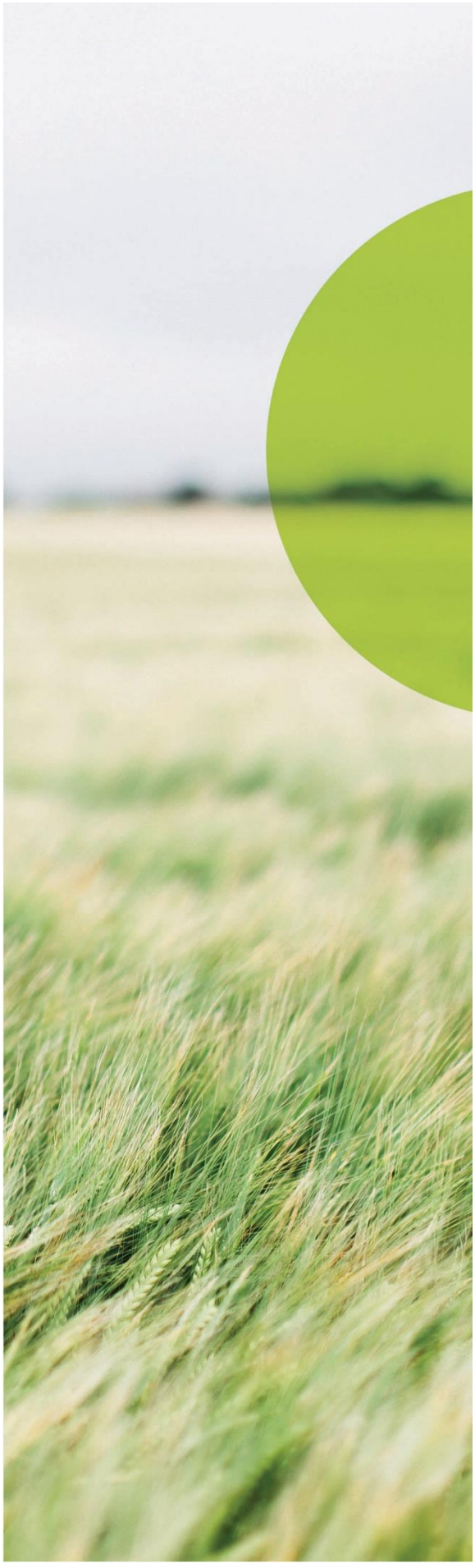

MedImpact **Clinical Document**

Kentucky Medicaid
Prior Authorization Criteria

VERSION: FEBRUARY 9, 2024

Prior Authorization Criteria

Kentucky Medicaid

Table of Contents

Table of Contents i
INTRODUCTION 1
CARDIOVASCULAR: ANGIOTENSIN RECEPTOR MODULATORS 2
CARDIOVASCULAR: ANTI-ANGINAL & ANTI-ISCHEMIC AGENTS 5
CARDIOVASCULAR: ANTIARRHYTHMICS (ORAL ANTI-ARRHYTHMICS) 6
CARDIOVASCULAR: BETA BLOCKERS 8
CARDIOVASCULAR: CALCIUM CHANNEL BLOCKERS 10
CARDIOVASCULAR: ANTICOAGULANTS 12
CARDIOVASCULAR: PLATELET AGGREGATION INHIBITORS 13
CARDIOVASCULAR: PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS, ORAL AND INHALED 14
CARDIOVASCULAR: LIPOTROPICS 17
GASTROINTESTINAL: ANTIEMETICS AND ANTIVERTIGO AGENTS 21
GASTROINTESTINAL: ANTIDIARRHEALS 25
GASTROINTESTINAL: ANTISPASMODICS/ANTICHOLINERGICS 27
GASTROINTESTINAL: ANTI-ULCER PROTECTANTS 29
GASTROINTESTINAL: BILE SALTS 30
GASTROINTESTINAL: H. PYLORI TREATMENT 33
GASTROINTESTINAL: HISTAMINE II (H2) RECEPTOR BLOCKERS 34
GASTROINTESTINAL: LAXATIVES AND CATHARTICS 35
GASTROINTESTINAL: GI MOTILITY AGENTS 36
GATROINTESTINAL: PROTON PUMP INHIBITORS 40
GATROINTESTINAL: ULCERATIVE COLITIS AGENTS 42
RESPIRATORY: ANTIBIOTICS, INHALED 44
RESPIRATORY: ANTIHISTAMINES, MINIMALLY SEDATING 46
RESPIRATORY: INTRANASAL RHINITIS AGENTS 47
RESPIRATORY: LEUKOTRIENE MODIFIERS 48
RESPIRATORY: BRONCHODILATORS, BETA-AGONIST 49
RESPIRATORY: EPINEPHRINE, SELF-INJECTABLE 51
RESPIRATORY: COPD AGENTS 52
RESPIRATORY: IMMUNOMODULATORS, ASTHMA 54
RESPIRATORY: GLUCOCORTICOIDS, INHALED 56

