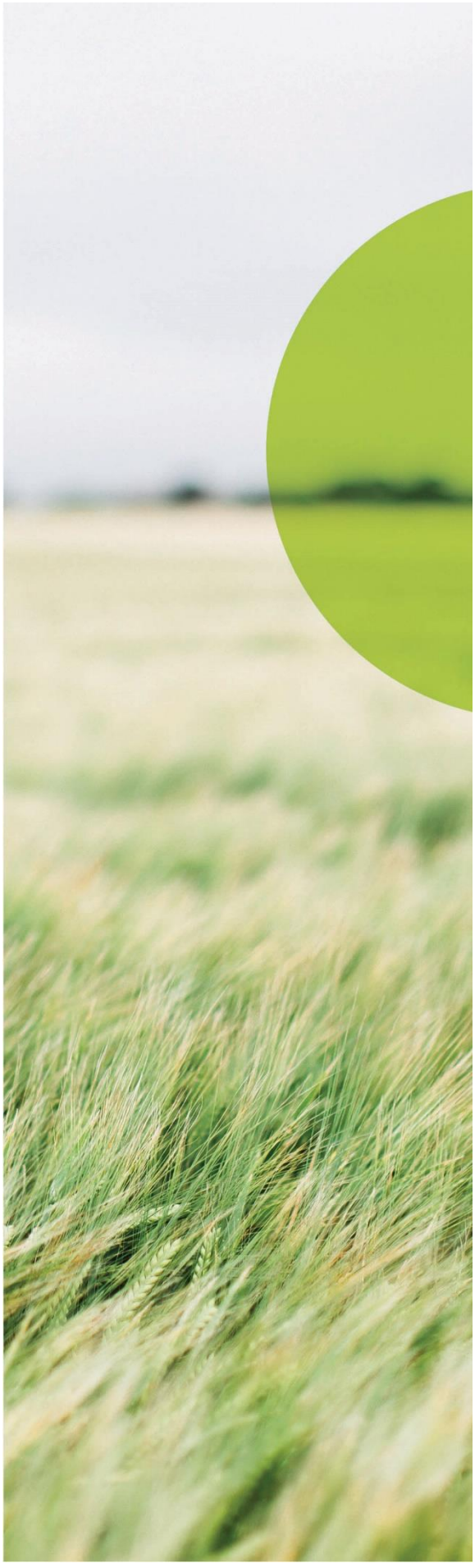

MedImpact **Clinical Document**

Kentucky Medicaid
Prior Authorization Criteria

VERSION: MAY 31, 2025

Prior Authorization Criteria

Kentucky Medicaid

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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.

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

Prior Authorization Criteria

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CARDIOVASCULAR: ANGIOTENSIN RECEPTOR MODULATORS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Epaned CC Qbrelis CC	• NPD criteria; **OR** • Unable to swallow whole or consume crushed generic tablets.

CURRENT PDL STATUS

ACE INHIBITORS

Preferred Agents	Non-Preferred Agents
benazepril	Accupril
enalapril tablets	Altace
enalapril solution	captopril
lisinopril	Epaned CC
quinapril	fosinopril
ramipril	Lotensin

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Preferred Agents	Non-Preferred Agents
	moexipril
	perindopril
	Qbrelis CC, QL
	trandolapril
	Vasotec
	Zestril

ACE INHIBITORS + DIURETIC COMBINATIONS

Preferred Agents	Non-Preferred Agents
benazepril/HCTZ	Accuretic
enalapril/HCTZ	captopril/HCTZ
fosinopril/HCTZ	Lotensin HCT
lisinopril/HCTZ	quinapril/HCTZ
	Vaseretic
	Zestoretic

ANGIOTENSIN RECEPTOR BLOCKERS (ARB)

Preferred Agents	Non-Preferred Agents
Entresto	Atacand
irbesartan	Avapro
losartan	Benicar
olmesartan	candesartan
valsartan	Cozaar
	Diovan
	Edarbi
	Entresto Sprinkle
	eprosartan
	Micardis
	sacubitril/valsartan
	telmisartan
	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

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DIRECT RENIN INHIBITORS

Preferred Agents	Non-Preferred Agents
	aliskiren
	Tekturna
	Tekturna HCT

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CARDIOVASCULAR: ANTI-ANGINAL & ANTI-ISCHEMIC AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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

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Preferred Agents	Non-Preferred Agents
	ivabradine CC

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CARDIOVASCULAR: ANTIARRHYTHMICS (ORAL ANTI-ARRHYTHMICS)

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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 100, 200 mg	amiodarone 400 mg
disopyramide	Betapace
dofetilide	Betapace AF
flecainide	Multaq
mexiletine	Norpace
propafenone	Norpace CR
Sorine	Pacerone
sotalol	propafenone SR/ER
sotalol AF	quinidine sulfate

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Preferred Agents	Non-Preferred Agents
	quinidine gluconate ER
	Rythmol SR
	Sotylize[CC]
	Tikosyn

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CARDIOVASCULAR: BETA BLOCKERS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

BETA BLOCKERS

Preferred Agents	Non-Preferred Agents
atenolol	acebutolol
atenolol/chlorthalidone	betaxolol
bisoprolol 2.5 mg QL	Bystolic
bisoprolol 5, 10 mg	carvedilol ER
bisoprolol/HCTZ	Coreg CR
carvedilol	Coreg
Hemangeol CC	Corgard

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Preferred Agents	Non-Preferred Agents
labetalol	Inderal LA
metoprolol succinate ER	Inderal XL
metoprolol tartrate	Innopran XL
nadolol	Kapspargo
nebivolol	Lopressor
propranolol ER	metoprolol/HCTZ
propranolol solution	pindolol
propranolol tablet	propranolol/HCTZ
	Tenoretic
	Tenormin
	timolol
	Toprol XL
	Ziac

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CARDIOVASCULAR: CALCIUM CHANNEL BLOCKERS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
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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CURRENT PDL STATUS

CALCIUM CHANNEL BLOCKERS

Preferred Agents	Non-Preferred Agents
amlodipine	Calan SR
Cartia XT	Cardizem
diltiazem	Cardizem CD
diltiazem CD capsule	Cardizem LA
diltiazem ER 24HR capsule	diltiazem ER 12HR capsule
diltiazem XR	Diltiazem ER (LA) tablet
Dilt-XR	felodipine ER
nifedipine ER	isradipine
Taztia XT	Katerzia
Tiadylt ER	levamlodipine
verapamil tablet	Matzim
verapamil ER tablet	nicardipine
	nifedipine IR
	nimodipine
	nisoldipine ER
	Norliqva
	Norvasc
	Nymalize solution
	Nymalize syringe
	Procardia XL
	Sular ER
	Tiazac ER
	verapamil ER capsule
	verapamil ER PM capsule
	verapamil SR capsule
	Verelan PM

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
	trandolapril/verapamil
	Tribenzor

CARDIOVASCULAR: ANTICOAGULANTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Eliquis	Arixtra
enoxaparin	dabigatran
Jantoven	fondaparinux
Pradaxa	Fragmin
warfarin	Lovenox
Xarelto	Pradaxa pellet pack
	rivaroxaban
	Savaysa
	Xarelto granules for suspension

CARDIOVASCULAR: PLATELET AGGREGATION INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

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

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

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Alyq CC, QL ambrisentan CC sildenafil suspension CC sildenafil tablets CC tadalafil CC, QL Tracleer tablets 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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Opsynvi CC, QL	**Approval Duration: 1 year** **Initial Approval Criteria:** • Diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1; **AND**

Agent(s) Subject to Criteria	Criteria for Approval

	• 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**
	• 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 tablet per day

Tracleer 32mg tablets for suspension CC	• PDP criteria; **AND** • Unable to swallow Tracleer tablets.
Tyvaso, Tyvaso DPI CC	**Approval Duration:** 1 year **Initial Approval Criteria:** *Pulmonary Arterial Hypertension (PAH)* • Diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1 • Prescribed by, or in consultation with, a cardiologist or a pulmonologist • 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 • Prescribed by, or in consultation with, a cardiologist or a pulmonologist • Baseline forced vital capacity < 70% for patients with connective tissue disease • Patient had a right heart catheterization (documentation required)

Agent(s) Subject to Criteria	Criteria for Approval
	• Results of the right heart catheterization confirm the diagnosis of WHO Group 3 interstitial lung disease associated with pulmonary hypertension **Renewal Criteria:** • Patient has a documented response to therapy

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Alyq CC, QL	Adcirca QL
ambrisentan CC	Adempas QL
sildenafil suspension CC	bosentan tablet
sildenafil tablet CC	Letairis
tadalafil CC, QL	Liqrev
Tracleer tablet CC	Opsumit QL
	Opsynvi CC, QL
	Orenitram ER
	Revatio suspension CC
	Revatio tablet CC
	Tadliq
	Tracleer 32 mg tablets for suspension CC, QL
	Tyvaso CC
	Tyvaso DPI CC
	Uptravi QL
	Ventavis

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CARDIOVASCULAR: LIPOTROPICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

2. Not applicable. All preferred agents are preferred without PA.

3. NON-PREFERRED (NPD) CRITERIA

Approval of non-preferred agents requires **≥ 3 months** 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.

4. BRAND MEDICALLY NECESSARY CRITERIA

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

5. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

6. 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
Juxtapid CC	**Approval Duration:** 6 months initial; 12 months 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
Agent(s) Subject to Criteria	**Criteria for Approval**

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Agent(s) Subject to Criteria	Criteria for Approval
	Renewal Criteria: • Documentation (e.g., progress note or lab report) that demonstrate a reduction in LDL-C when compared to the baseline values.

Nexletol CC, AE, QL
Nexlizet CC, AE, 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**
	  ○ 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 CC, AE
Praluent CC
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**
	• Medication is used to reduce the risk of cardiovascular (CV) events (e.g., myocardial infarction, stroke) in a patient with established CV disease; **OR**
	• Diagnosis of primary hyperlipidemia, including heterozygous and homozygous familial hypercholesterolemia; **AND**
	  ○ 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**
	  ○ Maximum tolerated doses of lipid-lowering therapies (e.g., statin, ezetimibe, omega-3-acid ethyl esters) will continue to be used in combination with PCSK9 therapy.

Agent(s) Subject to Criteria	Criteria for Approval
	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 light powder packet	colesevelam powder packet
cholestyramine light powder	colesevelam tablet
cholestyramine powder packet	Colestid granules
cholestyramine powder	Colestid packet
colestipol	Colestid tablet
ezetimibe	colestipol granules
fenofibrate capsule (generic Lofibra)	colestipol packet
fenofibrate nanocrystallized (generic Tricor)	fenofibrate tablet
fenofibric acid DR capsule	fenofibric acid tablet
gemfibrozil	Fenoglide tablet
Niacin ER	icosapent ethyl capsule
omega-3 acid ethyl esters	Juxtapid CC
Prevalite powder packet	Leqvio CC, AE
Prevalite powder	Lipofen
	Lopid
	Lovaza
	Nexletol CC, AE, QL
	Nexlizet CC, AE, QL
	Praluent CC
	Questran Light powder
	Questran powder packet
	Questran powder
	Repatha CC
	Tricor
	Trilipix
	Vascepa
	Welchol powder packet
	Welchol tablet
	Zetia

LIPOTROPICS: STATINS

Preferred Agents	Non-Preferred Agents
atorvastatin QL	Altoprev QL
lovastatin QL	amlodipine/atorvastatin CC, QL
pravastatin QL	Atorvaliq

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Preferred Agents	Non-Preferred Agents
rosuvastatin QL	Caduet QL
simvastatin QL	Crestor QL
	Ezallor Sprinkle QL
	ezetimibe/simvastatin QL
	Fibricor
	fluvastatin QL
	Flolipid QL
	fluvastatin ER QL
	Lescol XL QL
	Lipitor QL
	Livalo 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 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.
Diclegis CC, QL	• Patient is a pregnant female; **AND** • Diagnosis of nausea and vomiting of pregnancy; **AND** • Documentation (e.g., progress note) of trial and failure of dietary and lifestyle modifications without adequate control of symptoms.

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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; **AND** • Documentation (e.g., progress note) of trial and failure of dietary and lifestyle modifications without adequate control of symptoms.
Cesamet CC, QL	• NPD Criteria; **AND** • Dronabinol is one of the NPD drug trials.
Sancuso CC, QL	• NPD criteria; **OR** • Used for preventing nausea and vomiting associated with moderately- or highly- emetogenic cancer chemotherapy.

Gimoti CC, QL	**Criteria for Initial Approval** (duration 8 weeks):
	• 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).
	
	Renewal Criteria (duration 8 weeks)
	• 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**

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

Agent(s) Subject to Criteria	Criteria for Approval
	• 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

Prior Authorization Criteria

Kentucky Medicaid

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
aprepitant capsule dose pack QL	Akynzeo capsule QL
aprepitant capsule QL	Antivert chewable tablet
Bonjesta tablet	Antivert tablet
Diclegis tablet CC, QL	Anzemet tablet
dronabinol capsule CC, QL	Compro suppository
meclizine tablet	doxylamine/pyridoxine tablet CC, QL
metoclopramide solution	Emend capsule dose pack QL
metoclopramide tablet	Emend capsule QL
ondansetron solution	Emend suspension QL
ondansetron tablet	Gimoti nasal spray CC, QL
ondansetron ODT	granisetron tablet
prochlorperazine tablet	Marinol capsule CC, QL
promethazine 12.5 mg, 25 mg suppository	prochlorperazine suppository
promethazine syrup	Promethegan 50 mg suppository
promethazine tablet	Reglan tablet
Promethegan 12.5 mg, 25 mg, suppository	Sancuso patch CC, QL
scopolamine patch	Transderm-Scop patch
	trimethobenzamide capsule

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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Mytesi 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

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

Prior Authorization Criteria

Kentucky Medicaid

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
diphenoxylate with atropine tablets	diphenoxylate with atropine liquid
loperamide capsule	Lomotil tablet
	Motofen tablet
	Mytesi tablet CC, QL
	Opium tincture

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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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	chlordiazepoxide/clindinium capsule
dicyclomine solution	Cuvposa solution CC
dicyclomine tablet	Dartisla ODT
ED-Spaz ODT	Donnatal elixir
glycopyrrolate tablet	Glycate tablet
hyoscyamine sulfate drops	glycopyrrolate solution

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
hyoscyamine sulfate elixir	Hyosyne drops
hyoscyamine sulfate ER tablet	Hyosyne elixir
hyoscyamine sulfate ODT tablet	Levsin tablet
hyoscyamine sulfate SL tablet	Levsin/SL tablet
hyoscyamine sulfate tablet	Librax capsule
methoscopolamine tablet	phenobarbital/hyoscyamine/atropine/scopolamine elixir
NuLev ODT	phenobarbital/hyoscyamine/atropine/scopolamine tablet
Oscimin SL tablet	Phenohytro elixir
Oscimin tablet	Phenohytro tablet
	Robinul Forte tablet
	Robinul tablet

