcers in a patient with Behcet's disease; **AND**
	• Prescribed by, or in consultation with a rheumatologist or other specialist in the treatment of *Behçet's* Disease; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication; **AND**
	• Trial and failure of ≥ 1 of the following conventional therapies
	  ○ Azathioprine
	  ○ Sulfasalazine
	  ○ Colchicine
	  ○ Topical or oral steroids (e.g., triamcinolone, prednisone).
	
	Renewal Criteria (Behcet's Disease):
	• Documentation (e.g., progress note) of response to therapy compared to baseline.

Pyzchiva CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria
Rinvoq tablet AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Crohn's Disease (CD) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Non-radiographic axial spondylarthritis (nr-axSpA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Giant Cell Arteritis (GCA):** • Prescribed by a rheumatologist, vascular medicine, or other specialist in the diagnosis and treatment of GCA; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to Criteria	Criteria for Approval

	Refractory, Moderate-to-Severe Atopic Dermatitis:
	• Patient has moderate-to-severe atopic dermatitis (AD) defined by ≥ 1 of the following:
	  ○ Involvement of ≥ 10% of body surface area (BSA); **OR**
	  ○ Eczema Area and Severity Index (EASI) score of ≥ 16; **OR**
	  ○ Investigator's Global Assessment (IGA) score of ≥ 3; **OR**
	  ○ Scoring Atopic Dermatitis (SCORAD) score of ≥ 25; **OR**
	  ○ Pruritus Numerical Rating Scale (NRS) score of ≥ 4; **OR**
	  ○ Incapacitation due to AD lesion location (head and neck, palms, soles, or genitalia); **AND**
	• Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND**
	• Trial and failure, contraindication, or intolerance to ≥ 1 agent in each of the following categories:
	  ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **AND**
	  ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **AND**
	  ○ Immunomodulating systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.); **AND**
	• Not used in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	
	Renewal Criteria (Atopic Dermatitis):
	• Documentation (e.g., progress note) of response to therapy relative to baseline measure(s) (e.g., BSA involvement, EASI, IGA, SCORAD).
	
	Quantity Limit: 1 per day

Rinvoq LQ AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria **Age Limit:** 2-17 years **Quantity Limit:** 360 mL per 30 days
Taltz CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Non-radiographic axial spondyloarthritis (nr-axSpA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria

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Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limit: 1 pen/syringe per 28 days
Tyenne CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria **Giant Cell Arteritis (GCA):** • Prescribed by a rheumatologist, vascular medicine, or other specialist in the diagnosis and treatment of GCA; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Quantity Limit:** 162 mg (1 pen/syringe) per week
Xeljanz IR tablet CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Quantity Limit:** 2 per day
Xeljanz IR solution CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria **Quantity Limit:** 10 mL per day
Yesintek CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Quantity Limit:** 1 syringe/vial per 56 days

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of **1 preferred agent**, unless otherwise specified (e.g., no preferred agents are indicated).

Biosimilar agents must also meet PREFERRED WITH PA (PDP) OR DRUG-SPECIFIC CRITERIA for the reference product.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. ANKYLOSING SPONDYLITIS (AS) OR NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (NR-AXSPA) CLINICAL CRITERIA

- Diagnosis of Ankylosing Spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA); **AND**
- Prescribed by, or in consultation with, a rheumatologist or other specialist in the treatment of AS/nr-axSpA; **AND**
- Trial and failure of, contraindication, or intolerance to ≥ 1 non-steroidal anti-inflammatory drug (NSAID); **AND**
- NOT used in combination with any other biologic agent; **AND**
- For non-preferred agents: 3-month trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

- Documentation (e.g., progress note) of response to therapy.

6. CROHN'S DISEASE (CD) OR ULCERATIVE COLITIS (UC) CLINICAL CRITERIA

- Diagnosis of Crohn's disease (CD) or Ulcerative Colitis (UC); **AND**
- For patients ≥ 18 years of age, the medication is prescribed by, or in consultation with, a gastroenterologist or other specialist in the treatment of CD/UC. For patients < 18 years of age, prescriber is a ***pediatric*** gastroenterologist/CD/UC specialist; **AND**
- Patient is deemed high-risk for intestinal complications or post-operative recurrence; **AND**
- For patients ≥ 18 years of age only: trial and failure of ≥ 1 of the following conventional therapies:

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- Oral/rectal 5-aminosalicylic acid agents (e.g., balsalazide, Lialda, mesalamine, sulfasalazine);
- Oral/rectal steroids (e.g., budesonide, hydrocortisone, prednisone);
- Immunosuppressant (e.g., azathioprine, mercaptopurine); **AND**

- NOT used in combination with any other biologic agent; **AND**
- For non-preferred agents: 3-month trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; **AND**
- Patient must meet the minimum age (and weight, when applicable) recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

- Documentation (e.g., progress note) of response to therapy.

7. HIDRADENITIS SUPPURATIVA (HS) CLINICAL CRITERIA

- Diagnosis of moderate to severe hidradenitis suppurativa (HS); **AND**
- Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of HS; **AND**
- Trial and failure (at least 3 months) of ≥ 1 non-biologic therapy:
  - Contraceptives (e.g., ethinyl estradiol/norgestimate);
  - Oral retinoid (e.g., acitretin);
  - Systemic antibiotic (e.g., clindamycin, minocycline, doxycycline, rifampin) ; **AND**
- NOT used in combination with any other biologic agent; **AND**
- For non-preferred agents: **3-month** trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

- Documentation (e.g., progress note) of response to therapy.

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8. JUVENILE IDIOPATHIC ARTHRITIS (JIA) CLINICAL CRITERIA

- Diagnosis of active polyarticular or systemic juvenile idiopathic arthritis (JIA); **AND**
- Prescribed by, or in consultation with, a rheumatologist or other specialist in the treatment of JIA; **AND**
- Trial and failure (at least 3 months), contraindication, or intolerance to ≥ 1 disease-modifying anti-rheumatic drug (DMARD), such as methotrexate; **AND**
- NOT used in combination with any other biologic agent; **AND**
- For non-preferred agents: 3-month trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

- Documentation (e.g., progress note) of response to therapy.

9. PLAQUE PSORIASIS CLINICAL CRITERIA

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of psoriasis; **AND**
- Symptoms persistent for ≥ 6 months with at least 1 of the following:
    - Involvement of at least 3% of body surface area (BSA);
    - Psoriasis Area and Severity Index (PASI) score of 10 or greater;
    - Incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia); **AND**
- Trial and failure (at least 3 months) of ≥ 1 conventional therapy:
    - Disease-modifying anti-rheumatic drug (DMARD) (e.g., methotrexate);
    - Immunosuppressant (e.g., cyclosporine);
    - Oral retinoid (e.g., acitretin); **AND**
- NOT used in combination with any other biologic agent; **AND**
- For non-preferred agents: 3-month trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

- Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score.

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10. PSORIATIC ARTHRITIS (PSA) CLINICAL CRITERIA

- Diagnosis of psoriatic arthritis (PsA); **AND**
- Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of PsA; **AND**
- NOT used in combination with any other biologic agent; **AND**
- For non-preferred agents: 3-month trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

- Documentation (e.g., progress note) of response to therapy.

11. RHEUMATOID ARTHRITIS (RA) CLINICAL CRITERIA

- Diagnosis of rheumatoid arthritis (RA) based on the American College of Rheumatology (ACR) criteria; **AND**
- Prescribed by, or in consultation with, a rheumatologist or other specialist in the treatment of RA; **AND**
- Documentation (e.g., progress note) of baseline RA disease activity measure using ≥ 1 of the following scales:
    - Clinical Disease Activity Index (CDAI);
    - Disease Activity Score in 28 Joints with Erythrocyte Sedimentation Rate or C-Reactive Protein Level (DAS28-ESR/CRP);
    - Simplified Disease Activity Index (SDAI);
    - Routine Assessment of Patient Index Data 3 (RAPID3);
    - Patient Activity Scale-II (PAS-II); **AND**
- Trial and failure (at least 3 months), contraindication, or intolerance to ≥ 1 disease-modifying anti-rheumatic drug (DMARD) (e.g., methotrexate); **AND**
- NOT used in combination with any other biologic agent; **AND**
- For non-preferred agents: 3-month trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

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- Documentation (e.g., progress note) of improved RA disease activity measure from baseline while on therapy.

12. UVEITIS CLINICAL CRITERIA

- Diagnosis of non-infectious intermediate, posterior, or panuveitis; **AND**
- Prescribed by, or in consultation with, a rheumatologist, ophthalmologist or other specialist in the treatment of uveitis; **AND**
- Failure of a ≥ 2-week trial of a systemic corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; **AND**
- Failure of a trial of a non-biologic immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil, cyclosporine, tacrolimus, cyclophosphamide, chlorambucil) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; **AND**
- NOT used in combination with any other biologic agent; **AND**
- For non-preferred agents: 3-month trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

- Documentation (e.g., progress note) of response to therapy.

13. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Actemra syringe CC, QL Actemra Actpen CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria **Giant Cell Arteritis (GCA):** • Prescribed by a rheumatologist, vascular medicine, or other specialist in the diagnosis and treatment of GCA; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD):** • Diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD); **AND** • Prescribed by a pulmonologist, or other specialist in the diagnosis and treatment of SSc-ILD; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

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Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limit: 4 pens/syringes per 28 days

adalimumab biosimilars CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Patient has had a trial and failure or has a known or suspected allergy, intolerance, or contraindication to 1 preferred adalimumab product; **AND**
	• One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met:
	  ○ Ankylosing Spondylitis (AS) Clinical Criteria
	  ○ Crohn's Disease (CD) Clinical Criteria
	  ○ Hidradenitis Suppurativa (HS) Clinical Criteria
	  ○ Juvenile Idiopathic Arthritis (JIA) Clinical Criteria
	  ○ Non-radiographic axial spondylarthritis (nr-axSpA) Clinical Criteria
	  ○ Plaque Psoriasis Clinical Criteria
	  ○ Psoriatic Arthritis (PsA) Clinical Criteria
	  ○ Rheumatoid Arthritis (RA) Clinical Criteria
	  ○ Ulcerative Colitis (UC) Clinical Criteria
	  ○ Uveitis Clinical Criteria

Avtozma CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria **Giant Cell Arteritis (GCA) Criteria:** • Prescribed by a rheumatologist, vascular medicine, or other specialist in the diagnosis and treatment of GCA; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Cytokine Release Syndrome (CRS) Criteria:** • Diagnosis of chimeric antigen receptor (CAR) T cell-induced CRS; **AND** • Prescribed by a hematologist, oncologist, or other specialist in the diagnosis and treatment of CRS; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Quantity Limit:** 162 mg (1 pen/syringe) per week
Bimzelx AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Non-radiographic axial spondyloarthritis (nr-axSpA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Hidradenitis Suppurativa (HS) Clinical criteria **Age Limit:** ≥ 18 years **Quantity Limit:** 2 mL per 28 days

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Agent(s) Subject to Criteria	Criteria for Approval

Cibinqo CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Patient has moderate-to-severe atopic dermatitis (AD) defined by ≥ 1 of the following:
	  ○ Involvement of ≥ 10% of body surface area (BSA); **OR**
	  ○ Eczema Area and Severity Index (EASI) score of ≥ 16; **OR**
	  ○ Investigator's Global Assessment (IGA) score of ≥ 3; **OR**
	  ○ Scoring Atopic Dermatitis (SCORAD) score of ≥ 25; **OR**
	  ○ Pruritus Numerical Rating Scale (NRS) score of ≥ 4; **OR**
	  ○ Incapacitation due to AD lesion location (head and neck, palms, soles, or genitalia); **AND**
	• Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of atopic dermatitis; **AND**
	• Patient is up to date with all vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**
	• Patient will NOT receive live vaccines during therapy; **AND**
	• The medication will NOT be used in combination with other monoclonal antibody biologics; **AND**
	• Patient is NOT on concomitant antiplatelet therapies during the first 3 months of treatment (Note: excludes the use of low-dose aspirin) **AND**
	• Patient does NOT have any clinically relevant laboratory abnormalities (e.g., platelet count <150,000/mm3, an absolute lymphocyte count <500/mm3, an absolute neutrophil count <1,000/mm3, or a hemoglobin value <8 g/dL); **AND**
	• Patient has had a ≥ 3 month trial and failure, contraindication, or intolerance to ≥ 1 agent in each of the following categories:
	  ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **AND**
	  ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **AND**
	  ○ Immunomodulating systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, dupilumab); **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria:
	• Patient has disease response as indicated by improvement in signs and symptoms compared to baseline in ≥ 1 of the following: pruritus, the amount of surface area involvement, EASI, IGA, SCORAD, and/or NRS; **AND**
	  ○ Patient has achieved clear or almost clear skin defined as achievement of an IGA 0/1 or EASI-75 at week 16; **OR**
	  ○ Patient has had an inadequate response to standard doses of therapy after an adequate trial of ≥ 12 weeks OR patient experienced a disease flare and will require higher dosing; **AND**
	  ○ Patient requires an increase in dose, in accordance with prescribing information recommended dosages (e.g., up to 200 mg daily); **AND**
	• Patient has NOT experienced a myocardial infarction or stroke
	
	Quantity Limit: 1 per day

Cimzia CC, QL	**Approval Duration:** 6 months initial; 1 year renewal

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Agent(s) Subject to Criteria	Criteria for Approval
	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Crohn's Disease (CD) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Non-radiographic axial spondyloarthritis (nr-axSpA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria
Cosentyx CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Hidradenitis Suppurativa (HS) Clinical Criteria • Non-radiographic axial spondylarthritis (nr-axSpA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria **Enthesitis-related arthritis:** • Diagnosis of active enthesitis-related arthritis; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Juvenile Psoriatic Arthritis:** • Diagnosis of juvenile psoriatic arthritis; **AND** • Prescribed by, or in consultation with, a rheumatologist or other specialist in the treatment of juvenile psoriatic arthritis; **AND** • At least 2 years of age; **AND** • Trial and failure (at least 3 months), contraindication, or intolerance to ≥ 1 disease-modifying anti-rheumatic drug (DMARD), such as methotrexate; **AND** • NOT used in combination with any other biologic agent; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Renewal Criteria (Juvenile Psoriatic Arthritis):** • Documentation (e.g., progress note) of response to therapy.