Prior Authorization Criteria

Kentucky Medicaid

CENTRAL NERVOUS SYSTEM: ALZHEIMER'S AGENTS 57
CENTRAL NERVOUS SYSTEM: ANXIOLYTICS 59
CENTRAL NERVOUS SYSTEM: ANTICONVULSANTS 61
CENTRAL NERVOUS SYSTEM: ANTIPSYCHOTICS: FIRST GENERATION (TYPICAL) 66
CENTRAL NERVOUS SYSTEM: ANTIPSYCHOTICS: SECOND GENERATION (ATYPICAL) AND INJECTABLE 67
CENTRAL NERVOUS SYSTEM: DOPAMINE RECEPTOR AGONISTS 75
CENTRAL NERVOUS SYSTEM: PARKINSON'S DISEASE (ANTIPARKINSON'S AGENTS) 76
CENTRAL NERVOUS SYSTEM: MOVEMENT DISORDERS 79
CENTRAL NERVOUS SYSTEM: ANTIDEPRESSANTS 81
CENTRAL NERVOUS SYSTEM: ANTI-MIGRAINE AGENTS, TRIPTANS 85
CENTRAL NERVOUS SYSTEM: ANTI-MIGRAINE AGENTS, CGRP INHIBITORS 87
CENTRAL NERVOUS SYSTEM: STIMULANTS AND RELATED AGENTS 92
CENTRAL NERVOUS SYSTEM: NARCOLEPSY AGENTS 96
CENTRAL NERVOUS SYSTEM: NEUROPATHIC PAIN 100
CENTRAL NERVOUS SYSTEM: SEDATIVE HYPNOTICS 102
CENTRAL NERVOUS SYSTEM: SKELETAL MUSCLE RELAXANTS 105
CENTRAL NERVOUS SYSTEM: TOBACCO CESSATION 107
SPINAL MUSCULAR ATROPHY 109
ANALGESICS: NARCOTICS, LONG-ACTING 114
ANALGESICS: NARCOTICS, SHORT-ACTING 120
ANALGESICS (CLINICAL CRITERIA FOR SHORT-ACTING AND LONG-ACTING OPIOIDS) 126
ANALGESICS: NARCOTICS, FENTANYL BUCCAL PRODUCTS 129
ANALGESICS: NARCOTIC AGONISTS/ANTAGONISTS 131
ANALGESICS: NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS) 132
ANALGESICS: OPIATE DEPENDENCE TREATMENTS 135
ANTI-INFECTIVE: ORAL ANTIFUNGALS 137
ANTI-INFECTIVE: ORAL ANTIVIRALS 140
ANTI-INFECTIVE: ORAL ANTIBIOTICS 142
ANTI-INFECTIVE: VAGINAL ANTIBIOTICS 147
ANTIRETROVIRALS: HIV/AIDS 148
HEPATITIS B AGENTS 153
HEPATITIS C AGENTS: INTERFERONS AND RIBAVIRINS 155
HEPATITIS C AGENTS: DIRECT-ACTING ANTIVIRALS 156

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

DIABETES: INSULINS AND RELATED AGENTS 159
DIABETES: GLP-1 RECEPTOR AGONISTS 161
DIABETES: DPP-4 INHIBITORS 163
DIABETES: SGLT2 INHIBITORS 165
DIABETES: ALPHA-GLUCOSIDASE INHIBITORS 166
DIABETES: METFORMINS 168
DIABETES: MEGLITINIDES 169
DIABETES: SULFONYLUREAS 170
DIABETES: THIAZOLIDINEDIONES (TZDS) 171
ENDOCRINE AND METABOLIC AGENTS: GLUCAGON AGENTS 172
ENDOCRINE AND METABOLIC AGENTS: GROWTH HORMONES 173
ENDOCRINE AND METABOLIC AGENTS: GLUCOCORTICOIDS, ORAL (ORAL STEROIDS) 176
ENDOCRINE AND METABOLIC AGENTS: PANCREATIC ENZYMES 179
ENDOCRINE AND METABOLIC AGENTS: PROGESTINS FOR CACHEXIA 180
ENDOCRINE AND METABOLIC AGENTS: ANDROGENIC AGENTS 181
ENDOCRINE AND METABOLIC AGENTS: BONE RESORPTION SUPRESSION AND RELATED AGENTS 182
ENDOCRINE AND METABOLIC AGENTS: UTERINE DISORDER TREATMENTS 184
IMMUNOSUPPRESSANTS 185
MULTIPLE SCLEROSIS AGENTS 188
CYTOKINE AND CAM ANTAGONISTS 194
IMMUNOLOGIC AND GENETIC: IMMUNOMODULATORS, ASTHMA 212
IMMUNOMODULATORS, ATOPIC DERMATITIS 214
BLOOD MODIFIERS: ANTIHYPERURICEMICS 218
BLOOD MODIFIERS: COLONY STIMULATING FACTORS 221
BLOOD MODIFIERS: ERYTHROPOIESIS STIMULATING AGENTS 223
BLOOD MODIFIERS: PHOSPHATE BINDERS 225
BLOOD MODIFIERS: SICKLE CELL ANEMIA TREATMENTS 226
BLOOD MODIFIERS: THROMBOPOIESIS STIMULATING PROTEINS 228
OPHTHALMIC ANTIBIOTICS AND ANTIVIRALS 231
OPHTHALMICS FOR ALLERGIC CONJUNCTIVITIS 233
OPHTHALMICS: GLAUCOMA AGENTS 234
OPHTHALMICS: NSAIDS 236
OPHTHALMICS: ANTI-INFLAMMATORY STEROIDS 237
OPHTHALMICS: IMMUNOMODULATORS 238

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

OPHTHALMIC: MYDRIATIC....240
OTICS....241
RENAL AND GENITOURINARY: ALPHA BLOCKERS FOR BPH & 5-ALPHA REDUCTASE INHIBITORS....243
BLADDER RELAXANTS....245
DERMATOLOGICS: TOPICAL ANTIBIOTIC AGENTS....247
DERMATOLOGICS: TOPICAL ANTIPARASITICS....248
DERMATOLOGICS: ORAL ANTIPSORIATICS....249
DERMATOLOGICS: ORAL ACNE AGENTS....250
DERMATOLOGICS: TOPICAL ACNE....251
DERMATOLOGICS: TOPICAL ROSACEA AGENTS....253
DERMATOLOGICS: TOPICAL ANTIFUNGAL AGENTS....255
DERMATOLOGICS: TOPICAL ANTIVIRAL AGENTS....258
DERMATOLOGICS: TOPICAL ANTIPSORIATICS....259
DERMATOLOGICS: TOPICAL STEROIDS....259

Prior Authorization Criteria

Kentucky Medicaid

INTRODUCTION

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

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

Kentucky Medicaid

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

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Epaned [CC, QL] 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
	moexipril
	perindopril

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

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

ACE INHIBITORS + DIURETIC COMBINATIONS

Preferred Agents	Non-Preferred Agents
benazepril/HCTZ	Accuretic
lisinopril/HCTZ	captopril/HCTZ
	enalapril/HCTZ
	fosinopril/HCTZ
	Lotensin HCT
	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
	eprosartan
	Micardis
	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

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

Prior Authorization Criteria

Kentucky Medicaid

DIRECT RENIN INHIBITORS

Preferred Agents	Non-Preferred Agents
N/A	aliskiren
	Tekturna
	Tekturna HCT

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

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	• 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
	Ranexa

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

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
quinidine sulfate	Pacerone
Sorine	propafenone SR/ER
sotalol	qunidine gluconate ER

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
sotalol AF	Rythmol SR
	Sotylize[CC]
	Tikosyn

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

CARDIOVASCULAR: BETA 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 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	Bystolic
bisoprolol/HCTZ	carvedilol ER
carvedilol	Coreg CR
labetalol	Coreg
metoprolol succinate ER	Corgard
metoprolol tartrate	Hemangeol
nadolol	Inderal LA
nebivolol	Inderal XL
propranolol ER	Innopran XL

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
propranolol solution	Kapspargo
propranolol tablet	Lopressor
	Metoprolol/HCTZ
	Pindolol
	Propranolol/HCTZ
	Tenoretic
	Tenormin
	Timolol
	Toprol XL
	Ziac

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

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

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

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 capsule	Diltiazem ER (LA) tablet
diltiazem XR	felodipine ER
Dilt-XR	isradipine
nifedipine ER	Katerzia
Taztia XT	levamlodipine
Tiadylt ER	Matzim
verapamil tablet	nicardipine
verapamil ER tablet	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	Azor
amlodipine/olmesartan	Exforge HCT
amlodipine/valsartan	Exforge
amlodipine/valsartan/HCTZ	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

Not applicable.