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

GASTROINTESTINAL: ANTI-ULCER PROTECTANTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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 tablets	

GASTROINTESTINAL: BILE SALTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Bylvay CC, QL	**Approval Duration:** 1 year **Initial Approval Criteria** *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** • Patient has experienced a reduction in serum bile acids from baseline; **AND** • Patient has experienced an improvement in pruritus

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

Agent(s) Subject to Criteria	Criteria for Approval

	Initial Approval Criteria
	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
	  ○ 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
	• 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

Iqirvo CC, QL	**Approval Duration:** 1 year
	
	Initial Approval Criteria:
	• 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**

Agent(s) Subject to Criteria	Criteria for Approval

	• 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 tablet per day

Livdelz AE, CC, QL	**Approval Duration:** 1 year
	
	Initial Approval Criteria:
	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**
	  ○ 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 provided
	
	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 of age or older
	Quantity Limit: 1 capsule per day

Livmarli CC, QL	**Approval Duration:** 1 year
	
	Initial Approval Criteria:
	• Patient is diagnosed with Alagille syndrome; **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

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

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 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:** • Patient has experienced a reduction in serum bile acids from baseline and 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
Ocaliva CC	• Diagnosis of primary biliary cholangitis (PBC); **AND** • Prescriber is a gastroenterologist, hepatologist, or liver transplant specialist; **AND** • Contraindication or intolerance to, or 12-month trail and failure of, ursodiol. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
ursodiol capsule	Bylvay capsule CC, QL
ursodiol tablet	Bylvay pellet CC, QL
	Chenodal tablet
	Cholbam capsule
	Iqirvo tablet CC, QL
	Livdelzi AE, CC, QL
	Livmarli solution CC, QL
	Livmarli tablet CC, QL
	Ocaliva tablet CC, QL, AE
	Reltone capsule
	Urso Forte tablet
	Urso tablet

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

GASTROINTESTINAL: HELICOBACTER PYLORI (H. PYLORI) TREATMENT

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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 of age **Quantity Limit:** • Voquezna Dual Pak: 1 carton of 28 tablets and 84 capsules per 14-day supply

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

Agent(s) Subject to Criteria	Criteria for Approval
	Voquezna Triple Pak: 1 carton of 56 tablets and 56 capsules per 14-day supply

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Pylera capsule QL	bismuth subcitrate potassium/metronidazole/ tetracycline capsule QL
	lansoprazole/amoxicillin/clarithromycin pack QL
	Omeclamox-Pak QL
	Talicia capsule
	Voquezna Dual Pak AE, CC, QL
	Voquezna Triple Pak AE, CC, QL

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

GASTROINTESTINAL: HISTAMINE II (H2) RECEPTOR BLOCKERS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

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

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

GASTROINTESTINAL: LAXATIVES AND CATHARTICS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
constulose solution	alvimopan capsule
enulose solution	Clenpiq solution
Gavilyte-C	Entereg capsule
Gavilyte-G	GoLytely solution
generlac solution	Kristalose packet
lactulose solution	lactulose packet
MoviPrep powder packet	Osmoprep tablet
PEG 3350/Electrolyte solution	PEG 3350/Sod Sul/NaCl/KCl/AsbC powder packet
PEG-3350 and Electrolytes	Plenvu powder packet
	Sodium Sulfate/Potassium Sulfate/Magnesium Sulfate solution
	Suflave solution
	Suprep solution

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Sutab tablet

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

GASTROINTESTINAL: GASTROINTESTINAL MOTILITY AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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 6 years old; **AND** ○ Diagnosis of functional constipation (FC); **OR** • Patient is at least 18 years old; **AND** ○ Diagnosis of one of the following conditions: ▪ Chronic idiopathic constipation (CIC); **OR** ▪ Irritable bowel syndrome with constipation (IBS-C). **Age Limit:** 72 mcg capsule (≥ 6 years old); 145 mcg and 290 mcg capsule (≥ 18 years old) **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
Trulance AE, CC, QL	• Diagnosis of one of the following conditions: ○ Chronic idiopathic constipation (CIC); **OR** ○ Irritable bowel syndrome with constipation (IBS-C).

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

Agent(s) Subject to Criteria	Criteria for Approval
	Age Limit: ≥ 18 years **Quantity Limit:** 1 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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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
	  ○ Xifaxan® (rifaximin) for at least one 14-day course
	
	Age Limit: ≥ 18 years

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**

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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 diarrhea (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** ○ 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:** 60 tablets/ 30 day
Relistor AE, CC, QL	• Diagnosis of opiate-induced constipation (OIC) in adult patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care (injection only): **OR** • 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] or advanced illness; **AND** • Trial and failure of ≥ 2 preferred agents in this class UNLESS preferred agents are not indicated (i.e., used for OIC associated with advanced illness); **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 ○ Pregnant or breastfeeding, if female **Age Limit:** ≥ 18 years **Quantity Limit:** 3 tablets 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**

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval

	• 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
	  ○ Xifaxan (rifaximin) for at least one 14-day course
	
	Age Limit: ≥ 18 years
	Quantity Limit: 2 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Linzess capsule AE, CC, QL	Alosetron tablet AE, CC, QL
Lubiprostone capsule AE, CC, QL	Amitiza capsule AE, CC, QL
Movantik tablet AE, CC, QL	Ibsrela tablet AE, CC, QL
Trulance tablet AE, CC, QL	Lotronex tablet AE, CC, QL
	Motegrity tablet AE, QL
	prucalopride AE, QL
	Relistor syringe AE, CC
	Relistor tablet AE, CC, QL
	Relistor vial AE, CC
	Symproic AE, CC, QL
	Viberzi AE, CC, QL

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

GATROINTESTINAL: PROTON PUMP INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Konvomep CC, QL	**Initial Approval Criteria:**
	• 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:

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

Agent(s) Subject to Criteria	Criteria for Approval

	• 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**
	• Patient has attempted 'step-down' therapy at any time from multiple to single daily dosing for at least 2 weeks.

Voquezna AE, CC, QL	**For Erosive Esophagitis:** **Approval Duration: 8 weeks initial approval, 6 months renewal** **Initial Approval Criteria:** • 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:** • 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. **For Non-Erosive Gastroesophageal Reflux Disease:** **Approval Duration: 4 weeks** **Initial Approval Criteria:** • 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.

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

Agent(s) Subject to Criteria	Criteria for Approval
	Renewal Criteria: • 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 of age **Quantity Limit:** 1 tablet 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 tablets 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
	Protonix tablet QL
	rabeprazole tablet QL
	Voquezna tablet AE, CC, QL
	Zegerid capsule QL
	Zegerid packet QL

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

GATROINTESTINAL: ULCERATIVE COLITIS AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Apriso capsule	Asacol HD tablet
balsalazide capsule	Azulfidine tablet
Lialda tablet	Azulfidine EN-Tabs
mesalamine enema	budesonide ER tablet
mesalamine kit	budesonide rectal foam
mesalamine suppository	Canasa suppository
Pentasa capsule	Colazal capsule
sulfasalazine DR tablet	Delzicol capsule
sulfasalazine tablet	Dipentum capsule
	mesalamine DR capsule
	mesalamine DR tablet
	mesalamine ER capsule
	sfRowasa enema
	Rowasa enema

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Uceris rectal foam
	Uceris tablet

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

RESPIRATORY: ANTIBIOTICS, INHALED

GUIDELINES FOR USE

Approval Duration: 1 year; Arikayce – 3 months initial; 1 year renewal

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Arikayce	• 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**

Agent(s) Subject to Criteria	Criteria for Approval
	• 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)

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Bethkis QL	Arikayce 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

RESPIRATORY: ANTIHISTAMINES, MINIMALLY SEDATING

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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 tablet
	levocetirizine solution

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

RESPIRATORY: INTRANASAL RHINITIS AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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 spray	azelastine/fluticasone nasal spray QL
Dymista nasal spray QL	Beconase AQ nasal spray QL
fluticasone propionate spray QL	flunisolide nasal spray QL
ipratropium bromide spray	mometasone nasal spray QL
oloptadine nasal spray	Omnaris nasal spray QL
	Patanase nasal spray
	Qnasl Children HFA QL
	Qnasl HFA QL
	Ryaltris nasal spray
	Xhance nasal spray

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Zetonna HFA QL

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

RESPIRATORY: LEUKOTRIENE MODIFIERS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
montelukast granules AE, 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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

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

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

RESPIRATORY: BRONCHODILATORS, BETA-AGONIST

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
AirDuo Respiclick CC, QL, AE AirDuo Digihaler 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
arformoterol CC, QL formoterol 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

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

CURRENT PDL STATUS

BETA AGONISTS: COMBINATION PRODUCTS

Preferred Agents	Non-Preferred Agents
Advair Diskus QL	AirDuo Digihaler CC, QL
Advair HFA QL	AirDuo Respiclick CC, QL, AE
Dulera HFA QL	Breo Ellipta QL
Symbicort HFA QL	Breyna HFA QL
	budesonide/formoterol HFA QL
	fluticasone/salmeterol inhalation powder QL
	fluticasone/salmeterol HFA QL
	fluticasone/vilanterol QL
	Wixela Inhub QL

LONG-ACTING BETA$_2$ ADRENERGIC AGONISTS

Preferred Agents	Non-Preferred Agents
Serevent Diskus QL	Arformoterol solution CC, QL
	Brovana solution CC, QL
	Formoterol solution CC, QL
	Perforomist CC, QL
	Striverdi Respimat QL

SHORT-ACTING BETA$_2$ ADRENERGIC AGONISTS

Preferred Agents	Non-Preferred Agents
albuterol sulfate solution QL	Airsupra HFA QL
Proventil HFA QL	albuterol sulfate HFA QL
terbutaline tablets QL	albuterol sulfate syrup QL
Ventolin HFA QL	albuterol sulfate ER tablet QL
	albuterol sulfate tablet QL
	levalbuterol concentrate solution QL
	levalbuterol HFA QL
	levalbuterol solution QL
	ProAir® Digihaler QL
	ProAir Respiclick QL
	Xopenex HFA QL

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

RESPIRATORY: EPINEPHRINE, SELF-INJECTABLE

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

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

RESPIRATORY: CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Breztri Aerosphere CC, QL	• Diagnosis of chronic obstructive pulmonary disorder (COPD); **AND** • 2-week trial and failure (e.g., limited ability to use or comply with multiple devices) of triple-ingredient therapy (such as, glucocorticoid, long-acting beta agonist, and long-acting muscarinic antagonist) among single- and dual-ingredient inhalers (e.g., Flovent HFA and Anoro Ellipta or Stiolto Respimat). **Age Limit:** ≥ 18 years
roflumilast CC, QL	• Diagnosis of chronic obstructive pulmonary disorder (COPD); **AND** • Documentation (e.g., progress notes) of FEV^1 ≤ 50% of predicted.

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Daliresp 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.

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

Agent(s) Subject to Criteria	Criteria for Approval

	Approval Duration: 6 months initial, 1 year renewal
	
	Initial Approval Criteria:
	• 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])
	
	Renewal Criteria:
	• Clinically significant improvement or stabilization in signs and symptoms
	
	Age Limit: 18 years of age or older
	Quantity Limit: 5 mL per day

Trelegy Ellipta CC, QL	**Asthma** • Diagnosis of asthma; **AND** • Failure (e.g., limited ability to use or comply with multiple devices) of at least a 2-week trial of triple-ingredient therapy (glucocorticoid, long-acting beta agonist, and long-acting muscarinic antagonist) among single- and dual-ingredient inhalers (e.g., Flovent HFA and Bevespi Aerosphere). **COPD** • Diagnosis of chronic obstructive pulmonary disease (COPD); **AND** • Patient has had at least a 30-day trial and failure of Breztri Aerosphere. **Age Limit:** ≥ 18 years
Yupleri CC, QL	• Diagnosis of chronic obstructive pulmonary disorder (COPD); **AND** • 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

CURRENT PDL STATUS

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

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Yupelri solution CC, QL

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

RESPIRATORY: GLUCOCORTICOIDS, INHALED

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
budesonide inhalation suspension AE, 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., Flovent HFA) 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 2 preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Asmanex Twisthaler QL	Alvesco QL
budesonide inhalation suspension AE, QL	ArmonAir Digihaler QL
Flovent HFA QL	Arnuity Ellipta QL
fluticasone propionate HFA QL	Asmanex HFA QL
Pulmicort Flexhaler QL	Flovent Diskus QL
	Pulmicort Respules QL
	Qvar Redihaler

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

CENTRAL NERVOUS SYSTEM: ALZHEIMER'S AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
donepezil ODT	Adlarity patch
Donepezil 5 mg, 10 mg tablet	Aricept tablet
Exelon patch	donepezil 23 mg tablet CC
memantine tablet dose pack	galantamine ER capsule
memantine tablet	galantamine solution
rivastigmine capsule	galantamine tablet
	memantine/donepezil HCl ER sprinkle capsule
	memantine ER sprinkle capsule
	memantine solution

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Namenda tablet dose pack
	Namenda tablet
	Namenda XR sprinkle capsule
	Namenda XR capsule dose pack
	Namzaric sprinkle dose pack
	Namzaric capsule dose pack
	rivastigmine patch

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

CENTRAL NERVOUS SYSTEM: ANXIOLYTICS

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 tablets MD chlordiazepoxide MD diazepam oral solution, tablets MD diazepam oral concentrate MD lorazepam MD alprazolam ER/XR MD alprazolam ODT MD alprazolam Intensol MD Ativan MD clorazepate MD diazepam Intensol MD lorazepam intensol MD oxazepam MD Xanax MD Xanax XR 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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
alprazolam IR tablets MD	alprazolam ER tablet MD
buspirone tablet	alprazolam intensol oral concentrate MD
chlordiazepoxide capsule MD	alprazolam ODT MD
diazepam oral solution MD	alprazolam XR tablet MD
diazepam oral tablet MD	Ativan tablet MD
lorazepam tablet MD	Bucapsol capsule
	clorazepate dipotassium tablet MD
	diazepam oral concentrate MD
	lorazepam intensol oral concentrate MD
	lorazepam oral concentrate MD
	Loreev XR capsule MD
	meprobamate tablet
	oxazepam capsule MD
	Xanax tablet MD
	Xanax XR tablet MD

CENTRAL NERVOUS SYSTEM: ANTICONVULSANTS

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.
phenobarbital CC primidone CC or Mysoline	**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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Briviact CC, QL	• Diagnosis of partial-onset seizures; **AND** • Trial and failure of at least 1 preferred agent **AND** • ≥ 1 month of age.

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

Agent(s) Subject to Criteria	Criteria for Approval
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** • Trial and failure (e.g., incomplete seizure control) of ≥ 2 anticonvulsants.