Enspryng AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Diagnosis of anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD); **AND**
	• Prescribed by a specialist (e.g., immunologist, neurologist, ophthalmologist, etc.) experienced in the diagnosis and treatment of neuromyelitis optica spectrum disorder (NMOSD); **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication; **AND**
	• Diagnosis of NMOSD confirmed by the following:
	  ○ Seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**
	  ○ Presence of ≥ 1 core clinical characteristic (e.g., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem

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Agent(s) Subject to Criteria	Criteria for Approval
	syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions); **AND** ○ Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection); **AND** • Patient meets ALL of the following conditions: ○ History of ≥ 1 relapse(s) that required rescue therapy within the prior year or ≥ 2 relapses that required rescue therapy within the prior 2 years; **AND** ○ Expanded Disability Status Score (EDSS) of ≤ 6.5 (e.g., requires 2 walking aids [pair of canes, crutches, etc.] to walk about 20 m without resting); **AND** ○ At risk of having a disabling relapse of NMOSD for which oral agents (e.g., corticosteroids and immunosuppressants such as azathioprine and mycophenolate) alone are inadequate and biologic therapy is necessary; **AND** ○ Screening for and absence of Hepatitis B, tuberculosis (TB), and other active infections prior to therapy initiation; **AND** • NOT previously treated with prolonged immunosuppressive therapy with alemtuzumab, cladribine, cyclophosphamide or mitoxantrone OR immunosuppressant procedures (e.g., bone marrow transplant, total lymphoid irradiation); **AND** • NOT to be used in combination with any of the following: ○ Multiple sclerosis agents (e.g., interferon, dimethyl fumarate, fingolimod, glatiramer, etc.) within 6 months of therapy initiation; **AND** ○ Other biologics used for the treatment of NMOSD (e.g., eculizumab, inebilizumab, rituximab). **Renewal Criteria:** • Disease response as indicated by stabilization/improvement in any of the following: neurologic symptoms as evidenced by a decrease in acute relapses, stability, or improvement in EDSS, reduced hospitalizations, reduction/discontinuation in plasma exchange treatments, and/or reduction/discontinuation of corticosteroids without relapse. **Quantity Limit:** 1 syringe per 28 days
Entyvio Pen CC, QL Entyvio vial CC	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Quantity Limit (pens only):** 2 pens per 28 days
Icotyde AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal • Diagnosis of moderate to severe plaque psoriasis; **AND** • Patient weighs ≥ 40 kg; **AND** • Patient is a candidate for systemic therapy or phototherapy; **AND** • Trial and failure (at least 3 months) of ≥ 1 conventional therapy:

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Disease-modifying anti-rheumatic drug (DMARD) (e.g., methotrexate) ○ Immunosuppressant (e.g., cyclosporine) ○ Oral retinoid (e.g., acitretin); **AND** • Trial and failure of ≥ 2 preferred biologics indicated for plaque psoriasis; **AND** • NOT used in combination with any other biologic agent; **AND** • Screening for and absence of tuberculosis (TB) and other active infections prior to therapy initiation; **AND** • NOT administered concurrently with live vaccines; **AND** • Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of psoriasis. **Renewal Criteria:** • Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score. **Age Limit:** ≥ 12 years **Quantity Limit:** 1 per day
Ilaris CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria **Cryopyrin-Associated Periodic Syndromes (CAPS):** • Patient must have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including: ○ Familial Cold Auto-inflammatory Syndrome (FCAS); **OR** ○ Muckle-Wells Syndrome (MWS); **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication; **AND** • Must be prescribed by or in consultation with a rheumatologist or other specialist in the diagnosis and treatment of CAPS; **AND** • Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND** • Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND** • Patient has documented baseline serum levels of inflammatory proteins (C-Reactive Protein [CRP] and Serum Amyloid A [SAA]); **AND** • Patient has documented laboratory evidence of a genetic mutation in the Cold Induced Autoinflammatory Syndrome 1, also known as NLRP3; **AND** • Other causes for recurrent fever have been excluded (e.g. recurrent bacterial/viral infection, other autoinflammatory disease, cancer, cyclic neutropenia, interferonpathies); **AND** • Patient has ≥2 of any of the CAPS-typical symptoms: ○ Urticaria-like rash ○ Cold-triggered episodes ○ Sensorineural hearing loss ○ Musculoskeletal symptoms

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Chronic aseptic meningitis ○ Skeletal abnormalities. **Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS):** • Patient has a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS); **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication; **AND** • Prescribed by or in consultation with a rheumatologist or other specialist in the diagnosis and treatment of TRAPS; **AND** • Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND** • Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND** • Patient has the presence of the TNFRSF1A mutation; **AND** • Patient has chronic or recurrent disease (defined as > 6 flares per year); **AND** • Other causes for recurrent fever have been excluded (e.g. recurrent bacterial/viral infection, other autoinflammatory diseases, cancer, cyclic neutropenia, interferonpathies). **Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD):** • Patient has a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD); **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication; **AND** • Prescribed by or in consultation with a rheumatologist or other specialist in the diagnosis and treatment of MKD; **AND** • Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND** • Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND** • Patient has a confirmed diagnosis based on elevated serum IgD levels and melvalonate kinase (MVK) gene mutation testing, if IgD levels are normal; **AND** • Patient has tried and failed nonsteroidal anti-inflammatory drugs (NSAIDs) and glucocorticoids; **AND** • Patient has a documented history of at least three (3) febrile episodes within a 6 month period or is steroid dependent; **AND** • Other causes have been excluded for recurrent fever (e.g. bacterial/viral/fungal infection, sarcoidosis, cancer,) and/or recurrent abdominal pain and/or elevated IgD. Documentation may be requested. **Familial Mediterranean Fever (FMF):** • Patient has a diagnosis of Familial Mediterranean Fever (FMF); **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication; **AND** • Prescribed by or in consultation with a rheumatologist or other specialist in the diagnosis and treatment of FMF; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND**
	• Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
	• Patient has a confirmed diagnosis based on of the following:
	  ○ Patient continues to have one or more attacks monthly after a six-month compliant trial of colchicine at maximum tolerated doses.; **OR**
	  ○ Patient has AA amyloidosis while on maximum tolerated doses of colchicine; **OR**
	  ○ Patient has an intolerance or contraindication to colchicine therapy.; **AND**
	• Other causes for recurrent fever have been excluded (e.g. bacterial/viral infection, other autoinflammatory diseases, cancer, other causes of abdominal pain). Documentation may be requested.
	
	Still's Disease (Adult-Onset Still's Disease [AOSD]):
	• Patient has a diagnosis of Still's Disease; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication; **AND**
	• Prescribed by or in consultation with a rheumatologist or other specialist with expertise in treating the diagnosis for AOSD; **AND**
	• Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND**
	• Patient is not on concurrent treatment with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND**
	• Patient has active disease; **AND**
	• Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
	• Patient has had at least a 1-month trial and failure (unless contraindicated or intolerant) of previous therapy with either oral non-steroidal anti-inflammatory drugs (NSAIDs) or a systemic glucocorticoid (e.g., prednisone, methylprednisolone); **AND**
	• Other causes for recurrent fever have been excluded (e.g., bacterial/viral infection, other autoinflammatory diseases, cancer, sarcoidosis). Documentation may be requested.
	
	Gout Flare:
	Approval Duration: 3 months
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication; **AND**
	• Prescribed by or in consultation with a rheumatologist; **AND**
	• Patient is not on concurrent therapy with other IL-1 blocking agents (e.g., anakinra, rilonacept); **AND**
	• Patient has had three or more flares in the past 12 months; **AND**
	• Patient is currently experiencing a gout flare; **AND**
	• Patient has tried and failed all the following unless contraindicated or intolerant:
	  ○ Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
	  ○ Systemic corticosteroids; **AND**
	  ○ Colchicine; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Patient must be taking a medication for prophylactic treatment of gout. **Renewal Criteria:** • Absence of unacceptable toxicity from the drug; **AND** • Canakinumab will not be used concurrently with a TNF inhibitor, biologic response modifier, or other non-biologic immunomodulating agent (i.e., apremilast, tofacitinib, baricitinib); **AND** • **Cryopyrin-Associated Periodic Syndromes:** Documentation submitted showing disease improvement or stabilization as symptom assessment and improvement in serum levels of inflammatory proteins (e.g., C-Reactive Protein [CRP] and/or Serum Amyloid A [SAA]) as compared to baseline; **OR** • **Tumor Necrosis Factor Receptor Associated Periodic Syndrome; Hyperimmunoglobulin D Syndrome/Mevalonate Kinase Deficiency; Familial Mediterranean Fever:** Documentation submitted showing disease improvement or stabilization as indicated by symptom assessment and changes in any clinically relevant lab values as compared to baseline assessments.; **OR** • **Adult-Onset Still's Disease/Systemic Juvenile Idiopathic Arthritis:** Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts and/or an improvement on a disease activity scoring tool (e.g., an improvement on a composite scoring index such as Juvenile Arthritis Disease Activity Score [JADAS] or the American College of Rheumatology [ACR] Pediatric [ACR-Pedi 30] of at least 30% improvement from baseline in three of six variables). • **Gout Flare:** must meet initial criteria for approval. **Quantity Limit:** 300 mg (2 vials) every 4 weeks
Ilumya AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Plaque Psoriasis Clinical Criteria **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe per 84 days
Imuldosa CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria • All indications require 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ALL preferred ustekinumab biosimilar products (Pyzchiva and Yesintek) in addition to 1 other preferred agent.

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limit: 1 syringe per 56 days
Infliximab vial (and biosimilars) CC	**Approval Duration:** 6 months initial; 1 year renewal Patient has a confirmed diagnosis of one of the following: • Crohn's Disease, Fistulizing One of the following diagnosis-based clinical criteria for an FDA-approved-indication has been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Crohn's Disease (CD) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria
Kevzara AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved-indication has been met: • Rheumatoid Arthritis (RA) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria **Polymyalgia Rheumatica (PMR):** • Diagnosis of polymyalgia rheumatica (PMR); **AND** • Prescribed by a rheumatologist, or other specialist in the diagnosis and treatment of PMR; **AND** • Patient has steroid-resistant active disease; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 pens/syringes per 28 days
Kineret CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved-indication has been met: • Rheumatoid Arthritis (RA) Clinical Criteria **DIRA:** • Diagnosis of deficiency of Interleukin-1 Receptor Antagonist (DIRA); **AND** • Prescribed by, or in consultation with, a pediatric rheumatologist, geneticist or other specialist in the diagnosis and treatment of DIRA; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **NOMID:** • Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID); **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Prescribed by, or in consultation with, a rheumatologist or other specialist in the diagnosis and treatment of NOMID; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Quantity Limit:** 1 syringe per day
Olumiant AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved-indication has been met: • Rheumatoid Arthritis (RA) Clinical Criteria **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Omvoh AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved-indication has been met: • Crohn's Disease (CD) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Age Limit:** ≥ 18 years **Quantity Limit:** • 1 vial per 28 days • 100 mg: 2 per 28 days • 200 mg, 300 mg: 1 per 28 days
Orencia CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved-indication has been met: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria **Quantity Limit:** 4 syringes/pen per 28 days
Otulfi CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria • All indications require 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ALL preferred ustekinumab biosimilar products (Pyzchiva and Yesintek) in addition to 1 other preferred agent.