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
	Savaysa
	Xarelto granules for suspension

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

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	
prasugrel	

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

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] Revatio 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
Tracleer 32mg tablets for suspension	• PDP criteria; **AND** • Unable to swallow Tracleer tablets.

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
Tyvaso, Tyvaso DPI	**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) • 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 • Patient has not experienced any treatment limiting adverse effects.

CURRENT PDL STATUS

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

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
	Uptravi QL
	Ventavis

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

CARDIOVASCULAR: LIPOTROPICS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Not applicable. All preferred agents are preferred without PA.

2. NON-PREFERRED (NPD) CRITERIA

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

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
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

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 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** • Documentation of low-density lipoprotein cholesterol (LDL-C) prior to/without bempedoic acid therapy; **AND** • Diagnosis of heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease; **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 with bempedoic acid. **Renewal Criteria** • Documentation (e.g., progress note or lab report) that demonstrate a reduction in LDL-C when compared to the baseline values. **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.

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 or lab report) that demonstrate a reduction in LDL-C when compared to the baseline values.

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

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

Prior Authorization Criteria

Kentucky Medicaid

LIPOTROPICS: STATINS

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

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

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**
	• Demonstrated improvement in signs and symptoms of diabetic gastroparesis (e.g., nausea, vomiting, early satiety, postprandial fullness, bloating, upper abdominal pain); **AND**

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

Agent(s) Subject to Criteria	Criteria for Approval
	• 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

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	• 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
hyoscyamine sulfate elixir	Hyosyne drops
hyoscyamine sulfate ER tablet	Hyosyne elixir
hyoscyamine sulfate ODT tablet	Levsin tablet
hyoscyamine sulfate SL tablet	Levsin/SL tablet

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 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 tablets	sucralfate suspension

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

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.*

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 has experienced a reduction in serum bile acids from baseline; **AND**
	• Patient has experienced an improvement in pruritus; **AND**
	• Patient has NOT experienced any treatment-restricting adverse effects
	
	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 pruritis 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 pruritis 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 NOT experienced any treatment-restricting adverse effects
	
	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

Livmarli CC, QL	**Length of Authorization: 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**

Agent(s) Subject to Criteria	Criteria for Approval
	• Patient has evidence of cholestasis, as evidenced by ≥ 1 of the following: ○ Serum bile acid > 3 times upper limit of normal (ULN) for age ○ Conjugated bilirubin > 1 mg/dL ○ Gamma glutamyl transferase (GGT) > 3 times ULN for age ○ Fat soluble vitamin deficiency not otherwise explained ○ Intractable pruritus only explained by liver disease; **AND** • Patient experiences persistent moderate to severe pruritus; **AND** • Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to at least 1 pruritus treatment (e.g.,ursodiol, cholestyramine, rifampin, naloxone, naltrexone, antihistamine). *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; **AND** • Patient has NOT experienced any treatment-restricting adverse effects Maximum Dose Limit: 28.5mg (3mL) 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
	Livmarli solution 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: 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

Not applicable.

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

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 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	Osmoprep tablet
MoviPrep powder packet	PEG 3350/Sod Sul/NaCl/KCl/AsbC powder packet
PEG 3350/Electrolyte solution	Plenvu powder packet
PEG-3350 and Electrolytes	Sodium Sulfate/Potassium Sulfate/Magnesium Sulfate solution
	Suflave solution
	Suprep solution
	Sutab tablet

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

GASTROINTESTINAL: GI MOTILITY AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Amitiza CC, AE, 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 CC, AE, 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 CC, AE, 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 CC, AE, QL	• Diagnosis of one of the following conditions: ○ Chronic idiopathic constipation (CIC); **OR** ○ Irritable bowel syndrome with constipation (IBS-C). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 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 **≥ 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 CC, AE, QL
Lotronex CC, AE, 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

Ibsrela CC, AE, 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

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

Agent(s) Subject to Criteria	Criteria for Approval
Reslistor CC, AE, 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
Symproic CC, AE, QL	• Diagnosis of opioid-induced constipation (OIC) related to chronic non-cancer pain [including patients with chronic pain related to prior cancer or its treatment who do NOT require frequent (e.g., weekly) opioid dosage escalation]; **AND** • Patient has been using opioids for at least 150 days within past 180 days; **AND** • Trial and failure of ≥ 2 preferred agents in this class; **AND** • Trial and failure of ≥ 2 different laxative drug classes, such as: ○ Stool softeners (e.g., docusate) ○ Stimulant laxatives (e.g., bisacodyl, sennosides) ○ Osmotic or saline laxatives (e.g., polyethylene glycol 3350) ○ Bulk forming laxatives (e.g., psyllium) ○ Lubricant laxatives (e.g., mineral oil) • Patient does NOT have any the following conditions: ○ Known or suspected gastrointestinal obstruction ○ Pregnancy ○ Severe hepatic impairment (Child-Pugh Class C) **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Viberzi CC, AE, 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):

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

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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
Amitiza capsule CC, AE, QL	Alosetron tablet CC, AE, QL
Linzess capsule CC, AE, QL	Ibsrela tablet CC, AE, QL
Movantik tablet CC, AE, QL	Lotronex tablet CC, AE, QL
Trulance tablet CC, AE, QL	Lubiprostone capsule AE, QL
	Motegrity tablet AE, QL
	Relistor syringe CC, AE
	Relistor tablet CC, AE, QL
	Relistor vial CC, AE
	Symproic CC, AE, QL
	Viberzi CC, AE, 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

Not applicable.