Epidiolex CC	• Patient is ≥ 1 year old; **AND**
	• Diagnosis of:
	  ○ Lennox-Gastaut syndrome (LGS); **OR**
	  ○ Dravet syndrome (DS); **OR**
	  ○ Tuberous Sclerosis Complex (TSC); **AND**
	• Prescriber is, or has a consultative relationship with, a neurology/epilepsy specialist; **AND**
	• Trial and failure (e.g., incomplete seizure control) of ≥ 2 anticonvulsants; **AND**
	• Must be used in adjunct with ≥ 1 anticonvulsant

levetiracetam tablet 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 CC, QL	• Clinical rationale that clobazam suspension or tablets cannot be used.
Vigafyde solution 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 Limits:** • 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

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
Ztalmy AE, CC, QL	**Approval Duration:** 1 year **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. **Renewal Criteria** • Patient must continue to meet the above criteria; **AND** • Prescriber attests to stabilization of disease or reduction in seizure frequency from baseline **Quantity Limit:** 1800mg (36mL) per day **Age Limit:** 2 years of age

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Banzel suspension CC, QL	Aptiom tablet QL
Banzel tablet CC, QL	Briviact solution CC, QL
carbamazepine ER capsule	Briviact tablet CC, QL
carbamazepine ER tablet	carbamazepine suspension
carbamazepine tablet	Carbatrol ER capsule
carbamazepine chewable tablet	clobazam syringe QL
Celontin capsule	clonazepam ODT QL
clobazam suspension QL	Depakote ER tablet
clobazam tablet QL	Depakote sprinkle capsule
clonazepam tablet QL	Depakote tablet
diazepam rectal gel QL	Diacomit capsule CC, QL
divalproex sodium DR sprinkle capsule	Diacomit powder packet CC, QL
divalproex sodium DR tablet	Diastat Acudial kit QL
divalproex sodium ER tablet	Diastat kit QL
Equetro	Dilantin capsule
ethosuximide capsule	Dilantin chewable tablet
ethosuximide solution	Dilantin-125 suspension
felbamate suspension	Elepsia XR tablet QL
felbamate tablet	Epidiolex solution CC
Gabitril tablet QL	Epitol tablet
lacosamide solution QL	Eprontia solution
lacosamide tablet QL	eslicarbazepine tablet QL
lamotrigine tablet	Felbatol suspension

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Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
lamotrigine chewable tablet	Felbatol tablet
levetiracetam ER tablet QL	Fintepla solution QL
levetiracetam solution QL	Fycompa suspension
levetiracetam tablet QL	Fycompa tablet QL
Nayzilam spray AE, QL	Keppra solution
oxcarbazepine suspension	Keppra tablet QL
oxcarbazepine tablet QL	Keppra XR tablet QL
phenobarbital elixir CC	Klonopin tablet QL
phenobarbital tablet CC	Lamictal tablet dose packs
phenytoin suspension	Lamictal ODT dose packs
phenytoin sodium ER capsule	Lamictal XR tablet dose packs
phenytoin chewable tablet	Lamictal ODT
primidone tablet	Lamictal tablet
Roweepra tablet QL	Lamictal chewable tablet
Sabril powder packet QL CC	Lamictal XR tablet QL
Sabril tablet CC, QL	lamotrigine tablet dose packs
Tegretol suspension	lamotrigine ODT dose packs
tiagabine tablet QL	lamotrigine ER tablet QL
topiramate sprinkle capsule QL	lamotrigine ODT
topiramate tablet QL	levetiracetam tablet suspension CC, QL
valproic acid capsule	Libervant film AE, QL
valproic acid solution	methsuximide capsule
Valtoco spray QL	Motpoly XR capsule
zonisamide capsule QL	Mysoline tablet CC
	Onfi suspension QL
	Onfi tablet QL
	Oxcarbazepine ER tablet QL
	Oxtellar XR tablet QL
	Phenytek capsule
	Qudexy XR sprinkle capsule QL
	rufinamide suspension QL
	rufinamide tablet QL
	Spritam suspension QL
	Subvenite tablet dose packs
	Subvenite tablet
	Sympazan film CC, QL
	Tegretol tablet
	Tegretol XR tablet
	Topamax sprinkle capsule QL
	Topamax tablet QL
	Topiramate ER capsule QL
	Topiramate ER sprinkle capsule QL
	Trileptal suspension
	Trileptal tablet QL
	Trokendi XR capsule QL
	Vigabatrin powder packet QL
	Vigabatrin tablet QL
	Vigadrone powder packet QL
	Vigadrone tablet QL
	Vigafyde solution QL

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Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Vimpat solution QL
	Vimpat tablet QL
	Xcorpi tablet dose pack AE, CC, QL
	Xcorpi tablet AE, CC, QL
	Zarontin capsule
	Zarontin solution
	Zonisamide suspension QL
	Ztalmy suspension AE, CC, QL

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CENTRAL NERVOUS SYSTEM: ANTIPSYCHOTICS: FIRST GENERATION (TYPICAL)

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY 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	

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

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

GUIDELINES FOR USE

Approval Duration: 1 year

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 Vraylar AE, 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.
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

Prior Authorization Criteria

Kentucky Medicaid

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.
Uzedy AE, CC, QL	• Patient has a diagnosis of schizophrenia **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe per 30 days

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

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

Prior Authorization Criteria

Kentucky Medicaid

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	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
	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

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

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	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
	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

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Abilify MyCite CC, QL	• Trial and failure of, or intolerance/contraindication to, ≥ 1 long-acting antipsychotic
Caplyta CC, QL	**Initial Criteria:**

Agent(s) Subject to Criteria	Criteria for Approval
	• 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. **OR** • Patient has a confirmed diagnosis of schizophrenia AND • Trial and failure of ≥ 2 preferred antipsychotics. **Renewal Criteria:** • 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	**Initial Approval Criteria** • 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 of age or older **Quantity Limit:** 2 capsules per day

Lybalvi AE, CC, QL	**Initial Approval Criteria**
	• 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

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

Agent(s) Subject to Criteria	Criteria for Approval
	Age Limit: ≥ 18 years of age **Quantity Limit:** 30 tablets/30 days
Nuplazid 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:** 2 tablets per day (60 tablets per 30 days)

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);
	  ○ 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 film: 1 per day
	• 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.

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

Agent(s) Subject to Criteria	Criteria for Approval
	Quantity Limit: 1 capsule 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 starter kit CC, QL
asenapine tablet CC, QL	Abilify MyCite maintenance kit CC, QL
clozapine tablet CC, QL	Abilify tablet QL
lurasidone tablet CC, QL	aripiprazole ODT
olanzapine ODT CC, QL	aripiprazole solution
olanzapine tablet CC, QL	Caplyta capsule CC, QL
quetiapine tablet CC, QL	clozapine ODT QL
quetiapine ER tablet CC, QL	Clozaril tablet QL
risperidone ODT CC, QL	Cobenfy capsule AE, CC, QL
risperidone solution CC, QL	Fanapt tablet dose pack QL
risperidone tablet CC, QL	Fanapt tablet QL
Vraylar capsule dose pack AE, CC, QL	Geodon capsule QL
Vraylar capsule AE, CC, QL	Invega ER tablet QL
ziprasidone capsule CC, QL	Latuda tablet QL
	Lybalvi tablet AE, CC, QL
	Nuplazid capsule CC, QL
	Nuplazid tablet CC, QL
	olanzapine/fluoxetine capsule CC, QL
	Opipza film CC, QL
	paliperidone ER tablet QL
	Rexulti tablet QL
	Risperdal solution QL
	Risperdal tablet QL
	Saphris SL tablet QL

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Secuado patch QL
	Seroquel tablet QL
	Seroquel XR tablet QL
	Symbyax capsule CC, QL
	Versacloz suspension QL
	Zyprexa tablet QL
	Zyprexa Zydis ODT QL

ANTIPSYCHOTICS: INJECTABLE

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

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CENTRAL NERVOUS SYSTEM: DOPAMINE RECEPTOR AGONISTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
pramipexole tablet	bromocriptine capsule
ropinirole tablet	bromocriptine tablet
	Mirapex ER tablet
	Neupro patch
	Parlodel capsule
	Parlodel tablet
	pramipexole ER tablet
	ropinirole ER tablet

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

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Nourianz 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)

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

Agent(s) Subject to Criteria	Criteria for Approval
	Age Limit: ≥ 18 years **Quantity Limit: 1** per day

Ongentys 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**
	• 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	**Initial Approval Criteria:**
	• 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 of age or older
	Quantity Limit: 2 vials (20 mL) per day

Xadago 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**

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
	• 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** tablet per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
amantadine capsule	Azilect tablet
amantadine solution	carbidopa tablet
amantadine tablet	Comtan tablet
benztropine tablet	Crexont IR ER capsule
carbidopa/levodopa ER tablet	Dhivy tablet
carbidopa/levodopa ODT	Duopa suspension
carbidopa/levodopa tablet	Gocovri capsule
carbidopa/levodopa/entacapone tablet	Inbrija inhalation
entacapone tablet	Lodosyn tablet
selegiline capsule	Nourianz tablet CC QL
selegiline tablet	Ongentys capsule CC, QL
trihexyphenidyl solution	Osmolex ER tablet
trihexyphenidyl tablet	rasagiline tablet
	Rytary ER capsule
	Sinemet tablet
	Stalevo tablet
	Tasmar tablet
	Vyalev vial AE, CC, QL
	Xadago CC, QL
	Zelapar ODT

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

CENTRAL NERVOUS SYSTEM: MOVEMENT DISORDERS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval

Austedo [CC, AE, QL]	**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:
	• 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:
	  ○ 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

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

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:** • 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

Not applicable.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval
Austedo XR [CC, QL]	**Huntington's Chorea** • Patient is diagnosed with chorea related to Huntington's disease; **AND**

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

Agent(s) Subject to PA Criteria	Criteria for Approval

	• 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:
	• 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).

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Austedo tablet CC, AE, QL	Austedo XR tablet CC, QL
Ingrezza capsule AE, CC, QL	Austedo XR tablet titration kit CC
Ingrezza sprinkle capsule AE, CC, QL	Xenazine
tetrabenazine tablet	

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CENTRAL NERVOUS SYSTEM: ANTIDEPRESSANTS

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

5. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

6. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Auvelity CC, AE, QL	**Approval Duration:** 1 year **Initial Approval Criteria** • Diagnosis of major depressive disorder**; 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)

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

Agent(s) Subject to Criteria	Criteria for Approval
	Renewal Criteria • Patient must continue to meet the above criteria; **AND** • Patient must have disease improvement and/or stabilization of disease; **AND** **Quantity Limit:** 60 tablets per 30 days **Age Limit:** ≥ 18 years old

Raldesy AE, CC	**Approval Duration: 6 months initial; 1 year renewal**
	
	Initial Approval Criteria
	• 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
	• 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 of age

Spravato CC, QL	**Approval Duration:** 4 weeks initial; 1 year renewal (treatment resistant depression only)
	
	Initial Approval Criteria
	
	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

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Agent(s) Subject to Criteria	Criteria for Approval
	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** ○ 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.

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Agent(s) Subject to Criteria	Criteria for Approval
	Age Limit: ≥ 18 years old **Quantity Limit:** 1 kit (56 or 84 mg) per week; overrides allowed for twice weekly)
Zurzuvae CC, QL	**Approval Duration**: 6 months with limit of 2 courses of treatment (28 days) **Initial Approval Criteria:** • Diagnosis of postpartum depression (PPD) in adults • Within one year of giving birth. **Quantity Limit:** maximum 14 day supply per fill, maximum 2 fills per 180 days

CURRENT PDL STATUS

ANTIDEPRESSANTS: OTHER

Preferred Agents	Non-Preferred Agents
bupropion tablet	Aplenzin ER tablet
bupropion SR tablet	Auvelity tablet CC, AE, QL
bupropion XL 150 mg, 300 mg tablet	bupropion XL 450 mg tablet
mirtazapine ODT	Forfivo XL tablet
mirtazapine tablet	nefazodone tablet
trazodone tablet	Raldesy solution AE, CC
	Remeron Soltab
	Remeron tablet
	Spravato spray CC, AE, QL
	Trintellix tablet
	Viibryd tablet dose pack
	Viibryd tablet
	Vilazodone tablet
	Wellbutrin SR tablet
	Wellbutrin XL tablet
	Zurzuvae capsule CC, QL

ANTIDEPRESSANTS: SNRIS

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

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Prior Authorization Criteria

Kentucky Medicaid

ANTIDEPRESSANTS: SSRIS

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

ANTIDEPRESSANTS: TRICYCLICS

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

ANTIDEPRESSANTS: MAOIs

Preferred Agents	Non-Preferred Agents
	Emsam patch
	Marplan tablet
	Nardil tablet
	phenelzine tablet
	tranylcypromine tablet

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CENTRAL NERVOUS SYSTEM: ANTI-MIGRAINE AGENTS, TRIPTANS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
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
   - CGRP inhibitor: Ajovy, Emgality 120 mg/mL
   - Botulinum toxin: Botox

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Imitrex nasal spray QL	almotriptan tablet QL
rizatriptan ODT QL	eletriptan tablet QL
rizatriptan tablet QL	Frova tablet QL
sumatriptan nasal spray QL	frovatriptan tablet QL
sumatriptan tablet QL	Imitrex cartridge QL
sumatriptan vial QL	Imitrex pen QL
	Imitrex tablet QL
	Maxalt-MLT ODT QL
	Maxalt tablet QL
	naratriptan tablet 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

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Aimovig CC, QL Ajovy CC, QL Emgality 120 mg/mL CC, QL Nurtec ODT CC, QL *(for prevention of episodic migraine)*	**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: 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**: ≥ 18 years
Nurtec ODT 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**

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Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
Qulipta AE, CC, QL	**Approval Duration:** 3 months initial; 1 year renewal **Initial Approval Criteria** *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 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 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:** • 30mg tablet and 60mg tablet: 30 tablets per 30 days • 10mg tablet: 60 tablets per 30 days
Ubrelvy 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.

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

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

Not applicable

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Emgality 100 mg/mL CC, AE, 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
Reyvow CC, AE, QL	• Diagnosis of migraine, with or without aura; **AND** • NOT have severe hepatic impairment (Child-Pugh C); **AND** • Trial and failure of at least one of the following: NSAID, non-opioid analgesic, acetaminophen, OR caffeinated analgesic combination; **AND** • Trial and failure, or contraindication to, ≥ 2 triptans; **AND** • Prescriber attests patient has been educated about need to refrain from driving or operating machinery for ≥ 8 hours after dose. **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:** 8 tablets (1 package) per 30 days – no exceptions

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

Agent(s) Subject to Criteria	Criteria for Approval
Zavzpret CC, AE, QL	**Initial Approval Criteria** • 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. **Quantity Limit:** 8 nasal spray devices per 30 days **Age Limit:** ≥ 18 years old

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

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Aimovig autoinjector CC, AE, QL	Emgality 100 mg/mL syringe CC, AE, QL
Ajovy autoinjector CC, AE, QL	Reyvow tablet CC, AE, QL
Ajovy syringe CC, AE, QL	Zavzpret CC, AE, QL
Emgality pen CC, AE, QL	
Nurtec ODT CC, AE, QL	
Qulipta tablet CC, AE, QL	
Ubrelvy tablet CC, AE, QL	

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CENTRAL NERVOUS SYSTEM: STIMULANTS AND RELATED AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval
Adderall XR CC, QL atomoxetine CC, QL clonidine ER CC, QL Concerta CC, QL dexmethylphenidate CC, QL dexmethylphenidate ER CC, QL dextroamphetamine 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 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) ○ 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 capsules, chewable 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** • 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.