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Agent(s) Subject to Criteria	Criteria for Approval
Remicade vial CC	**Approval Duration:** 6 months initial; 1 year renewal Patient has a confirmed diagnosis of one of the following: • Crohn's Disease, Fistulizing One of the following diagnosis-based clinical criteria for an FDA-approved-indication has been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria
Selarsdi CC, QL ustekinumab-aekn CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria • All indications require 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ALL preferred ustekinumab biosimilar products (Pyzchiva and Yesintek) in addition to 1 other preferred agent. • For brand Selarsdi: patient must also have trial and failure (e.g., allergy or intolerance to an inactive ingredient) with at least 2 generic manufacturers of the biosimilar. **Quantity Limit:** 1 syringe/vial per 56 days
Sotyktu AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Simponi CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria

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Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limit: 1 pen/syringe per 28 days
Simponi Aria CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria **Quantity Limit:** 4 vials per 56 days
Skyrizi AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria
Starjemza CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria • All indications require 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ALL preferred ustekinumab biosimilar products (Pyzchiva and Yesintek) in addition to 1 other preferred agent.
Stelara CC, QL ustekinumab CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Crohn's Disease (CD) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria • All indications require a 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ALL preferred ustekinumab biosimilar products (Pyzchiva and Yesintek) in addition to 1 other preferred agent. ○ Patients 2-17 years of age with CD may bypass trial of preferred ustekinumab biosimilar products, and instead must have a 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ONE of the following:

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	▪ One additional preferred agent; **OR** ▪ One of the following conventional therapies: • Oral/rectal 5-ASA (e.g., balsalazide, mesalamine, sulfasalazine) • Oral/rectal corticosteroids (e.g., budesonide, hydrocortisone, prednisone) • Immunosuppresants (e.g., azathioprine, mercaptopurine). • For brand Stelara: patient must also have trial and failure (e.g., allergy or intolerance to an inactive ingredient) with at least 2 generic manufacturers of the generic biosimilar.
Steqeyma CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria • All indications require 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ALL preferred ustekinumab biosimilar products (Pyzchiva and Yesintek) in addition to 1 other preferred agent. **Quantity Limit:** 1 syringe per 56 days
tofacitinib IR tablet CC, QL	**Approval Duration:** 6 months initial; 1 year renewal • Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation [Documentation required]; **AND** One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Quantity Limit:** 2 per day
tofacitinib IR solution CC, QL	**Approval Duration:** 6 months initial; 1 year renewal • Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation [Documentation required]; **AND** One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria

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Agent(s) Subject to Criteria	Criteria for Approval
	• Psoriatic Arthritis (PsA) Clinical Criteria **Quantity Limit:** 10 mL per day
Tremfya AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Age Limit:** ≥ 18 years **Quantity Limit:** • 100mg: 1 pen/syringe per 56 days • 200mg: 1 pen/syringe per 28 days
ustekinumab-ttwe CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria • All indications require 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ALL preferred ustekinumab biosimilar products (Pyzchiva and Yesintek) in addition to 1 other preferred agent. **Quantity Limit:** 1 syringe per 56 days

Velsipity AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Diagnosis of moderate to severe ulcerative colitis (UC); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist or other specialist in the treatment of UC; **AND**
	• Patient has had a trial and failure of ≥ 1 of the following conventional therapies:
	  ○ Oral/rectal 5-aminosalicylic acid agents (e.g., balsalazide, Lialda, mesalamine, sulfasalazine)
	  ○ Oral/rectal steroids (e.g., budesonide, hydrocortisone, prednisone)
	  ○ Immunosuppressant (e.g., azathioprine, mercaptopurine); **OR**
	• Patient is deemed high-risk for intestinal complications or post-operative recurrence; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient has had a 3-month trial and failure of, or contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of UC; **AND**
	• Patient meets the minimum age recommended by the package insert for use in UC.

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Agent(s) Subject to Criteria	Criteria for Approval
	Renewal Criteria: • Documentation (e.g., progress notes) of response to therapy compared to baseline. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Xeljanz XR CC, QL tofacitinib ER CC, QL	**Approval Duration:** 6 months initial; 1 year renewal One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Quantity Limit:** 1 per day

Zymfentra CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	• Diagnosis of moderate to severe Crohn's disease (CD) or ulcerative colitis (UC); **AND**
	• Patient has undergone induction therapy with intravenous infliximab; **AND**
	• Prescribed by, or in consultation with, a gastroenterologist or other specialist in the treatment of CD or UC; **AND**
	• Patient has had a trial and failure of ≥ 1 of the following conventional therapies:
	  ○ Oral/rectal 5-aminosalicylic acid agents (e.g., Apriso, balsalazide, Lialda, mesalamine, sulfasalazine)
	  ○ Oral/rectal steroids (e.g., budesonide, hydrocortisone, prednisone)
	  ○ Immunosuppressant (e.g., azathioprine, mercaptopurine); **OR**
	• Patient is deemed high-risk for intestinal complications or post-operative recurrence; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient has had a 3-month trial and failure of, or contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of CD or UC; **AND**
	• Patient meets the minimum age recommended by the package insert for use in CD or UC.
	
	Renewal Criteria:
	• Documentation (e.g., progress notes) of response to therapy compared to baseline.
	
	Quantity Limit: 2 pens/syringes per month

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
adalimumab-aaty CC, QL	Abrilada CC, QL

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Preferred Agents	Non-Preferred Agents
adalimumab-fkjp 40 mg CC, QL	Actemra CC, QL
Enbrel CC, QL	adalimumab-aacf CC, QL
Hadlima CC, QL	adalimumab-adaz CC, QL
Humira CC, QL	adalimumab-adbm CC, QL
Otezla CC, QL	adalimumab-fjkp 20 mg CC, QL
Otezla XR CC, QL	adalimumab-ryvk CC, QL
Pyzchiva CC, QL	Amjevita CC, QL
Rinvoq AE, CC, QL	Avsola vial CC
Rinvoq LQ AE, CC, QL	Bimzelx AE, CC, QL
Taltz CC, QL	Cibinqo CC, QL
Tyenne CC, QL	Cimzia CC, QL
Xeljanz IR CC, QL	Cosentyx CC, QL
Yesintek CC, QL	Cyltezo CC, QL
Yuflyma CC, QL	Enspryng AE, CC, QL
	Entyvio pen CC, QL
	Entyvio vial CC
	Hulio CC, QL
	Hyrimoz CC, QL
	Icotyde AE, CC, QL
	Idacio CC, QL
	Ilaris CC, QL
	Ilumya AE, CC, QL
	Imuldosa CC, QL
	Inflectra vial CC
	Infliximab vial CC
	Kevzara AE, CC, QL
	Kineret CC, QL
	Olumiant AE, CC, QL
	Omvoh AE, CC, QL
	Orencia CC, QL
	Otulfi CC, QL
	Remicade vial CC
	Renflexis vial CC
	Selarsdi CC, QL
	Simlandi CC, QL
	Simponi CC, QL
	Simponi Aria AE, CC, QL
	Skyrizi AE, CC, QL
	Sotyktu AE, CC, QL
	Starjemza CC, QL
	Stelara CC, QL
	Steqeyma CC, QL
	tofacitinib ER CC, QL
	tofacitinib IR CC, QL
	Tremfya AE, CC, QL
	ustekinumab CC, QL
	ustekinumab-aekn CC, QL
	ustekinumab-ttwe CC, QL
	Velsipity AE, CC, QL
	Xeljanz XR CC, QL
	Yusimry CC, QL
	Zymfentra CC, QL

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Fasenra AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	Asthma:
	• Diagnosis of eosinophilic asthma; **AND**
	• Patient's asthma is classified as severe, as defined by one of the following:
	  ○ Uncontrolled symptoms while on dose optimized high dose ICS-LABA therapy; **OR**
	  ○ Loss of symptom control when high dose ICS-LABA therapy is decreased; **OR**
	  ○ Use of oral steroids ≥ 2 times in the past year; **AND**
	• Fasenra will be used as adjunct therapy with inhaled maintenance asthma therapy; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, pulmonologist, or other applicable specialist in the diagnosis and treatment of eosinophilic asthma; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (Asthma):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure such as (but not limited to):
	  ○ Improved or maintained FEV_1
	  ○ Reduced number of asthma exacerbations
	  ○ Reduced number of missed days of school/work; **AND**
	• Fasenra will be used as adjunct therapy with inhaled maintenance asthma therapy.
	
	Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss):
	• Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) also known as Churg-Strauss; **AND**
	• Patient has had a ≥ 90 days of treatment with one of the following agents:
	  ○ Systemic glucocorticoids
	  ○ Azathioprine
	  ○ Methotrexate
	  ○ Cyclophosphamide
	  ○ Mycophenolate; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of eosinophilic granulomatosis with polyangiitis; **AND**

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to Criteria	Criteria for Approval

	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (EGPA):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure.
	
	Hypereosinophilic Syndrome (HES):
	• Diagnosis of hypereosinophilic syndrome (HES) without an identifiable non-hematologic secondary cause; **AND**
	• Patient is FIP1L1-PDGFRA kinase-negative; **AND**
	• Blood eosinophil count ≥ 1,000 cells/μL at the time of evaluation; **AND**
	• Signs or symptoms of HES flare, or at least 2 HES flares within the past 12 months; **AND**
	• Patient has been on stable HES therapy (which could include oral corticosteroids, immunosuppressive/cytotoxic therapy) for at least 4 weeks; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, hematologist, or other applicable specialist in the diagnosis and treatment of hypereosinophilic syndrome; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (HES):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure such as (but not limited to):
	  ○ Reduction in HES flare frequency,
	  ○ Reduction in oral corticosteroid use related to HES flares,
	  ○ Reduction in blood eosinophil count,
	  ○ Improvement in HES-related symptoms.
	
	Quantity Limit:
	Asthma: 1 pen/syringe per 56 days
	EGPA: 1 pen/syringe per 28 days
	HES: 1 pen/syringe per 28 days

Nucala AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	Asthma:
	• Diagnosis of eosinophilic asthma; **AND**
	• Patient's asthma is classified as severe, as defined by one of the following:
	  ○ Uncontrolled symptoms while on dose optimized ICS-LABA therapy; **OR**
	  ○ Loss of symptom control when high dose ICS-LABA therapy is decreased; **OR**
	  ○ Use of oral steroids ≥ 2 times in the past year; **AND**
	• Nucala will be used as adjunct therapy with inhaled maintenance asthma therapy; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Prescribed by, or in consultation with, an allergist, immunologist, pulmonologist, or other applicable specialist in the diagnosis and treatment of eosinophilic asthma; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (Asthma):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure such as (but not limited to):
	  ○ Improved or maintained FEV_1
	  ○ Reduced number of asthma exacerbations
	  ○ Reduced number of missed days of school/work; **AND**
	• Nucala will be used as adjunct therapy with inhaled asthma therapy.
	
	Chronic Obstructive Pulmonary Disease (COPD):
	• Diagnosis of chronic obstructive pulmonary disease (COPD) with eosinophilic phenotype; **AND**
	• At least 2 moderate exacerbations or 1 severe exacerbation in the past 12 months despite receiving triple therapy consistent of ALL of the following:
	  ○ 1 long-acting muscarinic antagonist (LAMA) (e.g. Spiriva Handihaler); **AND**
	  ○ 1 long-acting beta agonist (LABA) (e.g. Serevent); **AND**
	  ○ 1 inhaled corticosteroid (ICS) (e.g. budesonide, fluticasone propionate); **OR**
	• Clinical documentation indicated that the patient has a contraindication or intolerance to drugs in ONE of the following classes:
	  ○ 1 long-acting muscarinic antagonist (LAMA) (e.g. Spiriva Handihaler);
	  ○ 1 long-acting beta agonist (LABA) (e.g. Serevent);
	  ○ 1 inhaled corticosteroid (ICS) (e.g. budesonide, fluticasone propionate); **AND**
	• Medication will be used as an add-on maintenance therapy; **AND**
	• Prescribed by, or in consultation with, a pulmonologist or other specialist in the treatment of COPD; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	
	Renewal Criteria (COPD):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure such as (but not limited to):
	  ○ Improvement from baseline in FEV_1; **OR**
	  ○ Reduced use of systemic corticosteroids; **OR**
	  ○ Reduced use of antibiotics; **OR**
	  ○ Reduced number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition.
	
	Chronic Rhinosinusitis with Nasal Polyps*:*
	• Diagnosis of chronic rhinosinusitis with nasal polyps; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Trial and failure ≥ 1 intranasal corticosteroid, unless intolerant or otherwise ineligible; **AND**
	• Nucala will be used as adjunct therapy with an intranasal corticosteroid for maintenance, unless intolerant or otherwise ineligible asthma therapy; **AND**
	• Prescribed by, or in consultation with, an allergist; immunologist; ear, nose, and throat (ENT), or other applicable specialist in the diagnosis and treatment of chronic rhinosinusitis with nasal polyps; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (Rhinosinusitis with Nasal Polyps):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure.
	
	Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss):
	• Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) also known as Churg-Strauss; **AND**
	• Patient has had a ≥ 90 days of treatment with ONE of the following agents:
	  ○ Systemic glucocorticoids
	  ○ Azathioprine
	  ○ Methotrexate
	  ○ Cyclophosphamide
	  ○ Mycophenolate; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of eosinophilic granulomatosis with polyangiitis; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (EGPA):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure.
	
	Hypereosinophilic Syndrome (HES):
	• Diagnosis of hypereosinophilic syndrome (HES) ; **AND**
	• Symptoms have been present for > 6 months; **AND**
	• Provider attests that other underlying causes have been ruled out; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of hypereosinophilic syndrome; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (HES):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure.