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 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

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
	Protonix tablet QL
	rabeprazole tablet 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 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
	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
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 (Mylan) QL	Auvi-Q autoinjector QL
epinephrine 0.15 mg autoinjector (Mylan) QL	epinephrine 0.15 mg autoinjector QL
EpiPen QL	epinephrine 0.3 mg autoinjector QL
EpiPen Jr. QL	Symjepi QL

RESPIRATORY: COPD 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 **≥ 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.
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
Trelegy Ellipta [CC, QL]	• Diagnosis of chronic obstructive pulmonary disorder (COPD) or 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). • **Age Limit:** ≥ 18 years

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
albuterol-ipratropium inhalation solution QL	Bevespi Aerosphere QL
Anoro Ellipta QL	Breztri Aerosphere QL
Atrovent HFA QL	Daliresp tablet CC, QL
Combivent Respimat QL	Duaklir Pressair
ipratropium inhalation solution QL	Incruse Ellipta QL
Spiriva Handihaler QL	roflumilast tablet CC, QL
Stiolto Respimat QL	Spiriva Respimat QL
	Tiotropium QL
	Trelegy Ellipta CC, QL
	Tudorza Pressair QL
	Yupelri solution CC, QL

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

RESPIRATORY: IMMUNOMODULATORS, ASTHMA

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 **≥ 90 day** trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 1 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

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 1 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**

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

Agent(s) Subject to Criteria	Criteria for Approval
	○ FEV1; **AND** • Must not be used in combination with anti-lgE, anti-IL4, or anti-IL5 monoclonal antibody agents (e.g., benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab); **AND** • Patient does not have an active or untreated helminth infection; **AND** • Will not be administered concurrently with live vaccines; **AND** • Patient has had a trial and failure, contraindication, or intolerance to at least 1 preferred agent. **Renewal Criteria** • Improvement in 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** ○ Patient has not experienced any treatment-restricting adverse effects. **Age Limit:** ≥ 12 years old **Quantity Limit:** 1 prefilled syringe per 28 days (0.07 mL per day)

6. THERAPEUTIC DUPLICATON

Approval Duration: Date of Service Only

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

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Fasenra AE, QL	Tezspire CC, AE, QL
Nucala AE, QL	
Xolair AE, 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
	Flovent Diskus QL
	Pulmicort Flexhaler 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 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 days 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	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	• 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.
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

Sympazan [CC, QL]	• Clinical rationale that clobazam suspension or tablets cannot be used.
Xcopri [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: 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

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; **AND** • Patient has not experienced any treatment-restricting adverse effects (e.g., somnolence, pyrexia, suicidal thoughts or behavior) **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
Celotonin capsule	clonazepam ODT QL
clobazam suspension QL	Depakote ER tablet
clobazam tablet QL	Depakote sprinkle capsule
clonazepam tablet QL	Depakote tablet
diazepam kit 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

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
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	Felbatol suspension
lamotrigine tablet	Felbatol tablet
lamotrigine chewable tablet	Fintepla solution QL
levetiracetam ER tablet QL	Fycompa suspension
levetiracetam solution QL	Fycompa tablet QL
levetiracetam tablet QL	Keppra solution
Nayzilam spray AE, QL	Keppra tablet QL
oxcarbazepine suspension	Keppra XR tablet QL
oxcarbazepine tablet QL	Klonopin tablet QL
phenobarbital elixir CC	Lamictal tablet dose packs
phenobarbital tablet CC	Lamictal ODT dose packs
phenytoin suspension	Lamictal XR tablet dose packs
phenytoin sodium ER capsule	Lamictal ODT
phenytoin chewable tablet	Lamictal tablet
primidone tablet	Lamictal chewable tablet
Roweepra tablet QL	Lamictal XR tablet QL
Sabril powder packet QL CC	lamotrigine tablet dose packs
Sabril tablet CC, QL	lamotrigine ODT dose packs
Tegretol suspension	lamotrigine ER tablet QL
tiagabine tablet QL	lamotrigine ODT
topiramate sprinkle capsule QL	methsuximide capsule
topiramate tablet QL	Motpoly XR capsule
valproic acid capsule	Mysoline tablet CC
valproic acid solution	Onfi suspension QL
Valtoco spray QL	Onfi tablet QL
zonisamide capsule 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

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
	Vigabatrin powder packet QL
	Vigabatrin tablet QL
	Vigadrone powder packet QL
	Vigadrone tablet QL
	Vimpat solution QL
	Vimpat tablet QL
	Xcorpi tablet dose pack CC, QL
	Xcorpi tablet CC, QL
	Zarontin capsule
	Zarontin solution
	Zonisamide suspension QL
	Ztalmy suspension AE, CC, QL

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

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 olanzapine CC, QL quetiapine CC, QL quetiapine ER CC, QL risperidone CC, QL Vraylar AE, CC, QL ziprasidone capsules CC, QL Abilify Maintena CC, QL Aristada ER CC, QL Aristada Initio CC, QL fluphenazine decanoate CC, QL Geodon injection CC, QL haloperidol decanoate CC, QL haloperidol lactate CC, QL Invega Sustenna CC, QL olanzapine CC, QL Perseris ER CC Risperdal Consta 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; **AND** • Patient has had at least a 2-week trial of ONE preferred antipsychotic (oral or parenteral) at an appropriate dose; **AND** • Patient is established on oral aripiprazole with adequate response and tolerability. . **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe every 56 days
Uzedy AE, CC, QL	• Patient has a diagnosis of schizophrenia; **AND** • Patient has had at least a 2-week trial of ONE preferred antipsychotic (oral or parenteral) at an appropriate dose; **AND** • Patient is established on oral risperidone with adequate response and tolerability

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
	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
	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

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
	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
	F11.251	Opioid dependence with opioid-induced psychotic disorder with hallucinations
	F11.951	Opioid use, unspecified with opioid-induced psychotic disorder with hallucinations

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	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
	F18.951	Inhalant use, unspecified with inhalant-induced psychotic disorder with hallucinations

Approvable ICD-10 Group	Approvable ICD-10	Approvable ICD-10 Description
	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:** • 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

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

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; **AND**
	• Patient has NOT experienced any treatment-restricting adverse effects.
	