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

Agent(s) Subject to PA Criteria	Criteria for Approval
	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]

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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. 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.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Adderall XR capsule CC, QL	Adderall capsule QL
atomoxetine capsule CC, QL	Adzenys XR-ODT tablet AE, QL
clonidine ER tablet CC, QL	amphetamine sulfate tablet QL
Concerta tablet CC, QL	Aptensio XR sprinkle capsule QL
dexmethylphenidate ER tablet CC, QL	Azstarys capsule QL
dexmethylphenidate tablet CC, QL	Cotempla XR-ODT tablet AE, QL
dextroamphetamine sulfate tablet CC, QL	Daytrana patch QL
dextroamphetamine/amphetamine ER capsule CC, QL	Desoxyn tablet QL

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Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
dextroamphetamine/amphetamine ER capsule CC, QL	Desoxyn tablet QL
dextroamphetamine/amphetamine tablet CC, QL	Dexedrine capsule ER QL
dextroamphetamine sulfate 5 mg, 10 mg, 15 mg	dextroamphetamine ER capsule QL
guanfacine ER tablet CC, QL	dextroamphetamine solution QL
Methylin solution CC, QL	dextroamphetamine sulfate tablet 2.5 mg, 7.5 mg, 20 mg, 30 mg QL
methylphenidate solution CC, QL	Dyanavel XR suspension AE, QL
methylphenidate ER tablet 10 mg, 20 mg CC, QL	Dyanavel XR tablet AE, QL
methylphenidate tablet CC, QL	Evekeo ODT QL
Qelbree ER capsule CC, QL	Evekeo tablet QL
Vyvanse capsule CC, QL	Focalin tablet QL
Vyvanse chewable tablet CC, QL	Focalin XR capsule QL
	Intuniv ER tablet QL
	Jornay PM capsule AE, QL
	lisdexamfetamine capsule QL
	lisdexamfetamine chewable tablet QL
	methamphetamine tablet QL
	methylphenidate CD capsule QL
	methylphenidate ER capsule QL
	methylphenidate ER tablet 18 mg, 27 mg, 36 mg, 54 mg, 63 mg, 72 mg tablet QL
	methylphenidate ER sprinkle capsule QL
	methylphenidate LA capsule QL
	methylphenidate ER OROS QL
	methylphenidate chewable tablet QL
	methylphenidate patch QL
	Mydayis ER capsule AE, QL
	Onyda XR suspension AE, QL
	ProCentra solution QL
	QuilliChew ER tablet AE, QL
	Quillivant XR QL
	Relexxii tablet QL
	Ritalin LA capsule QL
	Ritalin tablet QL
	Strattera capsule QL
	Xelstrym patch QL
	Zenzedi QL

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CENTRAL NERVOUS SYSTEM: NARCOLEPSY AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to PA Criteria	Criteria for Approval
Nuvigil CC, QL Provigil 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). ○ 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
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	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

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Known or suspected allergy, intolerance, or contraindication to an *inactive* ingredient in the preferred brand formulation

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** o Trial and failure of ≥ 1 stimulant (e.g., amphetamine); **OR** • Diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA); **AND** o Member is using constant positive airway pressure (CPAP).
Wakix CC, QL	• Prescriber is a neurologist, sleep medicine, or other specialist in the treatment of narcolepsy; **AND**

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

Agent(s) Subject to Criteria	Criteria for Approval
	• 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 symptoms.
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 to be caused by high sodium content of Xyrem.
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**

Agent(s) Subject to Criteria	Criteria for Approval
	• 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** • 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.

CURRENT PDL STATUS

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

CENTRAL NERVOUS SYSTEM: NEUROPATHIC PAIN

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

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 • 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
	• Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to BOTH of the following:
	  ○ lidocaine 5% patch; AND
	  ○ capsaicin (OTC)
	• **Quantity Limit**: 3 per day

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Prior Authorization Criteria

Kentucky Medicaid

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
duloxetine DR capsule (generic Cymbalta)	Cymbalta DR capsule
gabapentin capsule QL	Drizalama sprinkle capsule
gabapentin solution QL	duloxetine DR capsule (generic Irenka)
gabapentin tablet QL	Gabarone tablet CC, QL
Lidocaine patch QL	Gralise tablet (brand and generic)
Lidoderm patch QL	Horizant tablet
pregabalin capsule QL	Lyrica capsule QL
pregabalin solution QL	Lyrica CR tablet QL
	Lyrica solution QL
	Neurontin capsule QL
	Neurontin solution QL
	Neurontin tablet QL
	pregabalin ER tablet QL
	Savella tablet dose pack
	Savella tablet
	ZTlido patch CC, QL

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CENTRAL NERVOUS SYSTEM: SEDATIVE HYPNOTICS

GUIDELINES FOR USE

Approval Duration: 1 year

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
Lunesta 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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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	**Initial Approval Criteria** • 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. **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**

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Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
	• Patient has not experienced any treatment-restricting adverse effects (e.g., syncope, orthostatic hypotension, fall, QT prolongation, symptomatic bradycardia). **Age Limit: ≥ 18 years** **Quantity Limit: 2 per day**
Quviviq AE, CC, MD, QL	• 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	• Trial of preferred agents can be waived if there is a history of substance abuse
temazepam 7.5 mg, 22.5 mg MD, QL	• Trial and failure of 15 mg dose; **OR** • Prescriber requests 7.5 mg starting dose

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
	Lunesta tablet MD, 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

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

Preferred Agents	Non-Preferred Agents
	zolpidem SL tablet MD, QL

CENTRAL NERVOUS SYSTEM: SKELETAL MUSCLE RELAXANTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
dantrolene QL, CC	• NPD criteria; **OR** • Prescribed for prophylaxis against malignant hyperthermia
tizanidine capsules QL	• Trial and failure of tizanidine tablets at the requested dose.
Amrix QL, MD carisoprodol QL, MD carisoprodol compound QL, MD Fexmid QL, MD Soma QL, MD	• 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.

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

CURRENT PDL STATUS

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

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

CENTRAL NERVOUS SYSTEM: TOBACCO CESSATION

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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	

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

SPINAL MUSCULAR ATROPHY

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable.

2. NON-PREFERRED (NPD) CRITERIA

Not applicable.

3. BRAND MEDICALLY NECESSARY CRITERIA

Not applicable.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Evrysdi oral solution [CC]
Evrysdi oral tablet [CC, QL]
	Initial Approval Criteria:
	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**

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

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).
	
	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**
	• 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:
	  ○ 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**

Agent(s) Subject to Criteria	Criteria for Approval
	▪ 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.). • Not to be used in combination with Spinraza (nusinersen); **AND** • Patient has not received treatment with Zolgensma (onasemnogene abeparvovec-xioi).
Spinraza CC	**Approval Duration: 6 months initial; 12 months renewal** **Initial Approval Criteria (must meet all requirements):** • 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**

Agent(s) Subject to Criteria	Criteria for Approval

	• 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**
	• 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

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

Agent(s) Subject to Criteria	Criteria for Approval

Zolgensma CC	**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).

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Not applicable	Evrysdi oral solution CC
	Evrysdi oral tablet CC, QL
	Spinraza vial CC
	Zolgensma kit CC

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

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 tramadol ER (generic Ultram ER)CC, AE, 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

1. OPIOID CLASS CRITERIA

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

2. 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.

3. 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.

4. BRAND MEDICALLY NECESSARY CRITERIA

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

5. GENERIC MEDICALLY NECESSARY CRITERIA

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

6. 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 has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); **AND**

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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
tramadol ER tablet (generic Ultram ER) CC, AE, QL	Diskets
	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
	OxyContin ER tablet QL
	oxymorphone ER tablet QL
	tramadol ER capsule AE, QL
	tramadol ER tablet (generic Ryzolt) AE, QL

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 CC, AE, 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 CC, MD, AE, QL
tramadol/APAP MD, AE, 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

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

Agent(s) Subject to Criteria	Criteria for Approval

	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**
	• 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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

5. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

6. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Ascomp® with codeine CC, AE, QL butalbital/APAP/caffeine/codeine CC, QL butalbital/ASA/caffeine/codeine CC, AE, QL butalbital compound/codeine CC, AE, 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 CC, AE, MD, QL	APAP/caffeine/dihydrocodeine capsule MD, QL
codeine/APAP tablet CC, AE, MD, QL	ASA/butalbital/caffeine/codeine capsule CC, AE, QL
hydrocodone/APAP solution CC, MD, QL	Ascomp with codeine capsule CC, AE, QL
hydrocodone/APAP tablet CC, MD, QL	butalbital/APAP/caffeine/codeine capsule CC, AE, QL
hydrocodone/ibuprofen tablet CC, MD, QL	butalbital/codeine capsule CC, AE, QL
hydromorphone tablet CC, MD, QL	codeine tablet MD, AE, 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 CC, AE, 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 CC, MD, AE, QL	meperidine tablet MD, QL
tramadol/APAP tablet MD, AE, 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

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Percocet tablet MD, QL
	Prolate solution MD, QL
	Prolate tablet MD, QL
	Qdolo MD, AE, QL
	Roxicodone tablet MD, QL
	Roxybond tablet MD, QL
	Seglentis tablet MD, AE, QL
	tramadol 25 mg tablet MD, AE, QL
	tramadol 75 mg tablet MD, AE, QL
	tramadol 100 mg tablet MD, AE, QL
	tramadol solution MD, AE, QL

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

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.

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.

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]).

ANALGESICS: NARCOTICS, FENTANYL BUCCAL 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. Opioid class general criteria has to be met, see pages for ANALGESICS (CLINICAL CRITERIA FOR SHORT-ACTING AND LONG-ACTING OPIOIDS); **AND**

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

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

d. 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

Approval of NON-PREFERRED branded agents requires:

a. tried and failed or had a contraindication to 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; **AND**

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

Prior Authorization Criteria

Kentucky Medicaid

CURRENT PDL STATUS

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

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

ANALGESICS: NARCOTIC AGONISTS/ANTAGONISTS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable.

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 in the Analgesics: Narcotics, Short-Acting class.

3. BRAND MEDICALLY NECESSARY CRITERIA

Not applicable.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

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

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

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

GUIDELINES FOR USE

Approval Duration: 1 year

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 2 preferred agents, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Duexis (ibuprofen/famotidine) CC naproxen/esomeprazole CC, QL Vimovo (naproxen/esomeprazole) CC, QL	• NPD Criteria above; **OR** • Trial and failure (e.g., poor adherence) of individual, generic components
Elyxyb solution AE, CC, QL meloxicam capsules CC Vivlodex (meloxicam submicronized) CC, QL Zorvolex (diclofenac submicronized) CC	• NPD Criteria above; **OR** • Trial and failure of the preferred, generic formulation of the same ingredient as 1 of the 2 NPD trials; **AND** **Age Edit:** ≥ 18 years old (Elyxyb)

diclofenac epolamine patches CC
diclofenac 2% solution pump CC
diclofenac topical solution CC
Flector CC
ketorolac nasal spray CC
Licart CC
Pennsaid 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.

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
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.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
celecoxib QL	Arthrotec
diclofenac sodium topical gel (1%)	Celebrex QL
diclofenac sodium DR/EC tablets	Daypro
Ibu tablet	diclofenac epolamine patch CC
Ibuprofen tablet	diclofenac potassium capsule
indomethacin capsule	diclofenac potassium powder pack
indomethacin ER capsule	diclofenac potassium tablet
ketorolac tablet	diclofenac topical solution CC
meloxicam tablet	diclofenac sodium SR/ER tablet
nabumetone tablet	diclofenac 2% solution pump CC
naproxen sodium tablet	diclofenac sodium/misoprostol
naproxen tablet	diflunisal tablet
piroxicam capsule	Dolobid tablet QL
sulindac tablet	Duexis tablet CC
	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/famotidine tablet
	indomethacin suppository
	indomethacin suspension QL
	ketoprofen ER capsule
	ketoprofen capsule
	ketorolac nasal spray CC
	Kiprofen capsule
	Licart patch CC
	Lofena tablet
	meclofenamate capsule
	mefenamic acid capsule
	meloxicam capsule CC, QL
	Nalfon capsule
	Nalfon tablet
	Naprelan CR tablet

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Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Naprosyn
	naproxen DR tablet
	naproxen suspension
	naproxen sodium CR/ER tablet
	naproxen/esomeprazole DR tablet CC, QL
	oxaprozin tablet
	Pennsaid CC
	Relafen tablet
	Relafen DS tablet
	Tolectin 600 tablet
	tolmetin capsule
	Tolmetin tablet QL
	Vimovo 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

Not applicable.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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.

Prior Authorization Criteria

Kentucky Medicaid

CURRENT PDL STATUS

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

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

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) or intolerance of or evidence of organism resistance to generic itraconazole (for systemic infection) or 2 preferred agents.

3. BRAND MEDICALLY NECESSARY CRITERIA

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Brexafemme CC, QL	**Initial Approval Criteria for Vulvovaginal Candidiasis Treatment:** • Patient is a post-menarchal female; **AND** • Diagnosis of vulvovaginal candidiasis (VVC); **AND**

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

Agent(s) Subject to Criteria	Criteria for Approval
	• Females of reproductive potential must have a negative pregnancy test; **AND** • Patient must have an adequate trial and failure, contraindication, resistance, or intolerance of single dose 150 mg oral fluconazole. **Renewal Criteria:** Cannot be renewed for the same course of infection. **Initial Approval Criteria for Vulvovaginal Candidiasis Prophylaxis:** • Patient is a post-menarchal female; **AND** • Patient has a history of recurrent vulvovaginal candidiasis (RVVC, defined as ≥ 3 culture-confirmed episodes in ≤ 12 months); **AND** • Used for recurrent vulvovaginal candidiasis prophylaxis; **AND** • Females of reproductive potential must have negative pregnancy test; **AND** • Patient must have an adequate trial and failure, contraindication, resistance, or intolerance to oral fluconazole or other triazoles. **Renewal Criteria:** • Females of reproductive potential must have negative pregnancy test; **AND** • Patient must have a reduction in the recurrence of vulvovaginal candidiasis; **AND** • Maintenance treatment cannot exceed 6 months of therapy. **Quantity Limit:** 4 tablets per fill
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. **Quantity Limit:** 18 tablets per treatment course

Prior Authorization Criteria

Kentucky Medicaid

CURRENT PDL STATUS

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

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

ANTI-INFECTIVE: ORAL ANTIVIRALS

GUIDELINES FOR USE

Approval Duration: 1 year

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 agents from the same sub-class, unless otherwise specified.