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Agent(s) Subject to Criteria	Criteria for Approval

Xolair AE, CC, QL,	**Approval Duration:** 6 months initial; 1 year renewal
	
	Asthma:
	• Diagnosis of moderate to severe persistent asthma; **AND**
	• Patient has had one of the following:
	  ○ Positive skin test to a perennial aeroallergen; **OR**
	  ○ Positive in vitro reactivity to a perennial aeroallergen; **AND**
	• Patient has experienced inadequate symptom control with inhaled corticosteroids; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, pulmonologist, or other specialist in the treatment of asthma; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (Asthma):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure such as (but not limited to):
	  ○ Improved or maintained FEV_1
	  ○ Reduced number of asthma exacerbations
	  ○ Reduced number of missed days of school/work.
	
	Chronic Rhinosinusitis with Nasal Polyps:
	• Diagnosis of chronic rhinosinusitis with nasal polyps; **AND**
	• Inadequate symptom control with use of ≥ 1 intranasal corticosteroid, unless intolerant or otherwise ineligible; **AND**
	• Prescribed by, or in consultation with, an allergist; immunologist; ear, nose, and throat (ENT), or other applicable specialist in the diagnosis and treatment of chronic rhinosinusitis with nasal polyps; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (Rhinosinusitis with Nasal Polyps):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure.
	
	Chronic Idiopathic Urticaria:
	• Diagnosis of chronic idiopathic urticaria; **AND**
	• Patient has had a ≥ 14 day trial and failure of therapy with an H1-receptor antagonist; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of chronic idiopathic urticaria; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria (Chronic Idiopathic Urticaria):

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Agent(s) Subject to Criteria	Criteria for Approval
	• Patient has experienced disease improvement and/or stabilization based on an objective measure. **IgE-Mediated Food Allergy:** • Diagnosis of IgE-mediated food allergy; **AND** • Patient will avoid further contact with food allergen; **AND** • Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of IgE-mediated food allergy; **AND** • NOT used in combination with any other biologic agent; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA approved indication. **Renewal Criteria (IgE-Mediated Food Allergy):** • Patient has experienced disease improvement and/or stabilization based on an objective measure.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 90-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Omlyclo AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal
	
	Asthma:
	• Diagnosis of moderate to severe persistent asthma; **AND**
	• Patient has had one of the following:
	  ○ Positive skin test to a perennial aeroallergen; **OR**
	  ○ Positive in vitro reactivity to a perennial aeroallergen; **AND**
	• Patient has experienced inadequate symptom control with inhaled corticosteroids; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, pulmonologist, or other specialist in the treatment of asthma; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Xolair.
	
	Renewal Criteria (Asthma):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure such as (but not limited to):
	  ○ Improved or maintained FEV_1
	  ○ Reduced number of asthma exacerbations
	  ○ Reduced number of missed days of school/work.
	
	Chronic Rhinosinusitis with Nasal Polyps:
	• Diagnosis of chronic rhinosinusitis with nasal polyps; **AND**
	• Inadequate symptom control with use of ≥ 1 intranasal corticosteroid, unless intolerant or otherwise ineligible; **AND**
	• Prescribed by, or in consultation with, an allergist; immunologist; ear, nose, and throat (ENT), or other applicable specialist in the diagnosis and treatment of chronic rhinosinusitis with nasal polyps; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication; **AND**
	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Xolair.
	
	Renewal Criteria (Rhinosinusitis with Nasal Polyps):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure.
	
	Chronic Idiopathic Urticaria:
	• Diagnosis of chronic idiopathic urticaria; **AND**
	• Patient has had a ≥ 14 day trial and failure of therapy with an H1-receptor antagonist; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of chronic idiopathic urticaria; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication; **AND**
	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Xolair.
	
	Renewal Criteria (Chronic Idiopathic Urticaria):
	• Patient has experienced disease improvement and/or stabilization based on an objective measure.
	
	IgE-Mediated Food Allergy:
	• Diagnosis of IgE-mediated food allergy; **AND**
	• Patient will avoid further contact with food allergen; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of IgE-mediated food allergy; **AND** • NOT used in combination with any other biologic agent; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA approved indication; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Xolair. **Renewal Criteria (IgE-Mediated Food Allergy):** • Patient has experienced disease improvement and/or stabilization based on an objective measure.

Tezspire AE, CC, QL	• Patient must have diagnosis chronic rhinosinusitis with nasal polyps (CRSwNP); **OR**
	• Patient must have a diagnosis of severe asthma; **AND**
	• Must be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
	  ○ Medium-to-high dose inhaled corticosteroids; **AND**
	  ○ An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers); **AND**
	• Patient must have had, in the previous year, at least 2 exacerbations requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) OR one exacerbation resulting in a hospitalization; **AND**
	• Baseline measurement of ≥ 1 of the following for assessment of clinical status:
	  ○ Use of systemic corticosteroids; **OR**
	  ○ Use of inhaled corticosteroids; **OR**
	  ○ Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition; **OR**
	  ○ FEV_1; **AND**
	• Must not be used in combination with anti-IgE, anti-IL4, or anti-IL5 monoclonal antibody agents (e.g., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab); **AND**
	• Patient does not have an active or untreated helminth infection; **AND**
	• Will not be administered concurrently with live vaccines; **AND**
	• Patient has had a trial and failure, contraindication, or intolerance to at least 1 preferred agent.
	
	Renewal Criteria:
	• Improvement in chronic rhinosinusitis with nasal polyps (CRSwNP) symptoms and/or based on an objective measure; **OR**
	• Improvement in asthma symptoms, asthma exacerbations, or airway function as evidenced by decrease in ≥ 1 of the following:
	  ○ Use of systemic corticosteroids; **OR**
	  ○ Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days; **OR**
	  ○ Hospitalizations; **OR**
	  ○ ER visits; **OR**
	  ○ Unscheduled visits to healthcare provider; **OR**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Improvement from baseline in FEV_1 of ≥ 15%. **Age Limit:** ≥ 12 years **Quantity Limit:** 1 pen/syringe per 28 days

6. THERAPEUTIC DUPLICATION

Approval Duration: Date of Service Only

Patients are limited to one immunomodulator used to treat asthma at a time within the quantity/dosing limits. Therapeutic duplication can be approved for DOS if patients are switching from one agent to another.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Fasenra AE, CC, QL	Omlyclo AE, CC, QL
Nucala AE, CC, QL	Tezspire AE, CC, QL
Xolair AE, CC, QL	

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Emflaza tablet AE, CC, QL
Emflaza suspension AE, CC
	• Diagnosis of Duchenne muscular dystrophy (DMD); **AND**
	• Patient is currently receiving, or planning to receive, physical therapy; **AND**
	• Patient has experienced 1 of the following adverse reactions directly attributable to previous therapy with prednisone:
	  ○ Significant behavioral changes negatively impacting function at school, home, day care, etc.; **OR**
	  ○ Significant weight gain (e.g., crossing 2 percentiles and/or reaching 98th percentile for age and sex).
	
	Renewal Criteria:
	• Patient continues to receive physical therapy; **AND**
	• Patient has received benefit from therapy, which may include 1 or more of the following supported by documentation (e.g., progress notes):
	  ○ Stability, improvement or slowing of decline in motor function;
	  ○ Stability, improvement or slowing of decline in respiratory function;
	  ○ Stability, improvement or slowing of decline in sequelae related to diminished strength of stabilizing musculature (e.g., scoliosis, etc.);
	  ○ Stability, improvement or slowing of decline in quality of life.
	
	Age Limit: ≥ 2 years
	Quantity Limits: 2 tablets per day

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 90-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Agamree AE, CC, QL	• Diagnosis of Duchenne Muscular Dystrophy (DMD); **AND**
	• Patient is currently receiving, or planning to receive, physical therapy; **AND**
	• Patient has had a trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to at least 1 preferred agent; **AND**
	• Patient has tried prednisone or prednisolone for at least 6 months; **OR**
	• Patient has experienced 1 of the following adverse reactions directly attributable to previous therapy with prednisone or prednisolone:
	  ○ Significant behavioral changes negatively impacting function at school, home, day care, etc.; **OR**
	  ○ Significant weight gain (e.g., crossing 2 percentiles and/or reaching 98th percentile for age and sex); **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Renewal Criteria:
	• Patient continues to receive physical therapy; **AND**
	• Patient has received benefit from therapy (i.e. stability, improvement or slowing of decline) in one or more of the following areas of assessment:
	  ○ Motor function (North Star Ambulatory Assessment (NSAA)
	  ○ Cardiology
	  ○ Endocrinology
	  ○ Orthopedics (e.g., scoliosis)
	  ○ Pulmonary function.
	
	Age Limit: ≥ 2 years
	Quantity Limit: 7.5 mL per day

deflazacort tablet AE, CC, QL deflazacort suspension AE, CC	• Diagnosis of Duchenne muscular dystrophy (DMD); **AND** • Patient is currently receiving, or planning to receive, physical therapy; **AND** • Patient has experienced 1 of the following adverse reactions

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to Criteria	Criteria for Approval
	directly attributable to previous therapy with prednisone: ○ Significant behavioral changes negatively impacting function at school, home, day care, etc.; **OR** ○ Significant weight gain (e.g., crossing 2 percentiles and/or reaching 98th percentile for age and sex); **AND** • Patient has a known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. **Renewal Criteria:** • Patient continues to receive physical therapy; **AND** • Patient has received benefit from therapy, which may include 1 or more of the following supported by documentation (e.g., progress notes): ○ Stability, improvement or slowing of decline in motor function; ○ Stability, improvement or slowing of decline in respiratory function; ○ Stability, improvement or slowing of decline in sequelae related to diminished strength of stabilizing musculature (e.g., scoliosis, etc.); ○ Stability, improvement or slowing of decline in quality of life. **Age Limit:** ≥ 2 years **Quantity Limit:** 2 per day
Duvyzat AE, CC, QL	**Approval Duration:** 6 months initial; 1 year renewal • Diagnosis of Duchenne muscular dystrophy (DMD) [G71.01]; **AND** • Platelet count within the last 30 days equals to or is greater than 150 x 10^9/L; **AND** • Prescribed by, or in consultation with, a neuromuscular specialist with expertise in the treatment of DMD; **AND** • Patient is ambulatory (e.g., ability to walk with or without assistive devices, not wheelchair dependent); **AND** • Patient's baseline ambulatory function has been or will be assessed prior to therapy initiation; **AND** • Patient has been on a stable systemic corticosteroid therapy for at least 6 months and will continue to be on the systemic corticosteroid therapy unless contraindicated or clinically significant adverse effects are experienced; **AND** • Prescriber provides a patient weight obtained within the past 3 months; **AND** • The requested dose meets the FDA-approved dosing recommendation; **AND** • Patient has not received treatment with gene therapy (e.g., Elevidys) or use concurrently with exon skipping therapy (e.g., Exondys, Amondys).

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Agent(s) Subject to Criteria	Criteria for Approval
	Renewal Criteria: • Documentation (e.g., progress note) of stabilized or improved ambulatory function from baseline; **AND** • Patient will continue systemic corticosteroid therapy unless contraindicated or clinically significant adverse effects are experienced; **AND** • Prescriber provides a patient weight obtained within the past 3 months; **AND** • The requested dose meets the FDA-approved dosing recommendation; **AND** • Patient has not received treatment with gene therapy (e.g., Elevidys) or use concurrently with exon skipping therapy (e.g., Exondys, Amondys). **Age Limit:** ≥ 6 years **Quantity Limit:** 12 mL per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Emflaza suspension AE, CC	Agamree suspension AE, CC, QL
Emflaza tablet AE, CC, QL	deflazacort suspension AE, CC
	deflazacort tablet AE, CC, QL
	Duvyzat AE, CC, QL

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IMMUNOMODULATORS, ATOPIC DERMATITIS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Adbry syringe AE, CC, QL Adbry autoinjector AE, CC, QL	• Diagnosis of moderate to severe atopic dermatitis with at least 1 of the following: ○ Involvement of at least 10% of body surface area (BSA); **OR** ○ Eczema Area and Severity Index (EASI) score of 16 or greater; **OR** ○ Investigator's Global Assessment (IGA) score of 3 or more; **OR** ○ Scoring Atopic Dermatitis (SCORAD) score of 25 or more; **OR** ○ Incapacitation due to AD lesion location (i.e., head and neck, palms, soles, or genitalia); **AND** • Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND** • Patient has had a trial and failure, contraindication, or intolerance to at least 1 agent from ≥ 2 of the following classes: ○ Prescription strength topical corticosteroids (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **OR** ○ Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus); **OR** ○ Topical phosphodiesterase-4 inhibitor (e.g., crisaborole); **OR** ○ Topical Janus kinase inhibitor (e.g., ruxolitinib); **OR** ○ Immunomodulating systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, dupilumab). **Renewal Criteria:** • Patient must have disease improvement and/or stabilization from baseline. **Age Limit:** • Adbry autoinjector: ≥ 18 years • Adbry syringe: ≥ 12 years **Quantity Limit:** • Adbry autoinjector: 2 injectors per 28 days • Adbry syringe: 4 syringes per 28 days (300 mg every other week)
Dupixent CC, QL	**Atopic Dermatitis:** • Diagnosis of moderate-to-severe atopic dermatitis (AD) with ≥ 1 of the following: ○ Involvement of at least 10% of body surface area (BSA); **OR** ○ Scoring Atopic Dermatitis (SCORAD) score of 25 or more; **OR** ○ Investigator's Global Assessment (IGA) with a score ≥ 3; **OR** ○ Eczema Area and Severity Index (EASI) score of ≥ 16; **OR**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); **AND** • Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND** • Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days): ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **AND** ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **OR** ○ Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.) • Patient must meet the minimum age recommended by the package insert for this FDA approved indication. **Asthma:** • Diagnosis of moderate-to-severe asthma; **AND** • Eosinophilic phenotype; **OR** • Use of oral steroids ≥ 2 times in the past year; **AND** • Prescribed by, or in consultation with, an allergist, immunologist, pulmonologist or other specialist in the treatment of asthma; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Bullous Pemphigoid:** • Diagnosis of bullous pemphigoid (BP); **AND** • Bullous Pemphigoid Disease Area Index (BPDAI) activity score of ≥ 20 at baseline; **AND** • Trial and failure, contraindication, or intolerance to ≥ 1 agent in any of the following categories: ○ Systemic corticosteroids (e.g. prednisone); • Immunosuppressive agents (e.g., azathioprine, methotrexate, mycophenolate mofetil); • Other BP-directed therapies (e.g., dapsone, doxycycline); **AND** • Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of bullous pemphigoid; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Chronic Obstructive Pulmonary Disease (COPD):** • Diagnosis of chronic obstructive pulmonary disease (COPD) with eosinophilic phenotype; **AND** • At least 2 moderate exacerbations or 1 severe exacerbation in the past 12 months despite receiving maintenance triple therapy consistent of all of the following: ○ 1 long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Handihaler); **AND** ○ 1 long-acting beta agonist (LABA) (e.g., Serevent); **AND** ○ 1 inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone propionate); **OR**