	Age Limit: ≥ 18 years 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
	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)

6. THERAPEUTIC DUPLICATION/MULTIPLE AGENTS CRITERIA

Prior authorization when ≥ 3 atypical antipsychotics are sued 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	Fanapt tablet dose pack QL
risperidone solution CC, QL	Fanapt tablet QL
risperidone tablet CC, QL	Geodon capsule QL
Vraylar capsule dose pack CC, QL	Invega ER tablet QL
Vraylar capsule CC, QL	Latuda tablet QL
ziprasidone capsule CC, QL	Lybalvi tablet AE, CC, QL
	Nuplazid capsule CC, QL
	Nuplazid tablet CC, QL
	olanzapine/fluoxetine capsule CC, 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
	paliperidone ER tablet QL
	Rexulti tablet QL
	Risperdal solution QL
	Risperdal tablet QL
	Saphris SL tablet CC, QL
	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	Haldol Decanoate ampule QL
Abilify Maintena syringe CC, QL	risperidone ER vial QL
Abilify Maintena vial CC, QL	Rykindo vial QL
Aristada syringe CC, QL	ziprasidone mesylate vial QL
Aristada Initio syringe CC, QL	Zyprexa Relprevv vial QL
fluphenazine decanoate vial CC, QL	Zyprexa vial QL
Geodon vial CC, QL	
haloperidol decanoate ampule CC, QL	
haloperidol decanoate vial CC, QL	
haloperidol lactate syringe CC, QL	
haloperidol lactate vial CC, QL	
Invega® Hafyera syringe CC, AE, QL	
Invega® Sustenna syringe CC, QL	
Invega Trinza syringe CC, QL	
olanzapine vial CC, QL	
Perseris suspension CC	
Risperdal Consta vial CC, QL	
Uzedy suspension CC, QL	

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

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

Kynmobi [CC, QL]	• Diagnosis of Parkinson's disease (PD); **AND**
	• Receiving PD therapy with carbidopa/levodopa; **AND**
	• Experiencing "off" episodes with carbidopa/levodopa for at least 2 hours per day; **AND**
	• Trial and failure of at least 2 adjunctive therapies, such as:
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole)
	  ○ Monoamine oxidase-B inhibitors (e.g., selegiline)
	  ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); **AND**
	• Patient will be offered a non-5HT3 antagonist antiemetic (e.g., trimethobenzamide); **AND**
	• NONE of the following contraindications:
	  ○ Receiving concomitant 5-HT3 antagonists (e.g., ondansetron); **OR**
	  ○ Major psychiatric disorder.

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 has clinically meaningful response to treatment (e.g., patient shows a reduction in time of “off” episodes) **Age Limit:** ≥ 18 years **Quantity Limit:** 5 per day

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)
	
	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

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

Agent(s) Subject to Criteria	Criteria for Approval

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**
	• 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	Dhivy tablet
carbidopa/levodopa ER tablet	Duopa suspension
carbidopa/levodopa ODT	Gocovri capsule
carbidopa/levodopa tablet	Inbrija inhalation
carbidopa/levodopa/entacapone tablet	Kynmobi film CC, QL
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
	Xadago CC, QL
	Zelapar ODT

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, 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, QL]	**Initial Approval Criteria:** • 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**

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

Agent(s) Subject to Criteria	Criteria for Approval

	• 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 tardive dyskinesia symptoms
	
	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.

CURRENT PDL STATUS

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

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

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.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

5. 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 must not have hypersensitivity to bupropion, dextromethorphan, or any component of the product; **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** • Patient has not experienced any treatment-restricting adverse effects (e.g., seizure, hypertension, psychosis, serotonin syndrome, angle-closure glaucoma) **Quantity Limit:** 60 tablets per 30 days **Age Limit:** ≥ 18 years old

Spravato CC, QL	**Approval Duration:** 4 weeks initial; 1 year renewal (treatment resistant depression only)
	
	Initial Approval Criteria
	• 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**
	• Diagnosis of major depressive disorder (MDD) considered treatment resistant as evidenced by BOTH of the following:
	  ○ Trial and failure (defined as < 50% reduction in symptom severity using any validated depression rating scale) of ≥ 2 antidepressants from different classes for a duration of ≥ 6 weeks each at generally accepted doses in the current depressive episode, unless contraindicated or clinically significant adverse effects are experienced; **AND**
	  ○ Trial and failure of antidepressant augmentation therapy for a duration of ≥ 6 weeks in the current depressive episode with ≥ 1 of the following, unless contraindicated or clinically significant adverse effects are experienced:
	  ▪ An atypical antipsychotic; **OR**
	  ▪ Lithium; **OR**
	  ▪ An antidepressant from a different class; **OR**
	• Diagnosis of MDD with acute suicidal ideation or behavior; **AND**
	• Used in conjunction with another antidepressant medication (not to be used as monotherapy); **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)

- Continue to meet initial approval criteria for treatment resistant depression; **AND**
- Prescriber attestation that patient has been compliant with doses/appointments; **AND**
- Attestation or documentation of disease improvement or stabilization as evidenced by improvement on a validated depression rating scale.

Age Limit: ≥ 18 years old
Quantity Limit: 1 kit (56 or 84 mg) per week; overrides allowed for twice weekly)

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	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

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
	Fetzima ER capsule dose pack
	Pristiq ER tablet
	venlafaxine besylate ER tablet
	venlafaxine ER tablet

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

Prior Authorization Criteria

Kentucky Medicaid

ANTIDEPRESSANTS: SSRIS

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

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

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 tablet QL	frovatriptan tablet QL
sumatriptan vial QL	Imitrex cartridge QL
	Imitrex pen QL
	Imitrex tablet QL
	Maxalt-MLT ODT QL
	Maxalt tablet QL
	naratriptan tablet QL
	Relpax tablet QL
	sumatriptan nasal spray QL
	sumatriptan cartridge QL
	sumatriptan injector QL
	sumatriptan/naproxen tablet QL
	Tosymra spray
	Zembrace SymTouch CC, QL
	zolmitriptan ODT QL
	zolmitriptan spray QL
	zolmitriptan tablet QL
	Zomig spray QL
	Zomig tablet QL