3. BRAND MEDICALLY NECESSARY CRITERIA

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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

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

CURRENT PDL STATUS

ANTIVIRALS: HERPES

Preferred Agents	Non-Preferred Agents
acyclovir	Sitavig
famciclovir	Valtrex
valacyclovir	

ANTIVIRALS: INFLUENZA

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

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 capsules, solution CC	• Diagnosis of *clostridium difficile*-associated diarrhea (ICD-10 = A04.7); **OR** • Diagnosis of *Staphylococcal* enterocolitis.

Xifaxan CC, QL	**200 mg tablets:**
	Approval Duration: Date of Service (3-day course of therapy)
	• Patient age ≥ 12 years; **AND**
	• Diagnosis of traveler's diarrhea caused by non-invasive strains of E. coli; **AND**
	• Trial and failure of ciprofloxacin.
	
	550 mg tablets:
	Approval Duration: 1 year (hepatic encephalopathy) or 3 treatment cycles (irritable bowel syndrome)
	• Patient age ≥ 12 years; **AND**
	• Diagnosis of hepatic encephalopathy (ICD-10 = K72.9); **AND**
	  ○ Trial and failure of lactulose or neomycin; **OR**
	• Diagnosis of irritable bowel syndrome with diarrhea (IBS-D); **AND**
	  ○ Trial and failure of ≥ 1 antidiarrheal agent.
	
	Quantity Limits:
	• **200 mg:** 2 per day
	• **550 mg:** 2 per day; allow 3 per day (42 tablets per 14 days) when used for IBS-D

linezolid tablets CC, QL, MD	• 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

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

Agent(s) Subject to Criteria	Criteria for Approval
	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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Dificid 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. **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**

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

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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 *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)

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

Agent(s) Subject to Criteria	Criteria for Approval

	Initial Approval Criteria:
	• 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 of age
	Quantity Limit: 12 capsules over 3 days

CURRENT PDL STATUS

ANTIBIOTICS: CEPHALOSPORINS 1ST GENERATION

Preferred Agents	Non-Preferred Agents
cefadroxil capsule, suspension	cefadroxil tablet
cephalexin capsule, suspension	cephalexin tablet

ANTIBIOTICS: CEPHALOSPORINS 2ND GENERATION

Preferred Agents	Non-Preferred Agents
cefaclor capsule	cefaclor suspension
cefprozil suspension, tablet	cefaclor ER tablet
cefuroxime axetil tablet	

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

ANTIBIOTICS: CEPHALOSPORINS 3RD GENERATION

Preferred Agents	Non-Preferred Agents
cefdinir capsule, suspension	cefixime capsule, suspension
	cefpodoxime suspension, 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	Firvanq CC
vancomycin capsule, solution CC	Flagyl
Xifaxan CC, QL	Likmez
	metronidazole capsule
	metronidazole 125 mg tablet CC
	nitazoxanide
	paromomycin
	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 200mg	EryPed
erythromycin base capsule DR	Ery-Tab DR 333 mg tablet
erythromycin base tablet DR 250, 500 mg tablet	Erythrocin
erythromycin ethylsuccinate suspension	erythromycin base tablet
Ery-Tab DR 250, 500 mg 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

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

Prior Authorization Criteria

Kentucky Medicaid

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
	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	Doryx, Doryx DR, Doryx MPC
doxycycline hyclate	doxycycline hyclate DR
doxycycline monohydrate 50 mg, 100 mg capsule	doxycycline IR-DR
doxycycline monohydrate suspension, tablet	doxycycline monohydrate 40, 75, 150 mg capsule
minocycline capsule	doxycycline “kit” or “pack”
tetracycline capsule	Lymepak
	minocycline tablet
	minocycline ER
	Minolira ER
	Morgidox capsule
	Morgidox Kit
	Nuzyra AE, CC, QL
	Oracea
	Solodyn
	tetracycline tablet
	Vibramycin

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

Prior Authorization Criteria

Kentucky Medicaid

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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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	metronidazole vaginal 1.30% gel
Nuvessa gel	Vandazole gel
	Xaciato gel

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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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.

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

Agent(s) Subject to Criteria	Criteria for Approval
	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** • 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 Limits**: 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:

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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** ○ Oral therapy for patients who plan to miss a dose of their cabotegravir/rilpivirine injection • 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 • Prescribed by or in consultation with an infectious disease specialist or HIV specialist. **Age Limit:** ≥ 12 years **Quantity Limit:** 1 per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
abacavir QL	Aptivus
abacavir-lamivudine	Atripla QL
atazanvir QL	Combivir
Biktarvy QL	darunavir
Cimduo QL	didanosine DR QL
Complera QL	efavirenz/lamivudine/tenofovir disoproxil fumarate QL
Delstrigo QL	emtricitabine QL

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
Descovy QL	Epivir QL
Dovato QL	Epzicom
Edurant Ped tablet suspension	etravirine
Edurant	fosamprenavir
efavirenz	Fuzeon
efavirenz/emtricitabine/tenofovir disoproxil fumarate QL	Kaletra solution, tablet
emtricitabine/tenofovir disoproxil fumarate QL	Lexiva
Emtriva QL	maraviroc
Evotaz QL	nevirapine QL
Genvoya QL	nevirapine ER QL
Intelence	Norvir tablet, powder packet
Isentress	Prezcobix QL
Juluca QL	Reyataz QL
lamivudine QL	Retrovir capsule, syrup
lamivudine-zidovudine	Rukobia AE, CC, QL
lopinavir-ritonavir solution	stavudine capsule QL
Odefsey QL	Sunlenca AE, CC, QL
Pifeltro QL	Tivicay suspension
Prezista	Triumeq suspension
ritonavir tablet	Truvada QL
Selzentry	Viracept
Stribild QL	Viread powder packet
Symfi QL	Viread tablet QL
Symfi Lo QL	Vocabria AE, CC, QL
Symtuza QL	Ziagen QL
tenofovir disoproxil fumarate tablet QL	zidovudine capsule
Tivicay tablets QL	
Triumeq tablet QL	
Trizivir	
Tybost	
zidovudine syrup, tablet	

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

HEPATITIS B AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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:** ≥ 18 years **Quantity Limit:** 1 per day (allow 2 per day for drug interactions)

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

Prior Authorization Criteria

Kentucky Medicaid

CURRENT PDL STATUS

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

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

HEPATITIS C AGENTS: INTERFERONS AND RIBAVIRINS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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	None

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

Prior Authorization Criteria

Kentucky Medicaid

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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. TREATMENT CRITERIA

Treatment Criteria Category	Criteria for Approval

Simplified HCV Treatment Criteria (treatment-naïve, non-cirrhotic, uncomplicated cases)	**Approval Duration**: Mavyret – 8 weeks; sofosbuvir/velpatasvir – 12 weeks
	• Diagnosis of chronic hepatitis C virus (HCV) infection; **AND**
	• Prescribed regimen is either of the following:
	  ○ Mavyret 8 weeks; **OR**
	  ○ sofosbuvir/velpatasvir for 12 weeks; **AND**
	• Documentation (e.g., progress note, prior authorization form questions) of the following clinical data confirming simplified treatment eligibility:

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

Treatment Criteria Category	Criteria for Approval
	○ 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** ○ 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 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 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.

Treatment Criteria Category	Criteria for Approval
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** • 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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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, one of which must be Humalog; **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, and vial CC	• Trial and failure of ≥ 2 preferred insulins, one of which must be Novolog or generic insulin aspart; **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.

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

CURRENT PDL STATUS

RAPID- AND SHORT-ACTING INSULINS

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

INTERMEDIATE-ACTING INSULINS

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

LONG-ACTING INSULINS

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

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

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

GUIDELINES FOR USE

Approval Duration: 6 months

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Byetta [CC, QL] Ozempic [AE, CC, QL] Trulicity [CC, QL] Victoza [CC, QL]	• Diagnosis of Type II Diabetes Mellitus (T2DM) confirmed with clinical documentation (e.g., progress note) of one of the following: ○ ICD-10 diagnosis of T2DM; **OR** ○ A1c lab value that correlates to a T2DM diagnosis (i.e., 6.5 or greater); **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 **UNLESS** the member is changing therapy; **AND** • The requested dose does not exceed the maximum FDA-approved dose for the treatment of diabetes mellitus. *Drugs used for anorexia, weight loss, or weight gain are excluded from coverage

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 agent**, unless otherwise specified. Preferred with PA (PDP) criteria must be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Not applicable.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
exenatide CC, QL liraglutide CC, QL	• Diagnosis of Type II Diabetes Mellitus (T2DM) confirmed with clinical documentation (e.g., progress note) of one of the following: ○ ICD-10 diagnosis of T2DM; **OR** ○ A1c lab value that correlates to a T2DM diagnosis (i.e., 6.5 or greater); **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 **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** • At least 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 1 preferred agent; **AND** • GMN Criteria *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. **Age Limit**: ≥ 18 years

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Byetta CC, QL	Bydureon BCise QL
Ozempic AE, CC, QL	exenatide CC, QL
Trulicity CC, QL	liraglutide CC, QL
Victoza CC, QL	Mounjaro AE, QL
	Rybelsus CC, QL
	Soliqua AE, CC, QL
	Xultophy AE, CC, QL

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

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

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Janumet CC, QL Janumet XR CC, QL Januvia CC, QL Jentadueto CC, QL Jentadueto XR CC, QL Nesina 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.

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
sitagliptin/metformin ER CC, QL Sitagliptin/Metformin 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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
	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 Janumet or Janumet XR; **AND** • At least 3-month trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 1 preferred agent
Zituvio 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** • 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

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Janumet CC, QL	alogliptin QL
Janumet XR CC, QL	alogliptin/metformin QL
Januvia CC, QL	alogliptin/pioglitazone QL
Jentadueto CC, QL	Glyxambi QL
Jentadueto XR CC, QL	Kazano QL
Nesina CC, QL	Kombiglyze XR QL
Tradjenta CC, QL	Onglyza QL
	Oseni QL
	Qtern QL
	saxagliptin QL
	saxagliptin/metformin ER QL
	sitagliptin QL
	sitagliptin/metformin ER CC, QL
	Sitagliptin/Metformin CC, QL
	Steglujan AE, QL
	Trijardy XR QL
	Zituvio CC, QL
	Zituvimet CC, QL
	Zituvimet XR CC, QL

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

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

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Invokana CC, QL Invokamet CC,QL 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.
Farxiga 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.
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.

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

Not applicable.

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

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Inpefa CC, AE, 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:** 30 tablets per 30 days

CURRENT PDL STATUS

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

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DIABETES: ALPHA-GLUCOSIDASE INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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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Prior Authorization Criteria

Kentucky Medicaid

DIABETES: METFORMINS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
metformin solution CC Riomet CC Riomet ER 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	Glumetza
metformin ER tablet (generic Glucophage XR)	metformin ER tablet (generic Fortamet, Glumetza)
	metformin solution CC
	metformin 625 mg, 750 mg tablet
	Riomet solution CC
	Riomet ER suspension CC

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

DIABETES: MEGLITINIDES

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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

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**

   Approval of NON-PREFERRED branded agents requires:

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

   b. NPD Criteria above.

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

   Not applicable.

5. **DRUG-SPECIFIC CLINICAL CRITERIA**

   Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
glimepiride	Glucotrol XL
glipizide	Glynase PresTab
glipizide ER	
glipizide XL	
glyburide	
glyburide micronized	

DIABETES: THIAZOLIDINEDIONES (TZDS)

GUIDELINES FOR USE

Approval Duration: 1 year

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**

   Approval of NON-PREFERRED branded agents requires:

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

   b. NPD Criteria above.

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

   Not applicable.

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

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

ENDOCRINE AND METABOLIC AGENTS: GLUCAGON AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Not applicable.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Baqsimi spray [CC]	diazoxide suspension
Glucagen	Gvoke autoinjector, syringe, vial
glucagon emergency kit	Zegalogue autoinjector [AE]
Proglycem suspension	Zegalogue syringe [AE]

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

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 Nutropin AQ NuSpin 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.*
Skytrofa CC	**Initial Approval Criteria** • Patient has growth failure secondary to growth hormone deficiency (GHD); **AND** • Patient must have tried and failed 1 preferred short-acting growth hormone products due to frequency of administration or adherence. **Renewal Criteria** • Patient continues to meet the above criteria; **AND** • Patient has a positive response compared to pre-treatment baseline.

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

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**. Preferred with PA (PDP) criteria must be met.

3. BRAND MEDICALLY NECESSARY CRITERIA

Not applicable.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Ngenla [CC, AE]	**Initial Approval Criteria**
	• 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**
	• Trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents.
	
	Renewal Criteria
	• Patient continues to meet the above criteria; **AND**
	• Patient has a positive response compared to pre-treatment baseline.
	
	Age Limit: ≥ 3 years

Sogroya [CC, QL]	**Initial Approval Criteria** • Patient will be at least 2.5 years old at the start of treatment; **AND** • Diagnosis of growth hormone deficiency; **AND** • Patient does NOT have a hypersensitivity to any somapacitan product or any of the excipients; **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**

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval

	• Patient does NOT have, or previously had, an intracranial tumor growth as confirmed by a sellar MRI scan with contrast; **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**
	• Trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents
	
	Renewal Criteria
	• Patient continues to meet the above criteria; **AND**
	• Patient has not had unacceptable toxicity from the drug; **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 CC, AE
Nutropin AQ NuSpin CC	Omnitrope cartridge, vial
Skytrofa cartridge CC	Serostim vial
	Sogroya CC, QL
	Zomacton vial

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

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

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

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	Hemady tablet
prednisolone solution	Medrol dose pack, tablet
prednisolone sodium phosphate solution 5 mg/5 mL, 15 mg/5 mL, 25 mg/5 mL	methylprednisolone 8 mg, 16 mg tablet
prednisone dose pack, solution, tablet	Millipred dose pack, tablet
	prednisolone tablet
	prednisolone sodium phosphate ODT, solution 10 mg/5 mL, 20 mg/5 mL
	prednisone Intensol oral concentrate

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Rayos DR tablet
	TaperDex dose pack
	Tarpeyo DR capsule

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

ENDOCRINE AND METABOLIC AGENTS: PANCREATIC ENZYMES

GUIDELINES FOR USE

Approval Duration: 1 year

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**

   Not applicable.

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

   Not applicable.

5. **DRUG-SPECIFIC CLINICAL CRITERIA**

   Not applicable.