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Agent(s) Subject to Criteria	Criteria for Approval

	• Clinical documentation indicated that the patient has a contraindication or intolerance to drugs in one of the following classes:
	  ○ 1 long-acting muscarinic antagonist (LAMA) (e.g., Spiriva Handihaler); **AND**
	  ○ 1 long-acting beta agonist (LABA) (e.g., Serevent); **AND**
	  ○ 1 inhaled corticosteroid (ICS) (e.g., budesonide, fluticasone propionate); **AND**
	• Symptoms of chronic productive cough for at least 3 months in the past 12 months; **AND**
	• Medication will be used as an add-on maintenance therapy; **AND**
	• Prescribed by, or in consultation with, a pulmonologist or other specialist in the treatment of COPD; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	
	Chronic Rhinosinusitis with Nasal Polyposis:
	• Diagnosis of chronic rhinosinusitis **with** nasal polyposis; **AND**
	• Prescribed by or in consultation with an allergist; immunologist; ear, nose, and throat (ENT), or other applicable specialist; **AND**
	• Trial and failure (and continued use of) ≥ 1 intranasal corticosteroid, unless intolerant or otherwise ineligible; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	
	Chronic Spontaneous Urticaria:
	• Diagnosis of chronic spontaneous urticaria (CSU); **AND**
	• Trial and failure of (≥ 14-day treatment course), contraindication, or intolerance to histamine-1 antihistamine (e.g. diphenhydramine, hydroxyzine); **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of chronic spontaneous urticaria; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	
	Eosinophilic Esophagitis:
	• Diagnosis of eosinophilic esophagitis; **AND**
	• Prescribed by, or in consultation with, an allergist, immunologist, gastroenterologist, or other specialist in the treatment of eosinophilic esophagitis; **AND**
	• Patient has tried and failed at least 8 weeks of treatment with a topical glucocorticoid; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	
	Prurigo Nodularis:
	• Diagnosis of prurigo nodularis; **AND**
	• Patient has severe pruritus based on an objective measure; **AND**
	• At least 20 nodular lesions; **AND**
	• Other causes of pruritus have been ruled out; **AND**
	• Trial and failure, contraindication, or intolerance to one of the following:

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Moderate to super potent topical corticosteroids [e.g., betamethasone dipropionate, (augmented), fluocinonide 0.1%, flurandrenolide, betamethasone dipropionate 0.05%, clobetasol propionate 0.025%, or desoximetasone 0.05%] for a minimum of 2 weeks; **OR** ○ Narrowband ultraviolet B (NBUVB) phototherapy or psoralen plus ultraviolet A (PUVA) phototherapy; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Allergic Fungal Rhinosinusitis:** • Diagnosis of allergic fungal rhinosinusitis (AFRS) confirmed by an objective measure (e.g., immunological testing, CT scan, endoscopic examination, surgical specimen analysis, fungal culture); **AND** • Documented history of sinus surgery; **AND** • Trial and failure, contraindication, or intolerance to ≥ 1 agent in any of the following categories: ○ Intranasal corticosteroids (e.g., fluticasone propionate spray); ○ Systemic corticosteroids (e.g., prednisone); **AND** • Prescribed by or in consultation with an allergist; immunologist; ear, nose, and throat (ENT), or other applicable specialist; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Renewal Criteria (all indications):** • Patient must have disease improvement and/or stabilization based on an objective measure
Ebglyss [AE, CC, QL]	• Diagnosis of moderate-to-severe atopic dermatitis (AD) with ≥ 1 of the following: ○ Involvement of at least 10% of body surface area (BSA); **OR** ○ Scoring Atopic Dermatitis (SCORAD) score of 25 or more; **OR** ○ Investigator's Global Assessment (IGA) with a score ≥ 3; **OR** ○ Eczema Area and Severity Index (EASI) score of ≥ 16; **OR** ○ Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); **AND** • Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND** • Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days): ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **AND** ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **OR** ○ Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil); **AND** • Patient must meet the minimum age and weight recommended by the package insert for the provided indication. **Renewal Criteria:**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Patient must have disease improvement and/or stabilization based on an objective measure. **Age Limit:** ≥ 12 years **Quantity Limit:** 1 pen/syringe per 28 days

Eucrisa AE, CC, QL	• Diagnosis of atopic dermatitis; **AND**
	• Trial and failure of ≥ 1 agent from either of the following classes, unless trial is not appropriate:
	  ○ Topical immunomodulator unless < 2 years of age; **OR**
	  ○ Topical steroid (e.g., triamcinolone, etc.) unless inappropriate for the affected area (e.g., face, groin).
	
	Age Limit: ≥ 3 months
	Quantity Limit: 300 grams per 365 days

Nemluvio AE, CC, QL	**Atopic Dermatitis:**
	• Diagnosis of moderate-to-severe atopic dermatitis (AD) with ≥ 1 of the following:
	  ○ Involvement of at least 10% of body surface area (BSA); **OR**
	  ○ Investigator's Global Assessment (IGA) with a score ≥ 3; **OR**
	  ○ Eczema Area and Severity Index (EASI) score of ≥ 16; **OR**
	  ○ Peak Pruritis Numeric Rating Scale (PP-NRS) score ≥ 4; **OR**
	  ○ Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); **AND**
	• Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND**
	• Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days):
	  ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **AND**
	  ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **OR**
	  ○ Immunosuppressive systemic agents (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.); **AND**
	• Nemluvio will be taken with topical corticosteroids and/or calcineurin inhibitors (e.g., pimecrolimus, tacrolimus); **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA approved indication.
	
	Prurigo Nodularis:
	• Diagnosis of prurigo nodularis; **AND**
	• At least 20 nodular lesions; **AND**
	• Other causes of pruritis have been ruled out; **AND**
	• Trial and failure, contraindication, or intolerance to one of the following:
	  ○ Moderate to super potent topical corticosteroids [e.g., betamethasone dipropionate, (augmented), fluocinonide 0.1%, flurandrenolide, betamethasone dipropionate 0.05%,

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Agent(s) Subject to Criteria	Criteria for Approval
	clobetasol propionate 0.025%, or dexamethasone 0.05%] for a minimum of 2 weeks; ○ Narrowband ultraviolet B (NBUVB) phototherapy or psoralen plus ultraviolet A (PUVA) phototherapy; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Renewal Criteria (all indications):** • Patient must have disease improvement and/or stabilization based on an objective measure. **Quantity Limit:** 2 pens per 28 days

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Anzupgo AE, CC, QL	• Diagnosis of moderate to severe chronic hand eczema (CHE); **AND** • Documentation of Investigator's Global Assessment for Chronic Hand Eczema (IGACHE) with a score ≥ 3; **AND** • Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of chronic hand eczema; **AND** • Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days): ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone); ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); ○ Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil); **AND** • No concurrent use of other biologics or JAK inhibitors or immunosuppressants; **AND** • Patient must meet the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Patient must have disease improvement and/or stabilization based on an objective measure.

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Agent(s) Subject to Criteria	Criteria for Approval
	Age Limit: ≥ 18 years **Quantity Limit**: 30 grams per month

Opzelura AE, CC, QL	**Approval Duration:** 1 year (initial and renewal)
	
	• Patient is not immunocompromised; **AND**
	• Diagnosis of mild to moderate atopic dermatitis; **AND**
	• Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 1 of the following classes:
	  ○ Prescription topical corticosteroids
	  ○ Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus)
	  ○ Topical phosphodiesterase-4 inhibitor (e.g., crisaborole);
	OR
	• Patient has a diagnosis of nonsegmental vitiligo; **AND**
	• Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to mid- to high-potency topical corticosteroids or topical calcineurin inhibitors.
	
	Renewal Criteria (all indications):
	• Patient must continue to meet the above criteria; **AND**
	• Patient must have disease improvement and/or stabilization.
	
	Age Limit:
	• ≥ 2 years for atopic dermatitis
	• ≥ 12 years for nonsegmental vitiligo
	Quantity Limit: 240 grams per year

Vtama AE, CC, QL	**Plaque Psoriasis:** • Diagnosis of plaque psoriasis; **AND** • Prescribed by or in consultation with a dermatologist or other disease state specialist; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to two preferred agents in the Dermatologics: Topical Antipsoriatics drug class. **Atopic Dermatitis:** • Diagnosis of atopic dermatitis; **AND** • Prescribed by or in consultation with a dermatologist or other disease state specialist; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to two preferred agents in the Immunomodulators, Atopic Dermatitis drug class. **Age Limit:** ≥ 2 years **Quantity Limit:** 2 grams per day
Zoryve 0.15% cream AE, CC, QL	**Atopic Dermatitis:** • Diagnosis of mild to moderate atopic dermatitis; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ONE preferred agent; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Age Limit:** ≥ 6 years **Quantity Limit:** 2 grams per day
Zoryve 0.05% cream AE, CC, QL	**Atopic Dermatitis:** • Diagnosis of mild to moderate atopic dermatitis; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ONE preferred agent; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Age Limit:** 2 to 5 years **Quantity Limit:** 2 grams per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Adbry autoinjector AE, CC, QL	Anzupgo CC, QL
Adbry syringe AE, CC, QL	Opzelura AE, CC, QL
Dupixent pen CC, QL	Vtama AE, CC, QL
Dupixent syringe CC, QL	Zoryve 0.15% cream AE, CC, QL
Ebglyss AE, CC, QL	Zoryve 0.05% cream AE, CC, QL
Eucrisa CC, QL	
Nemluvio AE, CC, QL	
pimecrolimus cream	
tacrolimus ointment	

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BLOOD MODIFIERS: ANTIHYPERURICEMICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
colchicine tablet CC	• Diagnosis of one of the following conditions: ○ Familial Mediterranean Fever (FMF) (ICD-10 = E85.0); **OR** ○ Pericarditis; **OR** ○ Gout prophylaxis; **OR** ○ Gout (acute attack) WITH trial and failure of, or contraindication/intolerance to, at least 1 of the following: ▪ Non-steroidal anti-inflammatory drug (NSAID); **OR** ▪ Oral steroid.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 90-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Colcrys CC	• NPD Criteria above when used for gout prophylaxis; **OR** • Diagnosis of one of the following conditions: ○ Familial Mediterranean Fever (FMF) (ICD-10 = E85.0); **OR** ○ Pericarditis; **OR** ○ Gout (acute attack) WITH trial and failure of, or contraindication/intolerance to, at least 1 of the following: ▪ Non-steroidal anti-inflammatory drug (NSAID); **OR** ▪ Oral steroid.
colchicine capsule CC Gloperba CC Mitigare CC	• NPD Criteria above; **AND** • Used for prophylaxis of gout flares.
Uloric QL	• NPD Criteria above: ○ Therapeutic failure is defined as serum urate/uric acid level ≥ 6.0 mg/dL.