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

CENTRAL NERVOUS SYSTEM: ANTI-MIGRAINE AGENTS, CGRP INHIBITORS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

<table>
<tr><th>Agent(s) Subject to Criteria</th><th>Criteria for Approval</th></tr>
<tr><td>Aimovig CC, QL
Ajovy CC, QL
Emgality 120 mg/mL CC, QL
Nurtec ODT CC, QL (for prevention of episodic migraine)</td><td>Approval Duration: 3 months initial; 1 year renewal
• Diagnosis of migraine with or without aura; AND
• Patient has tried and failed a ≥ 1-month trial (at maximally tolerated doses) of two medications listed below from the 2012 American Academy of Neurology/American Headache Society guidelines. At least ONE medication must be level A or B recommendation, unless ALL are contraindicated:
<table><tr><th>Level A</th><th>Level B</th><th>Level C</th></tr><tr><td>• divalproex sodium
• sodium valproate
• topiramate
• metoprolol
• propranolol
• timolol</td><td>• amitriptyline
• venlafaxine
• atenolol
• nadolol</td><td>• clonidine
• guanfacine
• lisinopril
• candesartan
• carbamazepine
• cyproheptadine
• nebivolol
• pindolol</td></tr></table>Renewal Criteria
• Patient has an overall improvement in function with therapy.
Age Limit: ≥ 18 years</td></tr>
<tr><td>Nurtec ODT CC, QL</td><td>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.</td></tr>
</table>

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: 8 tablets (1 package) per 30 days** • One-time fill of 16 tablets (2 packages) per 30 days allowed with prior authorization: concurrent use of any oral or injectable prophylactic agent.
Ubrelvy CC, QL	• Diagnosis of migraine, with or without aura; **AND** • NOT have end-stage renal disease (creatinine clearance [CrCl] < 15 mL/min); **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: 10 tablets (1 package) per 30 days** • One-time fill of 20 tablets (2 packages) per 30 days allowed with prior authorization: current use of any oral or injectable prophylactic agent listed below.

2. NON-PREFERRED (NPD) CRITERIA

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

3. BRAND MEDICALLY NECESSARY CRITERIA

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, 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**

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 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
Qulipta CC, AE, 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**

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

Agent(s) Subject to Criteria	Criteria for Approval
	• Medication overuse has been ruled out; **AND** • Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to 1 preferred CGRP inhibitor used for preventative treatment of migraine in adults. *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; **AND** • Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to 1 preferred CGRP inhibitor used for preventative treatment of migraine in adults. **Renewal Criteria** • Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches; **AND** • Patient has NOT experienced any treatment-restricting adverse effects. **Age Limit:** ≥ 18 years **Quantity Limit:** • 30mg tablet and 60mg tablet: 30 tablets/30 days • 10mg tablet: 60 tablets/30 days
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 NOT have hypersensitivity to any component of the product; **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**

Agent(s) Subject to Criteria	Criteria for Approval
	• 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	Qulipta tablet CC, AE, QL
Ajovy syringe CC, AE, QL	Reyvow talbet CC, AE, QL
Emgality pen CC, AE, QL	Zavzpret CC, AE, QL
Emgality 200 mg/mL syringe CC, AE, QL	
Nurtec ODT CC, AE, QL	
Ubrelvy tablet CC, AE, QL	

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

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 Concerta CC, QL dexmethylphenidate CC, QL dexmethylphenidate ER CC, QL dextroamphetamine CC, QL dextroamphetamine/amphetamine CC, QL guanfacine ER CC, QL Methylin solution CC, QL methylphenidate solution 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)
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. **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]

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
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
Concerta tablet CC, QL	amphetamine sulfate tablet QL
dexmethylphenidate ER tablet CC, QL	Aptensio XR sprinkle capsule QL
dexmethylphenidate tablet CC, QL	Azstarys capsule QL
dextroamphetamine sulfate tablet CC, QL	clonidine ER tablet QL
dextroamphetamine/amphetamine tablet CC, QL	Cotempla XR-ODT tablet AE, 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
guanfacine ER tablet CC, QL	Daytrana patch QL
Methylin solution CC, QL	Desoxyn tablet QL
methylphenidate solution CC, QL	Dexedrine capsule ER QL
methylphenidate tablet CC, QL	dextroamphetamine ER capsule QL
Vyvanse capsule CC, QL	dextroamphetamine solution QL
Vyvanse chewable tablet CC, QL	dextroamphetamine tablet QL
	dextroamphetamine/amphetamine ER capsule CC, QL
	Dyanavel XR suspension AE, QL
	Dyanavel XR tablet AE, QL
	Evekeo ODT QL
	Evekeo tablet QL
	Focalin tablet 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 sprinkle capsule QL
	methylphenidate LA capsule QL
	methylphenidate ER tablet QL
	methylphenidate ER OROS QL
	methylphenidate capsule QL
	methylphenidate chewable tablet QL
	methylphenidate patch QL
	Mydayis ER capsule AE, QL
	ProCentra solution QL
	Qelbree ER capsule 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

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

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
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
	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

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
Provigil tablet CC, QL	armodafinil tablet QL
	modafinil tablet QL
	Nuvigil 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
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

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	Gralise tablet
Lidocaine patch QL	Horizant tablet
Lidoderm patch QL	Lyrica capsule QL
pregabalin capsule QL	Lyrica CR 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
pregabalin solution 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

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

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]	• 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**

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 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**
ramelteon CC, MD, QL 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
temazepam 15 mg, 30 mg capsule MD, QL	Ambien tablet MD, QL
zolpidem tartrate MD, QL	Belsomra 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
	ramelteon tablet CC, MD, QL
	Restoril capsule MD, QL
	Rozerem tablet CC, MD, QL
	tasimelteon capsule CC, QL
	temazepam 7.5 mg, 22.5 mg capsule MD, QL
	triazolam tablet MD, QL
	zaleplon capsule MD, QL
	zolpidem capsule MD, QL
	zolpidem ER tablet MD, QL
	zolpidem SL tablet MD, QL

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

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 tablet QL	Amrix ER capsule QL, MD
chlorzoxazone tablet QL	baclofen suspension QL
cyclobenzaprine tablet QL	baclofen solution QL
methocarbamol tablet QL	carisoprodol tablet QL, MD
orphenadrine ER tablet	carisoprodol/ASA tablet QL, MD
tizanidine tablet QL	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
	Norgesic Forte tablet
	Norgesic tablet
	orphenadrine/ASA/caffeine tablet
	orphengesic forte tablet
	Soma tablet QL, MD
	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 cartridge QL	
Nicotrol nasal spray QL	
Varenicline dose pack AE, 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
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 [CC]	**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**
	• Not to be used in combination with Spinraza (nusinersen); **AND**
	• Patient has not received treatment with Zolgensma (onasemnogene abeparvovec-xioi).
	