CURRENT PDL STATUS

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

ENDOCRINE AND METABOLIC AGENTS: PROGESTINS FOR CACHEXIA

GUIDELINES FOR USE

Approval Duration: 1 year

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**

   Approval of NON-PREFERRED branded agents requires:

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

   b. NPD Criteria above.

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

   Not applicable.

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

ENDOCRINE AND METABOLIC AGENTS: ANDROGENIC AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Androderm patch	Androgel gel packet
Androgel gel pump	Fortesta gel pump
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)
	Vogelxo gel, gel packet, gel pump

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

ENDOCRINE AND METABOLIC AGENTS: BONE RESORPTION SUPRESSION AND RELATED AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Forteo 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 of age
	Quantity Limit: 20 mcg per day

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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Evenity AE, CC, QL	• Documented intolerance, contraindication or treatment failure/ineffective response to a minimum 12-month trial on previous therapy with teriparatide.
teriperatide AE, CC, QL	• Diagnosis of 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); **AND** • Patient has a known or suspected allergy, intolerance, or contraindication to an inactive ingredient in the preferred brand formulation.

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

Agent(s) Subject to Criteria	Criteria for Approval
	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 of age **Quantity Limit**: 20 mcg per day
Tymlos AE, CC, QL	• Documented intolerance, contraindication or treatment failure/ineffective response to a minimum 12-month trial on previous therapy with teriparatide.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
alendronate tablet QL	Actonel tablet QL
Forteo pen AE, CC, QL	alendronate solution QL
ibandronate tablet	Atelvia DR tablet QL
raloxifene tablet	Binosto tablet QL
	Boniva tablet QL
	calcitonin-salmon nasal spray, vial
	Evenity syringe AE, CC, QL
	Evista tablet
	Fosamax tablet QL
	Fosamax Plus D tablet QL
	Jubbonti syringe
	Miacalcin vial
	Prolia syringe
	Reclast solution
	risedronate sodium tablet QL, DR tablet QL
	teriperatide pen AE, CC, QL
	Tymlos pen AE, CC, QL
	zoledronic acid bag, bottle, vial

ENDOCRINE AND METABOLIC AGENTS: UTERINE DISORDER TREATMENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Myfembree	
Oriahnn	
Orilissa	

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IMMUNOSUPPRESSANTS

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Rezurock AE, CC, QL	**Initial Approval Criteria** • 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).

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

Agent(s) Subject to Criteria	Criteria for Approval
	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 old **Quantity Limit:** 1 per day

Tavneos AE, CC, QL	**Approval Duration: 6 months initial, 1 year renewal**
	
	Initial Approval Criteria
	• 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**

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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 capsules per day

CURRENT PDL STATUS

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

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

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
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.

Mavenclad 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 of the following:
	  ○ Screening for hepatitis B/C, HIV, and TB infections; **AND**

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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).
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** ○ 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).
Ponvory AE, CC, QL	• Initially prescribed by or in consultation with a neurologist or multiple sclerosis specialists; **AND**

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

Agent(s) Subject to Criteria	Criteria for Approval
	• 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).
Rebif CC, QL	• Diagnosis of multiple sclerosis (ICD-10 Disease Group G35).
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**

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

Agent(s) Subject to Criteria	Criteria for Approval

	• 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:
	  ○ Screening for clinically significant drug interactions; **AND**
	  ○ 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.
	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:
	  ○ 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**
	  ○ 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**

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval

	• Patient has trial and failure (at least 3 months) of ≥ 1 of the following conventional therapies:
	  ○ Oral/rectal 5-aminosalicylic acid agents (e.g., Apriso, 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.
	Renewal Criteria
	• Documentation of response to therapy (e.g., progress note).

CURRENT PDL STATUS

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

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Cosentyx CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) and nonradiographic axial spondylarthritis (nr-axSpA) Clinical Criteria • Hidradenitis Suppurativa (HS) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria **OR** • Diagnosis of active enthesitis-related arthritis ○ Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Juvenile Psoriatic Arthritis Criteria:** **Initial Criteria** • 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** • Documentation (e.g., progress note) of response to therapy.
Enbrel CC, QL	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

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Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
Humira (and adalimumab biosimilars) CC, QL Hadlima CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) and nonradiographic axial spondylarthritis (nr-axSpA) Clinical Criteria • Crohn's Disease (CD) or Ulcerative Colitis (UC) Clinical Criteria • Hidradenitis Suppurativa (HS) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Uveitis Clinical Criteria
Otezla CC, QL	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 Criteria:** **Initial Criteria** • 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** • 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** • 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 Criteria:** **Initial Criteria** • 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

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Colchicine ○ Topical or oral steroids (e.g., triamcinolone, prednisone) **Renewal Criteria** • Documentation (e.g., progress note) of response to therapy compared to baseline.
Rinvoq AE, CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) or nonradiographic axial spondylarthritis (nr-axSpA) Clinical Criteria • Crohn's Disease (CD) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria **Treatment of Refractory, Moderate-to-Severe Atopic Dermatitis Initial Criteria:** • 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:** • Continue to meet above criteria; **AND**

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

Agent(s) Subject to Criteria	Criteria for Approval
	Documentation (e.g., progress note) of response to therapy relative to baseline measure(s) (e.g., BSA involvement, EASI, IGA, SCORAD).
Rinvoq LQ AE, CC, QL	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 of age **Quantity Limit:** 360 mL per 30 days
Tyenne CC, QL	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. **Quantity Limit:** 162 mg (1 pen or 1 syringe) per week
Xeljanz CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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

a. Diagnosis of Ankylosing Spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA); **AND**

b. Prescribed by, or in consultation with, a rheumatologist or other specialist in the treatment of AS/nr-axSpA; **AND**

c. Trial and failure of, contraindication or intolerance to, ≥ 1 non-steroidal anti-inflammatory drug (NSAID); **AND**

d. NOT used in combination with any other biologic agent; **AND**

e. 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**

f. Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

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

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

a. Diagnosis of Crohn's disease (CD) or Ulcerative Colitis (UC); **AND**

b. Patient is 18 years or older, and medication is prescribed by, or in consultation with, a gastroenterologist or other specialist in the treatment of CD/UC; **AND**

c. Trial and failure of ≥ 1 of the following conventional therapies:

i. Oral/rectal 5-aminosalicylic acid agents (e.g., Apriso, balsalazide, Lialda, mesalamine, sulfasalazine)

ii. Oral/rectal steroids (e.g., budesonide, hydrocortisone, prednisone)

iii. Immunosuppressant (e.g., azathioprine, mercaptopurine); **OR**

d. Member is less than 18 years old and prescriber is a ***pediatric*** gastroenterologist/CD/UC specialist; **AND**

e. Patient is deemed high-risk for intestinal complications or post-operative recurrence; **AND**

f. NOT used in combination with any other biologic agent; **AND**

g. 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**

h. Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

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

7. HIDRADENITIS SUPPURATIVA (HS) CLINICAL CRITERIA

a. Diagnosis of moderate to severe hidradenitis suppurativa (HS); **AND**

b. Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of HS; **AND**

c. Trial and failure (at least 3 months) of **≥ 1 non-biologic therapy**s:

i. Contraceptives (e.g., ethinyl estradiol/norgestimate)

ii. Oral retinoid (e.g., acitretin)

iii. Systemic antibiotic (e.g., clindamycin, minocycline, doxycycline, rifampin) ; **AND**

d. NOT used in combination with any other biologic agent; **AND**

e. 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**

f. Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

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

8. JUVENILE IDIOPATHIC ARTHRITIS (JIA) CLINICAL CRITERIA

a. Diagnosis of active polyarticular or systemic juvenile idiopathic arthritis (JIA); **AND**

b. Prescribed by, or in consultation with, a rheumatologist or other specialist in the treatment of JIA; **AND**

c. Trial and failure (at least 3 months), contraindication or intolerance to, ≥ 1 disease-modifying anti-rheumatic drug (DMARD), such as methotrexate; **AND**

d. NOT used in combination with any other biologic agent; **AND**

e. 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**

f. Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

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

9. PLAQUE PSORIASIS CLINICAL CRITERIA

a. Diagnosis of moderate to severe plaque psoriasis; **AND**

b. Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of psoriasis; **AND**

c. Symptoms persistent for ≥ 6 months with at least 1 of the following:

i. Involvement of at least 3% of body surface area (BSA); **OR**

ii. Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**

iii. Incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia); **AND**

d. Trial and failure (at least 3 months) of ≥ 1 conventional therapy:

i. Disease-modifying anti-rheumatic drug (DMARD), such as methotrexate

ii. Immunosuppressant (e.g., cyclosporine)

iii. Oral retinoid (e.g., acitretin); **AND**

e. NOT used in combination with any other biologic agent; **AND**

f. 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**

g. Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

a. 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.

10. PSORIATIC ARTHRITIS (PSA) CLINICAL CRITERIA

a. Diagnosis of psoriatic arthritis (PsA); **AND**

b. Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of PsA; **AND**

c. NOT used in combination with any other biologic agent; **AND**

d. 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**

e. Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

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

11. RHEUMATOID ARTHRITIS (RA) CLINICAL CRITERIA

a. Diagnosis of rheumatoid arthritis (RA) based on the American College of Rheumatology (ACR) criteria; **AND**

b. Prescribed by, or in consultation with, a rheumatologist or other specialist in the treatment of RA; **AND**

c. Documentation (e.g., progress note) of baseline RA disease activity measure using the clinical disease activity index, Disease Activity Score in 28 Joints with Erythrocyte Sedimentation Rate or C-Reactive Protein Level, Simplified Disease Activity Index, Routine Assessment of Patient Index Data 3, or Patient Activity Scale-II; **AND**

d. Trial and failure (at least 3 months), contraindication or intolerance to, ≥ 1 disease-modifying anti-rheumatic drug (DMARD), such as methotrexate; **AND**

e. NOT used in combination with any other biologic agent; **AND**

f. 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**

g. Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

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

12. UVEITIS CLINICAL CRITERIA

a. Diagnosis of non-infectious intermediate, posterior, or panuveitis; **AND**

b. Prescribed by, or in consultation with, a rheumatologist, ophthalmologist or other specialist in the treatment of uveitis; **AND**

c. 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**

d. 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**

e. NOT used in combination with any other biologic agent; **AND**

f. 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**

g. Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

Renewal Criteria:

a. 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	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. **Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Criteria:** • Diagnosis of Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) • 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.

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

Agent(s) Subject to Criteria	Criteria for Approval
Adalimumab biosimilars CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) and nonradiographic axial spondylarthritis (nr-axSpA) Clinical Criteria • Crohn's Disease (CD) or Ulcerative Colitis (UC) Clinical Criteria • Hidradenitis Suppurativa (HS) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Uveitis Clinical Criteria
Bimzelx AE, CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Hidradenitis Suppurativa (HS) clinical criteria **Age Limit:** ≥ 18 years of age **Quantity Limit:** 2 mL per 28 days

Cibinqo CC, QL	• 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:

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA) 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
Enspryng AE, CC, QL	• Diagnosis of anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD) • 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. • Diagnosis of NMOSD confirmed by the following: ○ Seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND**

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Presence of ≥ 1 core clinical characteristic (e.g., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem 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.
Entyvio Pen CC, QL Entyvio vial CC	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Crohn's Disease (CD) or Ulcerative Colitis (UC) Clinical Criteria **Quantity Limit (pens only):** 2 pens per 28 days
Ilaris CC, QL	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

Agent(s) Subject to Criteria	Criteria for Approval

	Diagnosis of 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
	  ○ Chronic aseptic meningitis
	  ○ Skeletal abnormalities
	
	Diagnosis of 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**

Agent(s) Subject to Criteria	Criteria for Approval

	• Other causes for recurrent fever have been excluded (e.g. recurrent bacterial/viral infection, other autoinflammatory diseases, cancer, cyclic neutropenia, interferonpathies).
	
	Diagnosis of 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 maybe requested.
	
	Diagnosis of 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**
	• 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**

Agent(s) Subject to Criteria	Criteria for Approval

- 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 maybe requested.

Diagnosis of 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 maybe requested.

Diagnosis of 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**
- Patient must be taking a medication for prophylactic treatment of gout.

Renewal Criteria:

- Absence of unacceptable toxicity from the drug; **AND**

Agent(s) Subject to Criteria	Criteria for Approval
	• 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 every 4 weeks
Ilumya AE, CC, QL	The following diagnosis-based clinical criteria for an FDA-approved has been met: • Plaque Psoriasis Clinical Criteria must be met.
Infliximab vial (and biosimilars) CC	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) or Ulcerative Colitis (UC) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria
Kevzara AE, CC, QL	The following diagnosis-based clinical criteria for an FDA-approved: • Rheumatoid Arthritis (RA) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria

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

Agent(s) Subject to Criteria	Criteria for Approval
	Polymyalgia Rheumatica (PMR) Criteria • 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.
Kineret CC, QL	The following diagnosis-based clinical criteria for an FDA-approved: • Rheumatoid Arthritis (RA) Clinical Criteria must be met; **OR** **DIRA Criteria** • 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 Criteria** • Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID); **AND** • 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.
Olumiant AE, CC, QL	The following diagnosis-based clinical criteria for an FDA-approved: • Rheumatoid Arthritis (RA) Clinical Criteria must be met.
Omvoh AE, CC, QL	The following diagnosis-based clinical criteria for an FDA-approved-indication has been met: • Crohn's Disease (CD) or Ulcerative Colitis (UC) Clinical Criteria **Age Limit:** ≥ 18 years of age **Quantity Limit:** • 1 vial per 28 days • 100 mg: 2 per 28 days • 200 mg, 300 mg: 1 per 28 days
Orencia CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved: • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria **AND**

Agent(s) Subject to Criteria	Criteria for Approval
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
Otulfi CC, QL	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
Pyzchiva CC, QL	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
Remicade vial CC	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) or Ulcerative Colitis (UC) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria
Selarsdi CC, QL ustekinumab-aekn CC, QL	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
Siliq AE, CC, QL Sotyktu AE, CC, QL	• Plaque Psoriasis Clinical Criteria must be met.
Simponi CC, QL	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
Skyrizi AE, CC, QL	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

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Agent(s) Subject to Criteria	Criteria for Approval
	• Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria
Stelara CC, QL ustekinumab CC, QL	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
Steqeyma CC, QL	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
Taltz CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA) Clinical Criteria • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria
Tremfya AE, CC, QL	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
ustekinumab-ttwe CC, QL	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
Velsipity AE, CC, QL	**Initial Approval Criteria:** • 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., Apriso, balsalazide, Lialda, mesalamine, sulfasalazine)

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

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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. **Renewal Criteria:** • Documentation (e.g., progress notes) of response to therapy compared to baseline. **Age Limit:** ≥ 18 years of age **Quantity Limit:** 1 tablet per day
Xeljanz XR CC, QL	One of the following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication have been met: • Ankylosing Spondylitis (AS) or nonradiographic axial spondyloarthritis (nr-axSpA) Clinical Criteria • Juvenile Idiopathic Arthritis (JIA) Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria • Rheumatoid Arthritis (RA) Clinical Criteria • Ulcerative Colitis (UC) Clinical Criteria
Yesintek CC, QL	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
Zymfentra CC, QL	**Initial Approval Criteria:** • 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)