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CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
allopurinol tablet	colchicine capsule CC
colchicine tablet CC	Colcrys tablet CC
febuxostat tablet QL	Gloperba solution CC
probenecid tablet	Mitigare capsule CC
probenecid/colchicine tablet	Uloric tablet QL
	Zyloprim tablet

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BLOOD MODIFIERS: COLONY STIMULATING FACTORS (SHORT-ACTING)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Neupogen CC, QL Releuko CC, QL	Diagnosis of one of the following conditions: • Myelosuppressive chemotherapy; **OR** • Induction or consolidation chemotherapy in acute myeloid/myelogenous leukemia; **OR** • Bone marrow transplantation; **OR** • Bone marrow transplant failure or engraftment delay; **OR** • Peripheral blood progenitor cell collection and therapy; **OR** • Severe chronic neutropenia (ANC ≤ 500 mm_3); **OR** • Hematopoietic Subsyndrome of Acute Radiation Syndrome.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 7-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

Preferred with PA (PDP) Criteria must be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Neupogen CC, QL	Armlupeg QL
Releuko CC, QL	Granix QL
	Leukine QL
	Nivestym QL
	Zarxio QL

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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BLOOD MODIFIERS: COLONY STIMULATING FACTORS (LONG-ACTING)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Fulphila CC, QL Fylnetra CC, QL	Diagnosis of one of the following conditions: • Myelosuppressive chemotherapy; **OR** • Induction or consolidation chemotherapy in acute myeloid/myelogenous leukemia; **OR** • Bone marrow transplantation; **OR** • Bone marrow transplant failure or engraftment delay; **OR** • Peripheral blood progenitor cell collection and therapy; **OR** • Severe chronic neutropenia (ANC ≤ 500 mm_3); **OR** • Hematopoietic Subsyndrome of Acute Radiation Syndrome.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 7-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

Preferred with PA (PDP) Criteria must be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Neulasta CC, QL Neulasta Onpro CC, QL Nyvepria CC, QL Stimufend CC, QL Udenyca CC, QL Ziextenzo CC, QL	• PDP Criteria above; **AND** ○ NPD Criteria above; **OR** ○ Member is < 18 years old; **OR** ○ Prescriber is a pediatric oncologist.
Rolvedon AE, CC, QL Ryzneuta AE, CC. QL	• The medication is being used for chemotherapy-induced neutropenia prophylaxis, to decrease the incidence of febrile neutropenia; **AND** • Patient has a non-myeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia; **AND**

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to Criteria	Criteria for Approval
	• Patient has had at least a 7-day trial and therapeutic failure, allergy, contraindication, or intolerance of 2 preferred agents. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe per 14 days

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Fulphila CC, QL	Neulasta CC, QL
Fylnetra CC, QL	Neulasta Onpro CC, QL
	Nyvepria AE, CC,QL
	Rolvedon AE, CC, QL
	Ryzneuta AE, CC, QL
	Stimufend QL
	Udenyca CC, QL
	Ziextenzo CC, QL

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BLOOD MODIFIERS: ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE

Approval Duration: 3 months initial; 1 year renewal, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Aranesp CC	• Member is NOT receiving hemodialysis*; **AND**
	• Documentation (e.g., progress note, laboratory report) of hemoglobin (Hgb) < 10 g/dL in the past 90 days; **AND**
	• Prescribed for one of the following diagnoses:
	  ○ Anemia associated with chronic renal failure; **OR**
	  ○ Anemia associated with kidney transplantation; **OR**
	  ○ Treatment of chemotherapy-induced anemia for non-myeloid malignancies.
	
	Renewal Criteria:
	• Documentation (e.g., progress note, laboratory report) of response to therapy.

Retacrit CC
Epogen CC
	• Member is NOT receiving hemodialysis*; **AND**
	• Documentation (e.g., progress note, laboratory report) of hemoglobin (Hgb) < 10 g/dL in the past 90 days; **AND**
	• Prescribed for one of the following diagnoses:
	  ○ Anemia associated with chronic renal failure; **OR**
	  ○ Anemia associated with kidney transplantation; **OR**
	  ○ Treatment of chemotherapy-induced anemia for non-myeloid malignancies; **OR**
	  ○ Drug-induced anemia (e.g., Retrovir, Combivir or ribavirin); **OR**
	  ○ Autologous blood donations by patients scheduled to undergo nonvascular surgery.
	
	Renewal Criteria:
	• Documentation (e.g., progress note, laboratory report) of response to therapy.

Mircera CC	• Member is NOT receiving hemodialysis*; **AND** • Prescribed for anemia associated with chronic renal failure; **AND** • Documentation (e.g., progress note, laboratory report) of hemoglobin (Hgb) < 10 g/dL in the past 90 days. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of response to therapy.

*Providers should bill Medicare B if member is receiving hemodialysis.

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Jesduvroq CC, QL	**Approval Duration:** 6 months (initial and renewal) • Diagnosis of chronic kidney disease (N18.9); **AND** • Pretreatment hemoglobin level ≤ 11g/dl; **AND** • Patient has been receiving dialysis for at least 4 months; **AND** • Patient is not receiving treatment with any other erythropoiesis stimulating agents. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) demonstrating a positive response to therapy. **Quantity Limit:** • 1 mg, 2 mg, & 4 mg: one daily • 6 mg: two daily • 8 mg: three daily

Reblozyl AE, CC	• Prescribed by, or in consultation with, a hematology or oncology specialist; **AND**
	• Diagnosis of beta thalassemia requiring regular red blood cell (RBC) transfusions; **OR**
	• Diagnosis of anemia that is associated with low-to-moderate-risk myelodysplastic syndromes; **AND**
	  ○ Member has required 2 or more RBC units over an 8-week period; **AND**
	  ○ Serum erythropoietin (EPO) < 500 mU/mL; **OR**
	• Diagnosis of anemia that is associated with low-to-moderate-risk myelodysplastic syndromes with ring sideroblasts or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis; **AND**
	• Patient has required 2 or more RBC units over an 8-week period; **AND**
	  ○ Failure of an erythropoiesis stimulating agent (e.g., epoetin alfa); **OR**
	  ○ Serum erythropoietin (EPO) > 500 mU/mL.
	
	Renewal Criteria:
	• Attestation or documentation (e.g., progress note) of a reduction in transfusion burden or other clinical benefit.

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Agent(s) Subject to Criteria	Criteria for Approval
	Age Limit: ≥ 18 years
Vafseo CC, QL	**Approval Duration:** 6 months (initial and renewal) • Diagnosis of chronic kidney disease (N18.9); **AND** • Pretreatment hemoglobin level ≤ 11g/dl; **AND** • Patient has been receiving dialysis for at least 3 months; **AND** • Patient does not have uncontrolled hypertension; **AND** • Patient is not receiving treatment with any other erythropoiesis stimulating agents; **AND** • Patient meets the minimum age recommended by the package insert. **Renewal Criteria:** • Documentation (e.g., progress notes, laboratory report) of a positive response to therapy. **Quantity Limit:** • 150 mg: 4 per day • 300 mg: 2 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Aranesp CC	Jesduvroq CC, QL
Epogen CC	Procrit
Mircera CC	Reblozyl AE, CC
Retacrit CC	Vafseo CC, QL

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BLOOD MODIFIERS: PHOSPHATE BINDERS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 7-day** trial and failure within the past 90 days, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Xphozah AE, CC, QL	• Diagnosis of chronic kidney disease; **AND** • Diagnosis of elevated serum phosphorous; **AND** • Patient is on dialysis; **AND** • Patient has had a trial and failure, contraindication, intolerance, or inadequate response to at least 2 preferred phosphate binders. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
calcium acetate capsule, tablet	Auryxia
Phoslyra solution	ferric citrate tablet
sevelamer carbonate powder packet, tablet	Fosrenol chewable tablet, powder packet
sevelamer tablet	lanthanum carbonate chewable tablet
	Renagel
	Renvela powder packet, tablet
	Velphoro
	Xphozah AE, CC, QL

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BLOOD MODIFIERS: SICKLE CELL ANEMIA TREATMENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Endari AE, CC, QL	• Diagnosis of sickle cell disease; **AND** • Prescribed by or consultation with a hematologist or a provider that specializes in sickle cell disease; **AND** • Documentation that the member has had at least two vaso-occlusive crises within the past 12 months; **AND** • Patient has tried hydroxyurea for at least 3 months, unless contraindicated or intolerant. **Renewal Criteria:** • Patient must have disease improvement (decrease in the number of sickle cell crises). **Age Limit:** ≥ 5 years **Quantity Limit:** 6 packets (30 gm) per day

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-month** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

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Agent(s) Subject to Criteria	Criteria for Approval
L-glutamine (generic Endari) AE, CC, QL	• Diagnosis of sickle cell disease; **AND** • Prescribed by or consultation with a hematologist or a provider that specializes in sickle cell disease; **AND** • Documentation that the member has had at least two vaso-occlusive crises within the past 12 months; **AND** • Patient has tried hydroxyurea for at least 3 months, unless contraindicated or intolerant. **Renewal Criteria:** • Patient must have disease improvement (decrease in the number of sickle cell crises). **Age Limit:** ≥ 5 years **Quantity Limit:** 6 packets (30 gm) per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Droxia	L-glutamine (generic for Endari) AE, CC, QL
Endari AE, CC, QL	Xromi solution AE
Siklos	

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BLOOD MODIFIERS: THROMBOPOIESIS STIMULATING PROTEINS

GUIDELINES FOR USE

Approval Duration: 6 months, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Promacta tablet CC, QL	• Prescribed by, or in consultation with, a hematologist or liver disease specialist; **AND**
	• Diagnosis of one of the following conditions:
	  ○ Chronic immune (idiopathic) thrombocytopenic purpura (ITP); **OR**
	  ○ Treatment of thrombocytopenia in patients with chronic hepatitis C (to allow the initiation & maintenance of interferon-based therapy); **OR**
	  ○ Treatment of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy.
	
	Renewal Criteria:
	• Documentation (e.g., progress note, laboratory report) of response to therapy.
	
	Quantity Limit:
	• 12.5 mg, 25 mg: 3 per day
	• 50 mg, 75 mg: 2 per day

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure within the past 90 days, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Alvaiz AE, CC, QL	• Prescribed by, or in consultation with, a hematologist or liver disease specialist; **AND** • Patient has one of the following indications:

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Diagnosis of persistent or chronic immune thrombocytopenia (ITP) with an insufficient response to corticosteroids, immunoglobulins, or splenectomy; **OR** ○ Used for the treatment of thrombocytopenia in patients with chronic hepatitis C (to allow the initiation and maintenance of interferon-based therapy); **OR** ○ Diagnosis of severe aplastic anemia with an insufficient response to immunosuppressive therapy; **AND** • Patient meets the minimum age recommended by the package insert for respective indications. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of response to therapy. **Age Limit:** ≥ 6 years **Quantity Limit:** 9 mg, 18 mg: 1 per day 36 mg: 3 per day 54 mg: 2 per day
Doptelet AE, CC, QL	**Approval Duration:** Date of service (CLD); 6 months (ITP) **Thrombocytopenia in Chronic Liver Disease (CLD):** • Diagnosis of chronic liver disease; **AND** • Documentation of platelet count < 50 x 10^9/L within the past 14 days; **AND** • Prescribed per FDA-approved labeling (10 tablets per 5 days for platelets ≥ 40 x 10^9/L or 15 tablets per 5 days for platelets < 40 x 10^9/L); **AND** • Confirmation (e.g., attestation or progress note) of a scheduled invasive procedure occurring 5 to 8 days following the last dose of avatrombopag; **AND** • Patient must meet the minimum age recommended by the package insert for the FDA-approved indication. **Persistent or chronic immune (idiopathic) thrombocytopenic purpura (ITP):** • Diagnosis of chronic immune (idiopathic) thrombocytopenia; **AND** • Prescribed by, or in consultation with a hematologist or immunologist, or other specialist in the treatment of ITP; **AND** • Documentation (e.g., progress note, laboratory report) of platelet count within the past 30 days; **AND** • Trial and failure (i.e., not achieved a platelet count ≥ 50 x 10^9/L) of at least one other therapy for chronic ITP, such as corticosteroids, IV immune globulin, RhO(D) immune globulin, thrombopoietin receptor antagonists, etc.; **AND** • Patient must meet the minimum age recommended by the package insert for the FDA-approved indication. **Renewal Criteria (all indications):** • Documentation (e.g., progress note, laboratory report) of response to therapy.

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Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limit: 2 per day (except where 15 tablet per 5-day course is indicated)
Doptelet Sprinkle AE, CC, QL	• Diagnosis of persistent or chronic immune thrombocytopenic purpura (ITP); **AND** • Prescribed by, or in consultation with a hematologist or immunologist, or other specialist in the treatment of ITP; **AND** • Documentation (e.g., progress note, laboratory report) of platelet count within the past 30 days; **AND** • Trial and failure (i.e., not achieved a platelet count ≥ 50 x 10^9/L) of at least one other therapy for ITP, such as corticosteroids, IV immune globulin, RhO(D) immune globulin, thrombopoietin receptor antagonists, etc. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of response to therapy. **Age Limit:** 1 to < 6 years of age **Quantity Limit:** 2 per day (except where 15 tablet per 5-day course is indicated)

eltrombopag olamine powder pack CC, QL
eltrombopag olamine tablet CC, QL
	• Prescribed by, or in consultation with, a hematologist or liver disease specialist; **AND**
	• Diagnosis of one of the following conditions:
	  ○ Chronic immune (idiopathic) thrombocytopenic purpura (ITP); **OR**
	  ○ Treatment of thrombocytopenia in patients with chronic hepatitis C (to allow the initiation & maintenance of interferon-based therapy); **OR**
	  ○ Treatment of severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy.
	
	Renewal Criteria:
	• Documentation (e.g., progress note, laboratory report) of response to therapy.
	