	Renewal criteria (all requests):
	• Documentation of repeat motor function testing showing motor improvements or clinically significant improvements in SMA associated symptoms such as:
	  ○ Lack of disease progression or 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 with current measurements using one of the assessments listed above); **AND**
	• Individual dose not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease.

Spinraza CC	**Approval Duration: 6 months initial; 12 months renewal**
	
	Initial Approval Criteria (must meet all requirements):
	• Clinical documentation (e.g., progress notes) supporting diagnosis of Spinal Muscular Atrophy (SMA) type I, II, or III **AND**
	• Diagnosis/genetic testing results (official laboratory results) confirming 5q SMA:
	  ○ Homozygous deletion or mutation of the survival motor neuron 1 (SMN1) gene; **OR**
	  ○ Compound heterozygous mutation of the SMN1 gene; **AND**
	  ○ At least two copies of the SMN2 gene.
	• Patient is non-ambulatory (unable to walk); **AND**

Agent(s) Subject to Criteria	Criteria for Approval
	• 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** • Drug is being prescribed by or in consultation with a neurologist or other specialist with expertise in the diagnosis and management of SMA; **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) • Spinraza is NOT being used in combination with Evrysdi (risidiplam); **AND** • Patient has not received treatment with Zolgensma (onasemnogen abeparvovec-xioi). **Renewal Criteria (must meet all requirements):** **If the patient becomes dependent on permanent assisted ventilation while on Spinraza, then continued therapy will no longer be authorized.** • All initial approval requirements continue to be met; **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 disease) evident by the comparative assessment of baseline motor function measurements using one of the following assessments:

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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** • Spinraza is NOT being used in combination with Evrysdi (risdiplam); **AND**
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**

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

Agent(s) Subject to Criteria	Criteria for Approval

	• 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**
	• Not to be used in combination with Spinraza (nusinersen); **AND**
	• Not to be used in combination with Evrysdi (risdiplam); **AND**
	• Therapy to be administered prior to recipient's 2nd birthday.

CURRENT PDL STATUS

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

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

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

2. OPIOID CLASS CRITERIA FOR INITIAL APPROVAL

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.

3. 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.

4. 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.

5. 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.

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. 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**

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]).

8. 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.

9. 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.

10. GENERIC MEDICALLY NECESSARY CRITERIA

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

11. DRUG-SPECIFIC CLINICAL CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Nucynta ER [CC, QL]	• Opioid Class Criteria for Initial Approval must be met; **AND** • NPD Criteria must met; **OR** • Diagnosis of diabetic peripheral neuropathy with trial and failure of: ○ 1 serotonin-norepinephrine reuptake inhibitor (SNRI; such as duloxetine); **AND** ○ 1 tricyclic antidepressant (TCA; such as amitriptyline)
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**

Prior Authorization Criteria

Kentucky Medicaid

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

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
	Nucynta ER tablet CC, 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
	Xtampza ER sprinkle capsule AE. QL

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

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, 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 FOR INITIAL APPROVAL

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.

3. 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.

4. 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.

5. 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.

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 must submit an assessment of current pain and function based on an objective measure; **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]).

8. 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.

9. 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.

10. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

11. 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)

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 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 solution CC, MD, QL	Dilaudid liquid MD, QL
morphine syringe CC, MD, QL	Dilaudid tablet MD, QL
morphine tablet CC, MD, QL	Fioricet with codeine capsule CC, AE, QL
oxycodone solution CC, MD, QL	hydromorphone liquid MD, QL
oxycodone tablet CC, MD, QL	hydromorphone suppository MD, QL
oxycodone/APAP tablet CC, MD, QL	levorphanol tablet MD, QL
tramadol 50 mg tablet CC, MD, AE, QL	meperidine solution MD, QL
tramadol/APAP tablet MD, AE, QL	meperidine tablet MD, QL
	morphine suppository MD, QL
	Nalocet tablet MD, QL
	Nucynta tablet MD, QL
	oxycodone capsule MD, QL
	oxycodone concentrate MD, QL
	oxycodone oral syringe MD, QL
	oxycodone/APAP solution MD, QL
	oxymorphone tablet MD, QL
	Percocet tablet MD, QL
	Prolate solution MD, QL
	Prolate tablet MD, QL
	Roxicodone tablet MD, QL
	Roxybond tablet MD, QL
	Seglentis tablet MD, AE, QL
	tramadol 25 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 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).

6. 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 suppository	diclofenac potassium tablet
ketorolac tablet	diclofenac topical solution CC
meloxicam tablet	diclofenac sodium SR/ER tablet
naproxen sodium tablet	diclofenac 2% solution pump CC
naproxen tablet	diclofenac sodium/misoprostol
sulindac tablet	diflunisal 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
	Flector patch CC
	flurbiprofen tablet
	ibuprofen/famotidine tablet
	indomethacin ER capsule
	indomethacin suspension QL
	ketoprofen ER capsule
	ketoprofen capsule
	ketorolac nasal spray CC
	Licart patch CC
	Lofena tablet
	meclofenamate capsule
	mefenamic acid capsule
	meloxicam capsule CC, QL
	nabumetone tablet
	Nalfon capsule
	Nalfon tablet
	Naprelan CR tablet
	naproxen DR tablet
	naproxen suspension

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
	naproxen sodium CR/ER tablet
	naproxen/esomeprazole DR tablet CC, QL
	oxaprozin tablet
	Pennsaid CC
	piroxicam capsule
	Relafen tablet
	Relafen DS tablet
	tolmetin capsule
	tolmetin tablet
	Vimovo CC, QL

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

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 AE	None
Buprenorphine SL tablet AE, QL	
buprenorphine/naloxone SL film AE, QL	
buprenorphine/naloxone SL tablet AE, QL	
Lucemyra tablet AE, QL	
naltrexone tablet AE	
Sublocade ER syringe AE, QL	
Suboxone film AE, QL	
Vivitrol ER suspension AE	
Zubsolv SL tablet AE, 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**

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 must not have hypersensitivity to any component of the product; **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
nystatin suspension, tablets	flucytosine
terbinafine	griseofulvin microsize tablet, ultramicrosize tablet
	itraconazole solution
	ketoconazole
	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
Firvanq [CC] vancomycin capsules [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 **NOTE:** linezolid suspension may be approved when the above criteria are met AND the member is unable to swallow linezolid tablets.