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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 or syringes per month

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Cosentyx CC, QL	Abrilada CC, QL
Enbrel CC, QL	Actemra CC, QL
Hadlima CC, QL	adalimumab-aacf CC, QL
Humira CC, QL	adalimumab-aaty CC, QL
Otezla CC, QL	adalimumab-adaz CC, QL
Rinvoq AE, CC, QL	adalimumab-adbm CC, QL
Rinvoq LQ AE, CC, QL	adalimumab-fjkp CC, QL
Tyenne CC, QL	adalimumab-ryvk CC, QL
Xeljanz CC, QL	Amjevita CC, QL
	Avsola vial CC
	Bimzelx AE, CC, QL
	Cibinqo CC, QL
	Cimzia CC, QL
	Cyltezo CC, QL
	Enspryng AE, CC, QL
	Entyvio pen CC, QL
	Entyvio vial CC
	Hulio CC, QL
	Hyrimoz CC, QL
	Idacio CC, QL
	Ilaris CC, QL
	Ilumya AE, CC, QL
	Inflectra vial CC
	Infliximab vial CC
	Kevzara AE, CC, QL
	Kineret CC, QL
	Olumiant AE, CC, QL

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Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Omvoh AE, CC, QL
	Orencia CC, QL
	Otulfi CC, QL
	Pyzchiva CC, QL
	Remicade vial CC
	Renflexis vial CC
	Selarsdi CC, QL
	Siliq AE, CC, QL
	Simponi CC, QL
	Simlandi CC, QL
	Skyrizi AE, CC, QL
	Sotyktu AE, CC, QL
	Stelara CC, QL
	Steqeyma CC, QL
	Taltz 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
	Yesintek CC, QL
	Yuflyma CC, QL
	Yusimry CC, QL
	Zymfentra CC, QL

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

IMMUNOLOGIC AND GENETIC: IMMUNOMODULATORS, ASTHMA

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 CC, QL, AE	**Approval Duration: 6 months Initial, 1 year Renewal**
	
	Asthma
	
	Initial Criteria
	• 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
	• 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)
	
	Initial Criteria
	• Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) also known as Churg-Strauss; **AND**

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

Agent(s) Subject to Criteria	Criteria for Approval

	• Patient has had a ≥ 90 days of treatment with one of the following agents:
	  ○ Systemic glucocorticoids
	  ○ Azathioprine
	  ○ Methotrexate
	  ○ Cyclophosphamide
	  ○ Mycophenolate
	• 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
	• Patient has experienced disease improvement and/or stabilization based on an objective measure

Nucala CC, QL, AE	**Approval Duration: 6 months Initial, 1 year Renewal**
	
	Asthma
	
	Initial Criteria
	• 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**
	• 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
	• 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**

Agent(s) Subject to Criteria	Criteria for Approval

- Nucala will be used as adjunct therapy with inhaled asthma therapy.

Chronic Rhinosinusitis with Nasal Polyps

Initial Criteria

- Diagnosis of chronic rhinosinusitis with nasal polyps; **AND**
- 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

- Patient has experienced disease improvement and/or stabilization based on an objective measure.

Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss)

Initial Criteria

- 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
- 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

- Patient has experienced disease improvement and/or stabilization based on an objective measure.

Agent(s) Subject to Criteria	Criteria for Approval
	Hypereosinophilic Syndrome (HES) **Initial Criteria** • 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** • Patient has experienced disease improvement and/or stabilization based on an objective measure.

Xolair CC, QL, AE	**Approval Duration: 6 months Initial, 1 year Renewal**
	
	Asthma
	
	Initial Criteria
	• 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
	• 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
	
	Initial Criteria
	• Diagnosis of chronic rhinosinusitis with nasal polyps; **AND**

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

Agent(s) Subject to Criteria	Criteria for Approval
	• 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** • Patient has experienced disease improvement and/or stabilization based on an objective measure. ***Chronic Idiopathic Urticaria*** **Initial Criteria** • 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** • Patient has experienced disease improvement and/or stabilization based on an objective measure. ***IgE-Mediated Food Allergy*** **Initial Criteria** • 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** • Patient has experienced disease improvement and/or stabilization based on an objective measure.

Agent(s) Subject to Criteria	Criteria for Approval

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Tezspire CC, AE, QL	**Initial Approval Criteria**
	• 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**
	  ○ FEV1; **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**

Agent(s) Subject to Criteria	Criteria for Approval

	• Patient has had a trial and failure, contraindication, or intolerance to at least 1 preferred agent.
	
	Renewal Criteria
	• 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**
	  ○ Improvement from baseline in FEV1 of ≥ 15%; **AND**
	
	Age Limit: ≥ 12 years old
	Quantity Limit: 1 prefilled syringe per 28 days (0.07 mL per day)

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 pen autoinjector CC, AE, QL	Tezspire pen CC, AE, QL
Fasenra syringe CC, AE, QL	Tezspire syringe CC, AE, QL
Nucala autoinjector CC, AE, QL	
Nucala syringe CC, AE, QL	
Nucala vial CC, AE, QL	
Xolair autoinjector CC, AE, QL	
Xolair syringe CC, AE, QL	
Xolair vial CC, AE, QL	

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IMMUNOLOGIC AND GENETIC: MUSCULAR DYSTROPHY 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
Emflaza tablets AE, CC, QL Emflaza suspension AE, CC	**Initial Approval Criteria** • 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

Agent(s) Subject to Criteria	Criteria for Approval

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Agamree AE, CC, QL	**Initial Approval Criteria:** • 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** **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:

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Agent(s) Subject to Criteria	Criteria for Approval
	○ Motor function (North Star Ambulatory Assessment (NSAA) ○ Cardiology ○ Endocrinology ○ Orthopedics (e.g., scoliosis) ○ Pulmonary function. **Age Limit:** ≥ 2 years of age **Quantity Limit:** 7.5 mL per day
deflazacort tablet AE, CC, QL deflazacort suspension AE, CC	**Initial Approval Criteria** • 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); **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 Limits:** 2 tablets per day
	Approval Duration: 6 months initial, 1 year renewal

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

Agent(s) Subject to Criteria	Criteria for Approval
	Initial Approval Criteria: • Diagnosis of Duchenne muscular dystrophy (DMD) [G71.01]; AND • Platelet count within the last 30 days equals to or is greater than 150 x 109/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. **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. **Age Limit**: 6 years of age or older **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

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

IMMUNOMODULATORS, ATOPIC DERMATITIS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Adbry Syringe AE, CC, QL
Adbry Autoinjector AE, CC, QL
	Approval Duration: 16 weeks initial, 1 year renewal
	
	Initial Approval Criteria:
	• 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)

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

Agent(s) Subject to Criteria	Criteria for Approval

Eucrisa 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 (e.g., Elidel) 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 g per 365 days

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**
	  ○ 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 is ≥ 6 years of age.
	
	Chronic Rhinosinusitis with Nasal Polyposis
	• Diagnosis of chronic rhinosinusitis **with** nasal polyposis; **AND**
	• Patient is ≥ 12 years of age; **AND**
	• Prescribed by or in consultation with an allergist; immunologist; ear, nose, and throat (ENT), or other applicable specialist; **AND**

Agent(s) Subject to Criteria	Criteria for Approval

	• Trial and failure (and continued use of) ≥ 1 intranasal corticosteroid, unless intolerant or otherwise ineligible.
	
	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:
	  ○ 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.
	
	Renewal Criteria:
	• Patient must continue to meet initial approval criteria; **AND**
	• Patient must have disease improvement and/or stabilization based on an objective measure

Opzelura [AE, CC, QL]	**Approval Duration:** 1 year
	
	Initial Approval Criteria:
	• 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**

Agent(s) Subject to Criteria	Criteria for Approval
	• 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:** • Patient must continue to meet the above criteria; **AND** • Patient must have disease improvement and/or stabilization **Age Limit:** ≥ 12 years old **Quantity Limit:** 240 grams per 365 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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Ebglyss AE, CC, QL	**Approval Duration: 4 months initial, 1 year renewal**
	
	Initial Approval Criteria:
	• 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**

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

Agent(s) Subject to Criteria	Criteria for Approval

	• 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**
	• Trial and failure, contraindication, or intolerance to at least one preferred injectable agent (Adbry or Dupixent); **AND**
	• Patient must meet the minimum age and weight recommended by the package insert for the provided indication.
	
	Renewal Criteria:
	• Patient must continue to meet initial approval criteria; **AND**
	• Patient must have disease improvement and/or stabilization based on an objective measure.
	
	Age Limit: 12 years of age or older
	Quantity Limit: 1 pen/syringe (2 mL) per 28 days

Nemluvio AE, CC, QL	**Approval Duration: 4 months initial, 1 year renewal**
	
	Initial Approval Criteria:
	
	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):

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 1 preferred injectable (Adbry, Dupixent) agent; **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%, clobetasol propionate 0.025%, or dexamethasone 0.05%] for a minimum of 2 weeks; **OR** ○ Narrowband ultraviolet B (NBUVB) phototherapy or psoralen plus ultraviolet A (PUVA) phototherapy; **AND** • Trial and failure, contraindication, or intolerance to Dupixent; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Renewal Criteria:** • Patient must continue to meet initial approval criteria; **AND** • Patient must have disease improvement and/or stabilization based on an objective measure **Quantity Limit:** 2 pens (60 mg) per 28 days
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.

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
	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 of age **Quantity Limit:** 2 grams per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Adbry autoinjector AE, CC, QL	Ebglyss AE, CC, QL
Adbry syringe AE, CC, QL	Elidel
Dupixent pen CC, QL	Nemluvio AE, CC, QL
Dupixent syringe CC, QL	Vtama AE, CC, QL
Eucrisa CC, QL	
Opzelura cream AE, CC, QL	
pimecrolimus cream	
tacrolimus ointment	

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

BLOOD MODIFIERS: ANTIHYPERURICEMICS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
colchicine tablets 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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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.

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
colchicine capsules 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.

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

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

BLOOD MODIFIERS: COLONY STIMULATING FACTORS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Fulphila CC, QL Fylnetra CC, QL Neupogen 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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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.

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
Rolvedon AE, CC, QL	• The medication is being used for chemotherapy-induced neutropenia prophylaxis, to decrease the incidence of febrile neutropenia; **AND** • Patient has a nonmyeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia; **AND** • 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	Granix QL
Fylnetra CC, QL	Leukine QL
Neupogen CC, QL	Neulasta CC, QL
	Neulasta Onpro CC, QL
	Nivestym QL
	Nyvepria CC,QL
	Releuko QL
	Rolvedon AE, CC, QL
	Stimufend QL
	Udenyca CC, QL
	Zarxio QL
	Ziextenzo CC, QL

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

BLOOD MODIFIERS: ERYTHROPOIESIS STIMULATING AGENTS

GUIDELINES FOR USE

Approval Duration: 3 months initial, 1 year renewal

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Aranesp CC
Retacrit CC (Pfizer)
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 diagnosis:
	  ○ 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) (Retacrit and Epogen only); **OR**
	  ○ Autologous blood donations by patients scheduled to undergo nonvascular surgery. (Retacrit and Epogen Only)
	
	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.

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Jesduvroq [CC]	**Approval Duration:** 6 months **Initial Approval Criteria:** • 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 [CC, AE]	**Initial Approval Criteria:**
	• 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**

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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. **Age Limit:** ≥ 18 years
Vafseo CC, QL	**Approval Duration:** 6 months **Initial Approval Criteria:** • 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 four tablets per day • 300 mg two tablets per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Aranesp CC	Jesduvroq CC, QL
Epogen CC	Procrit
Mircera CC	Reblozyl CC, AE
Retacrit CC (Pfizer)	Retacrit CC (Vifor)
	Vafseo CC, QL

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

BLOOD MODIFIERS: PHOSPHATE BINDERS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Xphozah CC, AE, 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 to, intolerance, or inadequate response to at least 2 preferred phosphate binders. **Age Limit:** ≥ 18 years of age **Quantity Limit:** 2 tablets daily

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
calcium acetate capsule, tablet	Auryxia
Phoslyra solution	ferric citrate tablet
Renvela powder packet, tablet	Fosrenol chewable tablet, powder packet

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
sevelamer carbonate tablet	lanthanum carbonate chewable tablet
	Renagel
	sevelamer carbonate powder packet
	Velphoro
	Xphozah CC, AE, QL

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

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 CC, AE, QL	**Initial Approval Criteria:** • 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 old **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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

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

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
L-glutamine (generic for Endari) CC, AE, QL	**Initial Approval Criteria:** • 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 old **Quantity Limit:** 6 packets (30 gm) per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Droxia	L-glutamine (generic for Endari) CC, AE, QL
Endari CC, AE, QL	Xromi solution AE
Siklos	

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

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 tablets CC, QL	**Initial Approval Criteria:**
	• 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.

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Alvaiz CC, AE, QL	**Initial Approval Criteria:**
	• Prescribed by, or in consultation with, a hematologist or liver disease specialist; **AND**
	• Patient has one of the following indications:
	  ○ 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 or older
	Quantity Limit: 9 mg: 1 per day
	18 mg: 1 per day
	36 mg: 3 per day
	54 mg: 2 per day

Doptelet CC, AE, QL	**Approval Duration:** Date of service (chronic liver disease); 6 months (ITP)
	
	Initial Approval Criteria:
	• 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; **OR**
	• 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

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

Agent(s) Subject to Criteria	Criteria for Approval
	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 (except where 15 tablet per 5-day course is indicated)

eltrombopag olamine powder pack CC, QL
eltrombopag olamine tablets CC, QL
	Initial Approval Criteria:
	• 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 CC, AE, 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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
Tavalisse CC, AE, 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

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Promacta tablet CC	Alvaiz CC, AE, QL
	Doptelet CC, AE, QL
	eltrombopag olamine powder pack CC, QL
	eltrombopag olamine tablet CC, QL
	Mulpleta CC, AE, QL
	Nplate
	Promacta powder packet QL
	Tavalisse CC, AE, QL

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OPHTHALMIC ANTIBIOTICS AND ANTIVIRALS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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	Besivance
moxifloxacin (generic Vigamox)	Ciloxan
ofloxacin	gatifloxacin
	levofloxacin
	moxifloxacin (generic Moxeza)
	Ocuflox
	Vigamox

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Preferred Agents	Non-Preferred Agents
	Zymaxid

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
polymyxin B/trimethoprim drops	Polytrim
sulfacetamide drops	sulfacetamide ointment
tobramycin drops	Tobrex

OPHTHALMIC ANTIBIOTIC-STEROID COMBINATIONS

Preferred Agents	Non-Preferred Agents
dexamethasone/neomycin sulfate/polymyxin B suspension	Blephamide S.O.P ointment
hydrocortisone/bacitracin zinc/neomycin sulfate/polymyxin B ointment, suspension	hydrocortisone/neomycin sulfate/polymyxin B suspension
Neo-Polycin hydrocortisone ointment	Maxitrol ointment, suspension
Tobradex ointment, suspension	prednisolone sodium phosphate/sulfacetamide sodium
tobramycin/dexamethasone suspension	Pred-G ointment
	Tobradex ST
	Zylet

OPHTHALMICS FOR ALLERGIC CONJUNCTIVITIS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable.