	Quantity Limit: 12.5 mg and 25 mg powder pack: 3 per day
	12.5 mg and 25 mg tablet: 3 per day
	50 mg and 75 mg tablet: 2 per day

Mulpleta AE, CC, QL	**Approval Duration:** Date of service • Diagnosis of chronic liver disease; **AND** • Documentation of platelet count < 50 x 10^9/L within the past 14 days; **AND** • NOT have severe hepatic impairment (Child-Pugh class C), absence of hepatopetal blood flow, a prothrombotic condition other than CLD or a history of splenectomy, partial splenic embolization, or thrombosis; **AND** • Confirmation (e.g., attestation or progress note) of a scheduled invasive procedure occurring 2 to 8 days following the last dose of lusutrombopag. **Age Limit:** ≥ 18 years **Quantity Limit:** 7 tablets per fill; no renewals

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Agent(s) Subject to Criteria	Criteria for Approval
Tavalisse AE, CC, QL	• Diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP); **AND** • Prescribed by, or in consultation with, a hematologist or liver disease specialist; **AND** • Documentation (e.g., progress note, laboratory report) of platelet count within the past 30 days; **AND** • Trial and failure (i.e., not achieved a platelet count ≥ 50 x 10^9/L) of at least one other therapy for chronic ITP, such as corticosteroids, IV immune globulin, RhO(D) immune globulin, thrombopoietin receptor antagonists, etc. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of response to therapy. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day
Wayrilz AE, CC, QL	**Approval Duration:** 6 months (initial and renewal) • Diagnosis of persistent or chronic immune thrombocytopenia (ITP); **AND** • Prescribed by, or in consultation with, a hematologist or liver disease specialist; **AND** • Documentation (e.g., progress note, laboratory report) of platelet count within the past 30 days; **AND** • Trial and failure (i.e., not achieved a platelet count ≥ 50 x 10^9/L) of at least one other therapy for persistent or chronic ITP, such as corticosteroids, IV immune globulin, RhO(D) immune globulin, thrombopoietin receptor antagonists, etc.; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to Promacta. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of response to therapy. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Promacta tablet CC	Alvaiz AE, CC, QL
	Doptelet sprinkles, tablet AE, CC, QL
	eltrombopag olamine powder pack CC, QL
	eltrombopag olamine tablet CC, QL
	Mulpleta AE, CC, QL
	Nplate
	Promacta powder packet QL
	Tavalisse AE, CC, QL
	Wayrilz AE, CC, QL

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OPHTHALMIC ANTIBIOTICS AND ANTIVIRALS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent within the same sub-class.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

OPHTHALMIC ANTIVIRALS

Preferred Agents	Non-Preferred Agents
trifluridine	Zirgan

OPHTHALMIC QUINOLONES

Preferred Agents	Non-Preferred Agents
ciprofloxacin	besifloxacin
moxifloxacin (generic Vigamox)	Besivance
ofloxacin	Ciloxan
	gatifloxacin
	levofloxacin
	moxifloxacin (generic Moxeza)
	Ocuflox
	Vigamox

OPHTHALMIC ANTIBIOTICS, NON-QUINOLONES

Preferred Agents	Non-Preferred Agents
bacitracin ointment	AzaSite
bacitracin/polymyxin B ointment	Natacyn
erythromycin 0.5% ointment	neomycin/polymyxin B/bacitracin ointment
gentamicin sulfate drops	neomycin/polymyxin B/gramicidin drops
Polycin	Neo/Polycin ointment

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Preferred Agents	Non-Preferred Agents
polymyxin B/trimethoprim drops	Polytrim
sulfacetamide drops	sulfacetamide ointment
tobramycin drops	Tobrex

OPHTHALMIC ANTIBIOTIC-STEROID COMBINATIONS

Preferred Agents	Non-Preferred Agents
neomycin sulfate/polymyxin B/dexamethasone suspension	Blephamide S.O.P ointment
neomycin sulfate/bacitracin zinc/polymyxin B /hydrocortisone ointment, suspension	neomycin sulfate/polymyxin B/hydrocortisone suspension
Neo-Polycin hydrocortisone ointment	Maxitrol suspension
Tobradex ointment	sulfacetamide sodium/ prednisolone sodium phosphate drops
tobramycin/dexamethasone suspension	Pred-G ointment
	Tobradex ST suspension
	tobramycin/loteprednol etabonate drops
	Zylet suspension

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OPHTHALMICS FOR ALLERGIC CONJUNCTIVITIS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

OPHTHALMIC ANTIHISTAMINES

Preferred Agents	Non-Preferred Agents
azelastine	bepotastine besilate
olopatadine 0.1% (generic Patanol)	Bepreve
olopatadine 0.2% (generic Pataday)	epinastine
	Zerviate

OPHTHALMIC MAST CELL STABILIZERS

Preferred Agents	Non-Preferred Agents
cromolyn sodium	Alocril
	Alomide

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OPHTHALMICS: GLAUCOMA AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
latanoprost CC, QL	• Diagnosis of one of the following conditions: o Open-angle glaucoma, OR o Ocular hypertension
Rhopressa AE, CC, QL Rocklatan AE, CC, QL	• Trial and failure of ≥ 1 preferred agent. **Age Limit:** ≥ 18 years **Quantity Limit:** 5 mL per 30 days

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
bimatoprost CC, QL Iyuzeh CC, QL Lumigan CC, QL tafluprost/PF CC, QL Travatan Z CC Travoprost CC Vyzulta AE, CC, QL Xalatan CC, QL Xelpros CC Zioptan CC, QL Zolymbus CC, QL	• Diagnosis of one of the following conditions: o Open-angle glaucoma, OR o Ocular hypertension; AND • Patient has had ≥ 30-day trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to ≥ 2 preferred agents any sub-class.
Vuity AE, CC, QL pilocarpine 1.25% AE, CC, QL	**Approval Duration:** 3 months initial; 1 year renewal • Diagnosis of presbyopia; **AND** • Prescribed by, or in consultation with, an ophthalmologist or optometrist; **AND** • Prescriber has provided documentation of trial and failure, contraindication, or clinically significant adverse effects of

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Agent(s) Subject to Criteria	Criteria for Approval
	corrective eyeglasses or contact lenses to resolve symptoms; **AND** • Patient has had ≥ 30-day trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ≥ 2 preferred agents for this FDA-approved indication (if available and covered). **Renewal Criteria:** • Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms. **Age Limit:** ≥ 40 years **Quantity Limit:** 1 bottle (2.5 mL) per month

CURRENT PDL STATUS

OPHTHALMIC PROSTAGLANDIN AGONISTS

Preferred Agents	Non-Preferred Agents
latanoprost CC, QL	bimatoprost CC, QL
	Iyuzeh CC, QL
	Lumigan CC, QL
	tafluprost/PF CC, QL
	Travatan Z CC
	travoprost CC,
	Vyzulta AE, CC, QL
	Xalatan CC, QL
	Xelpros CC
	Zioptan CC, QL
	Zolymbus CC, QL

OPHTHALMIC BETA BLOCKERS

Preferred Agents	Non-Preferred Agents
levobunolol	betaxolol
timolol maleate drops (except preservative-free)	Betimol
	Betoptic S
	carteolol
	Istalol
	timolol (generic Betimol)
	timolol maleate gel-solution
	timolol maleate once daily (generic Istalol)
	timolol PF
	Timoptic Ocudose

OPHTHALMIC CARBONIC ANHYDRASE INHIBITORS

Preferred Agents	Non-Preferred Agents
dorzolamide	Azopt
	brinzolamide

OPHTHALMIC COMBINATIONS FOR GLAUCOMA

Preferred Agents	Non-Preferred Agents
Combigan	brimonidine-timolol 0.2%-0.5%
dorzolamide/timolol (except preservative-free)	Cosopt
Simbrinza	Cosopt PF
	dorzolamide/timolol PF

OPHTHALMIC SYMPATHOMIMETICS

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Preferred Agents	Non-Preferred Agents
Alphagan P 0.15%	Alphagan P 0.1%
brimonidine 0.2% drops	apraclonidine
	brimonidine 0.1% drops, 0.15% drops
	lopidine 1% drops

OPHTHALMICS, GLAUCOMA AGENTS (OTHER)

Preferred Agents	Non-Preferred Agents
Rhopressa AE, CC, QL	phospholine iodide
Rocklatan AE, CC, QL	pilocarpine 1%, 2%, 4%
	pilocarpine 1.25% AE, CC, QL
	Vuity AE, CC, QL

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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OPHTHALMICS: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
diclofenac sodium drops	Acular
flurbiprofen sodium drops	Acular LS
ketorolac tromethamine drops	Acuvail
	bromfenac sodium drops
	BromSite
	Ilevro
	Nevanac
	Prolensa

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OPHTHALMICS: ANTI-INFLAMMATORY STEROIDS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
dexamethasone sodium phosphate drops	Alrex
Durezol	Byqlovi
fluorometholone suspension	difluprednate
Lotemax gel, ointment	Eysuvis
prednisolone acetate suspension	Flarex
prednisolone sodium phosphate drops	FML suspension, FML Forte suspension
	Inveltys
	Lotemax SM gel
	loteprednol etabonate 0.2% (generic Alrex)
	loteprednol etabonate 0.5% (generic Lotemax)
	Maxidex
	Pred Forte
	Pred Mild

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OPHTHALMICS: IMMUNOMODULATORS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Restasis (Blister Pack) [CC] Xiidra [AE, CC, QL]	• Prescribed following corneal transplant; **OR** • Trial and failure of ≥ 1 over-the-counter ophthalmic lubricant (e.g., polyvinyl alcohol). **Age limit:** ≥ 17 years (Xiidra) **Quantity Limit:** 2 blister packs per day (Xiidra)

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Meibo [CC, QL]	• Trial and failure of ≥ 1 over the counter ophthalmic lubricant (e.g., polyvinyl alcohol); **AND** • At least a 1-month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents. **Quantity Limit:** 0.4 mL (8 drops) per day
Restasis Multidose [CC]	• Patient has had ≥ 1 month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents; **AND** • Prescribed following corneal transplant; **OR** • Trial and failure of ≥ 1 over-the-counter ophthalmic lubricant (e.g., polyvinyl alcohol).
Tryptyr [AE, CC, QL]	**Approval Duration:** 3 months initial; 1 year renewal • Patient has diagnosis of dry eye disease (DED); **AND**

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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Agent(s) Subject to Criteria	Criteria for Approval

	• Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**
	• Patient has had a trial and failure of preservative-free, nonprescription lubricating eye drops (e.g., artificial tears); **AND**
	• Patient has had ≥ 1 month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents; **AND**
	• Prescriber has documented at least 1 of the following signs of DED:
	  ○ Corneal fluorescein staining (CFS) score of ≥ 2 points in any field on a 0-to-4-point scale; **OR**
	  ○ Schirmer tear test (STT) of 1 to 10 mm in 5 minutes.
	• Patient meets the minimum age recommended by the package insert for the provided indication.
	
	Renewal Criteria:
	• Patient continues to meet the above criteria; **AND**
	• Patient has improvement in signs of DED, as measured by at least 1 of the following:
	  ○ Decrease in corneal fluorescein staining score; **OR**
	  ○ Increase in number of mm per 5 minutes using Schirmer tear test.
	
	Age Limit: 18 years
	Quantity Limit: 2 vials per day

Tyrvaya AE, CC, QL	• Patient has diagnosis of dry eye disease (DED); **AND**
	• Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**
	• Patient has had a trial and failure of preservative-free, nonprescription lubricating eye drops (e.g., artificial tears); **AND**
	• Patient has had ≥ 1 month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents; **AND**
	• Prescriber has documented at least 1 of the following signs of DED:
	  ○ Corneal fluorescein staining (CFS) score of ≥ 2 points in any field on a 0 to 4 point scale; **OR**
	  ○ Schirmer tear test (STT) of 1 to 10 mm in 5 minutes.
	
	Renewal Criteria:
	• Patient continues to meet the above criteria; **AND**
	• Patient has improvement in signs of DED, as measured by at least 1 of the following:
	  ○ Decrease in corneal fluorescein staining score; **OR**
	  ○ Increase in number of mm per 5 minutes using Schirmer tear test.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 1 carton (2 bottles)/ 30 days

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Agent(s) Subject to Criteria	Criteria for Approval
Verkazia AE, CC	• Patient is 4 years of age or older; **AND** • Patient has diagnosis of vernal keratoconjunctivitis (VKC); **AND** • Patient has had ≥ 1-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 2 preferred agents. **Age Limit:** ≥ 4 years

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Restasis (Blister Pack) CC	Cequa
Xiidra AE, CC, QL	cyclosporine 0.05% emulsion
	Miebo CC, QL
	Restasis Multidose CC
	Tryptyr AE, CC, QL
	Tyrvaya AE, CC, QL
	Verkazia 0.1% AE, CC
	Vevye

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OPHTHALMIC: MYDRIATIC & CYCLOPLEGICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
atropine sulfate drops, ointment	Cyclogyl drops
atropine sulfate/PF droperrette	Cyclomydril drops
cyclopentolate drops	Mydriacyl drops
phenylephrine drops	
tropicamide drops	

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GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents (antibiotics) OR **1** preferred agent (anesthetics and anti-inflammatories).

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable

CURRENT PDL STATUS

OTIC ANTIBIOTICS

Preferred Agents	Non-Preferred Agents
ciprofloxacin/dexamethasone suspension	ciprofloxacin 0.2% drops
neomycin/polymyxin B/hydrocortisone solution	Cipro HC Otic
ofloxacin 0.3% solution	ciprofloxacin/fluocinolone
	ciprofloxacin/hydrocortisone drops
	Cortisporin-TC suspension
	Otovel

OTIC ANESTHETICS AND ANTI-INFLAMMATORIES

Preferred Agents	Non-Preferred Agents
acetic acid	DermOtic
fluocinolone acetonide 0.01% oil	Flac Otic Oil
	hydrocortisone/acetic acid drops

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RENAL AND GENITOURINARY: ALPHA BLOCKERS FOR BPH & 5-ALPHA REDUCTASE INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
finasteride 5 mg CC	• Diagnosis of benign prostatic hyperplasia (ICD-10 Disease Group N40).

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents in any sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

ALPHA BLOCKERS FOR BPH

Preferred Agents	Non-Preferred Agents
alfuzosin ER	Cardura
doxazosin	Cardura XL
tamsulosin	Flomax
terazosin	Rapaflo
	silodosin
	Tezruly QL

5-ALPHA REDUCTASE (5AR) INHIBITORS

Preferred Agents	Non-Preferred Agents
dutasteride	Avodart
finasteride 5 mg tablet CC	dutasteride/tamsulosin
	Jalyn
	Proscar

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BLADDER RELAXANTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Gemtesa AE, CC, QL	• Patient is ≥ 18 years of age; **AND** • Patient has a diagnosis of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency; **AND** • Patient must not have hypersensitivity to vibegron or any component of the product; **AND** • Patient must have an adequate trial and failure of behavioral therapy (bladder training, bladder control strategies, pelvic floor muscle training, and fluid management); **AND** • Patient has tried and failed at least one month, or has an intolerance, or contraindication to at least two preferred medications; **AND** • Patient has tried and failed at least one month of treatment with mirabegron. **Renewal Criteria:** • Patient has not experienced urinary retention; **AND** • Patient has experienced disease response as indicated by a reduction in the daily number of micturitions and the average daily number of urge urinary incontinence (UUI) episodes. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Oxytrol CC, QL	• Patient is unable to swallow or tolerate oral medications; **OR** • NPD criteria.

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Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limit: 8 per 28 days

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
oxybutynin solution QL, syrup QL, 5mg tablet QL	darifenacin ER QL
oxybutynin ER QL	Detrol QL
solifenacin QL	Detrol LA QL
tolterodine QL	fesoterodine ER QL
tolterodine ER QL	flavoxate QL
	Gemtesa AE, CC, QL
	mirabegron QL
	Myrbetriq QL
	oxybutynin 2.5mg tablet QL
	Oxytrol CC, QL
	Toviaz QL
	trospium QL
	trospium ER QL
	Vesicare QL
	Vesicare LS QL

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DERMATOLOGICS: TOPICAL ANTIBIOTIC AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Xepi CC, QL	• Diagnosis of impetigo; **AND** • Trial and failure with a preferred agent (e.g., mupirocin ointment); **AND** • Not have an affected body surface area (BSA) exceeding 100 cm^2 or 2% of total BSA, whichever is greater; **AND** • Will not be used for more than 5 days. **Quantity Limit:** Up to 30 grams per fill

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
gentamicin cream QL, ointment	Centany ointment QL, Centany AT kit
mupirocin ointment QL	mupirocin cream QL
	Xepi CC, QL

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DERMATOLOGICS: TOPICAL ANTIPARASITICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Natroba	Crotan
permethrin 5% cream	Elimite
spinosad	Eurax
	malathion
	Ovide
	Pruradik

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DERMATOLOGICS: ORAL ANTIPSORIATICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
acitretin	methoxsalen

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DERMATOLOGICS: ORAL ACNE AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Amnesteem	Absorica
Claravis	Absorica LD
isotretinoin 10 mg, 20 mg, 30 mg, 40 mg capsule	isotretinoin 25 mg, 35 mg capsule
Zenatane	

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DERMATOLOGICS: TOPICAL ACNE AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 30-day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of **≥ 4** preferred or over-the-counter (OTC) agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
tretinoin AE, CC tretinoin microsphere AE, CC clindamycin/tretinoin AE, CC	• Diagnosis of acne vulgaris; **AND** • Prescriber attestation that the medication is NOT being used solely for cosmetic purposes (e.g., photoaging, wrinkling, hyperpigmentation, melasma, roughness of skin, or sun damage); **AND** • NPD criteria. **Age Limit:** ≥ 12 years
Winlevi AE, CC	• Diagnosis of acne vulgaris; **AND** • Prescriber attestation that the medication is not being used solely for cosmetic purposes (e.g., hair loss); **AND** • Prescribed by, or in consultation with, a dermatologist or provider in the treatment of acne vulgaris. **Age Limit:** ≥ 12 years

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
adapalene gel, gel pump	adapalene cream
adapalene/benzoyl peroxide 0.3-2.5% (by Mayne Pharma)	adapalene/benzoyl peroxide gel

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Preferred Agents	Non-Preferred Agents
clindamycin gel, medicated swab (pledget), solution	Aklief [AE]
clindamycin/benzoyl peroxide (generic BenzaClin or Duac; excluding pumps)	Avar, Avar E, Avar E LS, Avar LS
erythromycin solution	BP 10-1 cleanser
erythromycin/benzoyl peroxide	BP Cleansing Wash
	Cleocin-T
	Clindacin
	Clindacin ETZ, Clindacin P, Clindacin PAC
	clindamycin foam, lotion
	clindamycin phosphate EQ 1% gel (generic Clindagel)
	clindamycin/benzoyl peroxide gel pump
	clindamycin/tretinoin gel [AE, CC]
	dapsone
	Differin
	Epiduo Forte
	Ery medicated swab
	Erygel
	erythromycin gel
	Evoclin
	Fabior
	Neuac gel
	Neuac Kit
	Ovace Plus shampoo, wash, wash cleanser gel
	Rosula
	sodium sulfacetamide cleanser, cleanser gel, shampoo, suspension
	sodium sulfacetamide/sulfur cleanser, cream, medicated pad, suspension
	SSS 10-5
	Sumadan, Sumadan XLT
	Sumaxin, Sumaxin CP, Sumaxin TS
	tazarotene
	tretinoin [AE, CC]
	tretinoin microsphere [AE, CC]
	Twyneo
	Winlevi [AE, CC]
	Zma Clear

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DERMATOLOGICS: TOPICAL ROSACEA AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Rhofade AE, CC, QL oxymetazoline cream AE, CC, QL	• Diagnosis of rosacea or facial erythema; **AND** • Trial and failure of topical metronidazole; **AND** • Trial and failure of an oral antibiotic (e.g., doxycycline). **Age Limit:** ≥ 18 years **Quantity Limit:** 60 grams per 30 days

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
azelaic acid gel	brimonidine tartrate 0.33% gel pump
metronidazole cream, gel, gel pump	Epsolay
	Finacea foam
	ivermectin 1% cream
	MetroCream
	MetroGel
	metronidazole lotion
	Mirvaso
	oxymetazoline cream AE, CC, QL
	Rhofade AE, CC, QL
	Rosadan
	Soolantra

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DERMATOLOGICS: TOPICAL ANTIFUNGAL AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 1-week** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Kerydin CC	• Diagnosis of toenail onychomycosis • Trial and failure of ciclopirox 8% nail solution or allergy to ciclopirox.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
ciclopirox cream, solution	Ciclodan cream, kit, solution
clotrimazole cream, solution	ciclopirox gel, kit, shampoo, suspension
clotrimazole/betamethasone cream	clotrimazole/betamethasone lotion
econazole cream	econazole foam
ketoconazole cream QL, shampoo	Ertaczo
Nyamyc	Extina
nystatin cream, ointment, powder QL	ketoconazole foam
nystatin/triamcinolone cream, ointment	Ketodan
Nystop	Kerydin CC
tavaborole	Loprox cream, cream kit, suspension, suspension kit
	miconazole/zinc oxide/petrolatum
	naftifine cream, gel
	Naftin
	oxiconazole QL
	Oxistat QL
	Vusion

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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DERMATOLOGICS: TOPICAL ANTIVIRAL AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **1** preferred agent.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Zelsuvmi AE, CC, QL	**Approval Duration:** 3 months
	
	• Diagnosis of molluscum contagiosum (MC); **AND**
	• Prescribed by, or in consultation with, a dermatologist; **AND**
	• Patient has had a trial and failure (at least 3 months) of ≥ 1 of the following conventional therapies:
	  ○ Cantharidin,
	  ○ Silver nitrate,
	  ○ Cryotherapy,
	  ○ Curettage; **AND**
	• Patient meets one of the following:
	  ○ Patient has atopic dermatitis (AD); **OR**
	  ○ Patient is immunocompromised; **OR**
	  ○ Patient has concomitant bacterial infection; **AND**
	• Patient is not on concurrent treatment for MC; **AND**
	• Patient meets the minimum age recommended by the package insert for the provided indication.
	
	Age Limit: ≥ 1 year
	Quantity Limit: 1 kit (31 grams) per month

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
acyclovir cream, ointment	Denavir
	penciclovir cream
	Zelsuvmi gel AE, CC, QL

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DERMATOLOGICS: TOPICAL ANTIPSORIATICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 1-week** trial and failure within the past 90 days, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Zoryve 0.3% cream AE, CC, QL	• Diagnosis of plaque psoarisis; **AND** • NPD Criteria; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Age Limit:** ≥ 2 years **Quantity Limit:** 2 grams per day

Zoryve 0.3% foam AE, CC, QL	**Plaque Psoarisis:**
	• Diagnosis of plaque psoriasis; **AND**
	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ONE preferred agent; **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	
	Seborrheic dermatitis:
	• Diagnosis of seborrheic dermatitis; **AND**
	• At least a 4-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to ONE of the following agents for the treatment of seborrheic dermatitis:
	  ○ Topical steriods (e.g., hydrocostisone butyrate), **OR**
	  ○ Topical antifungal (e.g., ketoconazole, ciclopirox); **AND**
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

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Agent(s) Subject to Criteria	Criteria for Approval
	Age Limit: ≥12 years for plaque psoriasis ≥9 years for seborrheic dermatitis **Quantity Limit:** 2 grams per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
calcipotriene cream, ointment, solution	calcipotriene foam
calcipotriene/betamethasone suspension	calcipotriene/betamethasone ointment
salicylic acid gel, liquid film	calcitriol ointment
urea cream QL	Dermacure cream QL
	Enstilar MD, AE
	salicylic acid foam, ointment
	Sorilux
	Taclonex suspension
	Uramaxin foam
	urea foam
	Vectical ointment
	Zoryve 0.3% cream AE, CC, QL, 0.3% foam AE, CC, QL

AE = Age Edit CC = Clinical Criteria MD = Maximum Duration QL = Quantity Limit ST = Step Therapy

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DERMATOLOGICS: TOPICAL STEROIDS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 1-week** trial and failure within the past 90 days, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of **2** preferred agents within the same sub-class.

3. BRAND MEDICALLY NECESSARY CRITERIA

Trial and failure (e.g., allergy or intolerance to an inactive ingredient) with **≥ 2** manufacturers (if available and covered) of the corresponding generic. [Documentation required]

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation. [Documentation required]

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

LOW POTENCY

Preferred Agents	Non-Preferred Agents
alclometasone dipropionate cream, ointment	desonide lotion
Derma-Smoothe-FS oil	fluocinolone acetonide oil
desonide cream, ointment	hydrocortisone butyrate cream, lotion, ointment, solution
hydrocortisone cream, lotion, ointment	hydrocortisone solution
Procto-Med-HC	hydrocortisone valerate cream, ointment
Proctosol-HC	Micort-HC cream
Proctozone-HC	Sanaderm Rx
	Texacort solution

MEDIUM POTENCY

Preferred Agents	Non-Preferred Agents
fluticasone propionate cream, ointment	Beser kit, lotion
mometasone furoate cream, ointment, solution	Capex shampoo
	clocortolone pivalate cream
	fluocinolone acetonide cream, ointment, solution
	flurandrenolide lotion, ointment
	fluticasone propionate lotion
	Pandel cream
	Synalar cream, kit, ointment, solution
	Synalar TS kit

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HIGH POTENCY

Preferred Agents	Non-Preferred Agents
betamethasone dipropionate (augmented) cream	amcinonide cream QL, ointment QL
betamethasone dipropionate cream, lotion	betamethasone dipropionate (augmented) gel, lotion, ointment
betamethasone valerate cream, ointment	betamethasone dipropionate ointment
fluocinonide ointment, solution	betamethasone valerate foam, lotion
triamcinolone acetonide cream, lotion, ointment	desoximetasone cream, gel, ointment, spray
	diflorasone diacetate cream, ointment
	Diprolene ointment
	fluocinonide cream, gel
	fluocinonide-E cream
	halcinonide cream, solution
	Halog cream, solution
	Kenalog aerosol
	Topicort cream, gel, ointment, spray
	triamcinolone acetonide spray

VERY HIGH POTENCY

Preferred Agents	Non-Preferred Agents
clobetasol propionate cream (except 0.025%), ointment, shampoo, solution	Apexicon E cream
Clodan shampoo	clobetasol emollient cream, foam
halobetasol propionate cream, ointment	clobetasol emulsion foam
	clobetasol propionate 0.025% cream
	clobetasol propionate foam, gel, lotion, spray
	Clobex spray
	Clodan kit
	halobetasol propionate foam, lotion
	Lexette foam
	Tovet emollient foam, kit
	Ultravate lotion

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