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

OPHTHALMIC PROSTAGLANDIN AGONISTS

Preferred Agents	Non-Preferred Agents
latanoprost QL	bimatoprost QL
	Iyuzeh QL
	Lumigan QL
	Tafluprost QL
	Travatan Z
	Travoprost
	Vyzulta AE, QL
	Xalatan QL
	Xelpros
	Zioptan QL

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Prior Authorization Criteria

Kentucky Medicaid

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 once daily (generic Istalol)
	timolol PF (preservative-free)
	timolol maleate gel-solution
	Timoptic Ocudose drops
	Timoptic/XE sol/gel

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 (preservative-free)

OPHTHALMIC SYMPATHOMIMETICS

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
	Iopidine

OPHTHALMICS, GLAUCOMA AGENTS (OTHER)

Preferred Agents	Non-Preferred Agents
Rhopressa	phospholine iodide
Rocklatan	pilocarpine
	Vuity

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

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

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

OPHTHALMICS: ANTI-INFLAMMATORY STEROIDS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
dexamethasone sodium phosphate drops	Alrex
Durezol	difluprednate
fluorometholone suspension	Eysuvis
Lotemax gel, ointment, suspension	Flarex
prednisolone acetate suspension	FML suspension, FML Forte suspension
prednisolone sodium phosphate drops	Inveltys
	Lotemax SM gel
	loteprednol etabonate gel, suspension
	Maxidex
	Pred Forte
	Pred Mild

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OPHTHALMICS: IMMUNOMODULATORS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Restasis (Blister Pack) [CC] Xiidra [CC, AE, QL]	• Prescribed following corneal transplant; **OR** • Trial and failure of ≥ 1 over-the-counter ophthalmic lubricant (e.g., polyvinyl alcohol).

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Miebo [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]	• Prescribed following corneal transplant; **OR** Trial and failure of ≥ 1 over-the-counter ophthalmic lubricant (e.g., polyvinyl alcohol).
Tyrvaya [CC, AE, QL]	**Initial Approval Criteria:** • Patient has diagnosis of dry eye disease (DED); **AND** • Prescribed by or in consultation with an ophthalmologist or optometrist; **AND**

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval

	• 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 old
	Quantity Limit: 1 carton (2 bottles)/ 30 days

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Restasis (Blister Pack) CC	Cequa
Xiidra AE, CC, QL	cyclosporine 0.05%
	Miebo CC, QL
	Restasis Multidose CC
	Tyrvaya AE, CC, QL
	Verkazia

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

OPHTHALMIC: MYDRIATIC

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

OPHTHALMIC MYDRIATICS & MYDRIATIC COMBINATIONS

Preferred Agents	Non-Preferred Agents
atropine sulfate drops, ointment	Cyclogyl
atropine sulfate/PF droperrette	Cyclomydril
cyclopentolate	Isopto Atropine
tropicamide	Mydriacyl

OPHTHALMIC MYDRIATICS & MYDRIATIC COMBINATIONS

Preferred Agents	Non-Preferred Agents
phenylephrine	

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OTICS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable

CURRENT PDL STATUS

OTIC ANTIBIOTICS

Preferred Agents	Non-Preferred Agents
CiproDex Otic	ciprofloxacin 0.2% drops
ciprofloxacin/dexamethasone suspension	Cipro HC Otic
hydrocortisone/neomycin/polymyxin B suspension, solution	ciprofloxacin/fluocinolone
ofloxacin 0.3% solution	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

RENAL AND GENITOURINARY: ALPHA BLOCKERS FOR BPH & 5-ALPHA REDUCTASE INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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

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5-ALPHA REDUCTASE (5AR) INHIBITORS

Preferred Agents	Non-Preferred Agents
dutasteride	Avodart
finasteride 5 mg tablet CC	dutasteride/tamsulosin
	Entadfi
	finasteride-tadalafil QL
	Jalyn
	Proscar

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BLADDER RELAXANTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Gemtesa CC, AE, QL	**Initial Approval Criteria:** • 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.

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval
	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.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
oxybutynin solution QL, syrup QL, 5 mg tablet QL	darifenacin ER QL
oxybutynin ER QL	Detrol QL
solifenacin QL	Detrol LA QL
Toviaz ER QL	Ditropan XL QL
	fesoterodine ER QL
	flavoxate QL
	Gelnique CC, QL
	Gemtesa CC, AE, QL
	Myrbetriq QL
	mirabegron ER QL
	oxybutynin 2.5mg tablet QL
	Oxytrol QL
	tolterodine QL
	tolterodine ER QL
	trospium QL
	trospium ER QL
	Vesicare QL
	Vesicare LS QL

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

DERMATOLOGICS: TOPICAL ANTIBIOTIC AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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

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

DERMATOLOGICS: TOPICAL ANTIPARASITICS

GUIDELINES FOR USE

Approval Duration: 1 year

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**

   Approval of NON-PREFERRED branded agents requires:

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

   b. NPD Criteria above.

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

   Not applicable

5. **DRUG-SPECIFIC CLINICAL CRITERIA**

   Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Natroba	Crotan
permethrin 5% cream	Elimite
	Eurax
	Lindane
	malathion lotion
	Ovide
	spinosad

DERMATOLOGICS: ORAL ANTIPSORIATICS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
acitretin	methoxsalen

DERMATOLOGICS: ORAL ACNE AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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**

   Approval of NON-PREFERRED branded agents requires:

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

   b. NPD Criteria above.

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

   Not applicable

5. **DRUG-SPECIFIC CLINICAL CRITERIA**

   Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Amnesteem	Absorica
Claravis	Absorica LD
Zenatane	isotretinoin capsule

DERMATOLOGICS: TOPICAL ACNE AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
adapalene/benzoyl peroxide 0.3-2.5% (Mayne Pharma)	Acanya
clindamycin gel, medicated swab (pledget), solution	adapalene cream, gel, gel pump
clindamycin/benzoyl peroxide (generic BenzaClin or Duac; excluding pumps)	adapalene/benzoyl peroxide gel
erythromycin solution	Aklief AE
erythromycin/benzoyl peroxide	Altreno
Retin-A cream, gel	Arazlo
	Atralin
	Avar, Avar E, Avar E LS, Avar LS
	Avita
	benzamycin
	BP 10-1 cleanser

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	BP Cleansing Wash
	Cabtreo
	Cleocin-T
	Clindacin ETZ kit, medicated swab
	Clindacin foam
	Clindacin P medicated swab
	Clindacin PAC kit
	Clindagel
	clindamycin foam, lotion
	clindamycin phosphate EQ 1% gel (Generic Clindagel)
	clindamycin/benzoyl peroxide gel pump (Generic Acanya)
	clindamycin/benzoyl peroxide gel pump
	clindamycin/tretinoin gel
	dapsone gel, gel pump
	Differin cream, gel pump, lotion
	Epiduo Forte
	Ery medicated swab
	Erygel
	erythromycin gel
	Evoclin
	Fabior
	Klaron
	Neuac gel
	Neuac Kit
	Onexton
	Ovace wash
	Ovace Plus cream, lotion, shampoo, wash, wash clean gel
	Retin-A Micro gel, gel pump
	Rosula
	sodium sulfacetamide cleanser, cleanser gel, shampoo, suspension
	sodium sulfacetamide/sulfur cleanser, cream, lotion, medicated pad, suspension
	sodium sulfacetamide/sulfur/urea cleanser
	SSS 10-5 cream, foam
	Sumadan cleanser, kit
	Sumadan XLT cleanser cream
	Sumaxin, Sumaxin CP, Sumaxin TS
	tazarotene cream, foam, gel
	tretinoin cream, gel, microsphere gel, microsphere gel pump
	Twyneo
	Winlevi AE
	Ziana
	Zma Clear suspension

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Prior Authorization Criteria

Kentucky Medicaid

DERMATOLOGICS: TOPICAL ROSACEA AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Rhofade CC, AE, 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). **Quantity Limit**: 60 grams per 30 days **Age Limit:** ≥ 18 years

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
azelaic acid gel	brimonidine tartrate 0.33% gel pump
Finacea gel	Epsolay
metronidazole cream, gel, gel pump	Finacea foam
	ivermectin 1% cream
	MetroCream
	MetroGel
	metronidazole lotion
	Mirvaso

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Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Noritate
	Rhofade CC, AE, QL
	Rosadan
	Soolantra

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DERMATOLOGICS: TOPICAL ANTIFUNGAL AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Jublia [CC] Kerydin [CC]	• Diagnosis of toenail onychomycosis • Trial and failure of ciclopirox 8% nail solution or allergy to ciclopirox
Triamazole [AE, CC, QL]	**Length of Authorization**: 1 month **Criteria for Approval:** • Trial and failure of **five** unique chemical entities within the topical antifungal preparations listed below if appropriate for the patient's diagnosis (preferred or non-preferred), unless contraindication, allergy, or intolerance; **AND** • Trial and failure of one topical steroid listed below, if appropriate for the patient's diagnosis, unless contraindication, allergy, or intolerance; **AND** • One of the trials must include econazole combined with triamcinolone

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

Prior Authorization Criteria

Kentucky Medicaid

Agent(s) Subject to Criteria	Criteria for Approval

Preferred Topical Antifungal Agents	Non-Preferred Topical Antifungal Agents	Topical Steroids
• clotrimazole 1% topical cream (OTC and prescription) • clotrimazole 1% solution (OTC and prescription) • clotrimazole-betamethasone 1%-0.05% cream • ketoconazole 2% cream • nystatin cream, ointment, powder • nystatin-triamcinolone cream, ointment • Nystop powder • Miconazole 2% cream (OTC) • Terbinafine 1% cream (OTC) • Tolnaftate 1% cream, powder (OTC)	• ciclopirox 0.77% cream • econazole 1% cream • Mentax 1% cream • Oxistat 1% cream, lotion **These products are subject to non-preferred medication criteria*	• betamethasone valerate cream, ointment • betamethasone dipropionate cream, lotion • fluocinonide solution • triamcinolone cream, ointment, lotion

Quantity Limit: 165 grams per month

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	Ertaczo
ketoconazole cream [QL], shampoo	Extina

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Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
Nyamyc	Jublia CC
nystatin cream, ointment, powder QL	Kerydin CC
nystatin/triamcinolone cream, ointment	ketoconazole foam
Nystop	Ketodan
tavaborole	Loprox cream, kit, suspension, suspension kit
	luliconazole
	Luzu
	miconazole/zinc oxide/petrolatum
	naftifine cream, gel
	Naftin
	oxiconazole QL
	Oxistat QL
	Vusion

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DERMATOLOGICS: TOPICAL ANTIVIRAL AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

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**

   Approval of NON-PREFERRED branded agents requires:

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

   b. NPD Criteria above.

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

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

5. **DRUG-SPECIFIC CLINICAL CRITERIA**

   Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
acyclovir cream, ointment	Denavir
	penciclovir cream
	Xerese
	Zovirax cream, ointment

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

DERMATOLOGICS: TOPICAL ANTIPSORIATICS

GUIDELINES FOR USE

Approval Duration: 1 year

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**

   Approval of NON-PREFERRED branded agents requires:

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

   b. NPD Criteria above.

4. **GENERIC MEDICALLY NECESSARY CRITERIA**

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

5. **DRUG-SPECIFIC CLINICAL CRITERIA**

   Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
calcipotriene cream, ointment, solution	Bensal HP
calcipotriene/betamethasone suspension	calcipotriene foam
salicylic acid gel, liquid film	calcipotriene/betamethasone ointment
Salyntra gel	calcitriol ointment
urea cream QL	Duobrii
	Enstilar MD, AE
	salicylic acid foam
	salicylic acid ointment
	Sorilux
	Taclonex ointment, suspension
	Uramaxin
	Uramaxin GT
	urea foam

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

Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
	Zoryve AE, QL

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

Prior Authorization Criteria

Kentucky Medicaid

DERMATOLOGICS: TOPICAL STEROIDS

GUIDELINES FOR USE

Approval Duration: 1 year

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

Approval of NON-PREFERRED branded agents requires:

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

b. NPD Criteria above.

4. GENERIC MEDICALLY NECESSARY CRITERIA

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

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
alclometasone dipropionate	amcinonide cream QL
betamethasone dipropionate cream, lotion	Ana-Lex QL
betamethasone dipropionate (augmented) cream	Anusol HC
betamethasone valerate cream, ointment	Apexicon E
clobetasol propionate 0.05% cream, ointment, shampoo, solution	Beser
Clodan shampoo	betamethasone dipropionate augmented ointment, lotion, gel
Derma-Smoothe/FS	betamethasone dipropionate ointment
desonide cream, ointment	betamethasone valerate foam, lotion
fluocinonide ointment, solution	Bryhali
fluticasone propionate cream, ointment	Capex Shampoo
halobetasol propionate cream, ointment	clobetasol emollient, emulsion
hydrocortisone cream, lotion, ointment	clobetasol propionate 0.025% cream

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Prior Authorization Criteria

Kentucky Medicaid

Preferred Agents	Non-Preferred Agents
mometasone furoate cream, ointment, solution	clobetasol propionate foam, gel, lotion, spray
Procto-Med HC	Clobex spray
Proctosol-HC	clocortolone cream
Proctozone-HC	Clodan shampoo kit
triamcinolone acetonide cream, lotion, ointment	Cloderm
	desonide lotion
	desoximetasone cream, gel, ointment, spray
	diflorasone diacetate cream, ointment
	Diprolene AF
	fluocinolone acetonide cream, oil, ointment, solution
	fluocinonide emollient cream
	fluocinonide cream, gel
	fluocinonide-E cream
	flurandrenolide
	fluticasone propionate lotion
	halcinonide cream, solution
	halobetasol propionate foam
	Halog cream, ointment, solution
	hydrocortisone butyrate cream, lotion, ointment, solution
	hydrocortisone butyrate/emollient cream
	hydrocortisone solution
	hydrocortisone valerate cream, ointment
	Impeklo
	Kenalog
	Lexette
	Locoid Lipocream
	Locoid lotion
	Luxiq
	Olux
	Pandel
	prednicarbate cream, ointment
	Proctocort
	Sanaderm Rx
	Synalar cream, ointment, solution, kit
	Synalar TS
	Temovate
	Texacort
	Topicort cream, gel, ointment, spray
	Tovet emollient foam, kit
	triamcinolone acetonide spray
	Ultravate
	Vanos

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