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 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)
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** • No hypersensitivity to nitroimidazole derivatives; **AND** • Trial and failure of, or contraindication to, at least 1 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** • No hypersensitivity to nitroimidazole derivatives **AND** • History of unacceptable/toxic side effects (not including hypersensitivity reactions) to at least two preferred medications not requiring prior approval.

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: > 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*.

CURRENT PDL STATUS

ANTIBIOTICS: CEPHALOSPORINS 1ST GENERATION

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

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

ANTIBIOTICS: CEPHALOSPORINS 2ND GENERATION

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

ANTIBIOTICS: CEPHALOSPORINS 3RD GENERATION

Preferred Agents	Non-Preferred Agents
cefdinir capsule, suspension	cefixime capsule, suspension
	cefpodoxime suspension, tablet

ANTIBIOTICS: GASTROINTESTINAL

Preferred Agents	Non-Preferred Agents
Firvanq CC	Aemcolo
metronidazole tablet	Dificid suspension, tablet CC, QL
neomycin	Flagyl
tinidazole	Likmez
vancomycin capsule CC	metronidazole capsule
Xifaxan CC, QL	nitazoxanide
	paromomycin
	Solosec AE, CC, QL
	Vancocin
	vancomycin solution

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
	Erythrocin
	erythromycin base tablet
	erythromycin ethylsuccinate suspension
	erythromycin ethylsuccinate 400 mg tablet
	erythromycin filmtab
	Zithromax

ANTIBIOTICS: OXAZOLIDINONES

Preferred Agents	Non-Preferred Agents
linezolid tablet CC, QL, MD	linezolid suspension QL, MD
Zyvox suspension QL, MD	Sivextro QL
	Zyvox 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 chewable tablet
amoxicillin/clavulanate tablet, suspension	amoxicillin/clavulanate ER
Ampicillin capsule	Augmentin
Dicloxacillin capsule	Augmentin XR
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
trimethoprim	Bactrim DS
	sulfadiazine
	Sulfatrim suspension

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”
Morgidox	Lymepak
tetracycline	minocycline tablet
	minocycline ER
	Minolira ER
	Morgidox Kit
	Nuzyra AE, CC, QL
	Solodyn
	Vibramycin

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
Clindesse vaginal cream	clindamycin vaginal 2% cream
metronidazole vaginal 0.75% gel	Vandazole gel
Nuvessa gel	Xaciato gel

ANTIRETROVIRALS: HIV/AIDS

GUIDELINES FOR USE

Approval Duration: 1 year, unless otherwise specified

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval

Descovy CC, QL	**Treatment of HIV Infection**
	Approval Duration: 1 year
	• Diagnosis of human immunodeficiency virus (HIV) infection (ICD-10 = B20 and/or Z21).
	
	Pre-Exposure Prophylaxis
	Approval Duration: 3 months
	• Prescribed for pre-exposure prophylaxis (PrEP) of HIV; **AND**
	• Prescriber submits prior authorization request; **AND**
	• Prescriber attests that:
	  ○ Patient is considered high-risk for HIV infection; **AND**
	  ○ Risk-reduction and medication adherence counseling were performed; **AND**
	• Negative HIV-1 test immediately prior to initiating; **AND**
	• Patient is not a recipient of vaginal sex (not FDA-approved in this population).
	Renewal Criteria
	• Negative HIV-1 test immediately prior to initiating; **AND**
	• Patient remains at high risk for HIV infection.
	
	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

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.

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

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 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); **AND** • Patient has not experienced any treatment-restricting adverse effects. **Age Limit**: ≥ 18 years **Quantity Limits**: 300 mg tablets: 5 tablets per fill 463.5 mg/1.5 mL vial: 2 vials per 6 months
Vocabria AE, CC, QL	**Pre-Exposure Prophylaxis** • Prescribed for pre-exposure prophylaxis (PrEP) of HIV; **AND** • Prescriber submits prior authorization request; **AND** • Used as an oral lead-in for Apretude (cabotegravir extended release injectable suspension) or for oral therapy for patients who will miss a planned injection of Apretude • Prescriber attests that: ○ Patient is considered high-risk for HIV infection; **AND** ○ Risk-reduction and medication adherence counseling were performed; **AND** ○ Negative HIV-1 test immediately prior to initiating. **Treatment of HIV Infection** • Patient has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection; **AND** • Patient is virologically suppressed with HIV-RNA < 50 copies/mL and is on a stable antiretroviral regimen; **AND** • Patient has no history of treatment failure or known or suspected resistance to cabotegravir or rilpivirine; **AND** • Patient has not had a previous hypersensitivity reaction 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

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

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

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
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 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 CC, QL	PEGASYS 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

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.
Vosevi [CC, QL]	• HCV Direct-Acting Antiviral Class Criteria (Non-Simplified) below must be met; **AND** • Additional Criteria for Patients Previously Treated with Direct-Acting Antiviral below must be 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**

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

Treatment Criteria Category	Criteria for Approval
	• Documentation (e.g., progress note, prior authorization form questions) of the following clinical data confirming simplified treatment eligibility: ○ Date of Hepatitis C diagnosis or earliest record of HCV infection; **AND** ○ Recent (within 3 months) 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) 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
Vosevi AE, CC, QL	ledipasvir/sofosbuvir AE, CC, QL
	Sovaldi AE, CC, QL
	Viekira Pak AE, CC, QL
	Zepatier AE, CC, QL

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

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; **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 and Humulin N KwikPen
Humulin 70/30 vial and KwikPen	insulin lispro protamine mix
insulin aspart/insulin aspart protamine pen and vial	Novolin 70/30 vial, pen
insulin lispro/insulin lispro protamine KwikPen	Novolin N vial, pen
Novolog Mix FlexPen	Novolog Mix vial

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: GLP-1 RECEPTOR AGONISTS

GUIDELINES FOR USE

Approval Duration: 1 year

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*; **AND** ○ 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) **AND** trial and failure of, intolerance, or contraindication to ≥ 1 SGLT2 inhibitor plus metformin; **OR** ○ Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR** ○ Diagnosis of heart failure with reduced ejection fraction **AND** trial and failure of, intolerance or contraindication to ≥ 1 SGLT2 inhibitor; **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 **1 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

Not applicable.

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
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
Mounjaro AE, CC, QL	• Diagnosis of Type II Diabetes Mellitus; **AND** • Trial and failure, intolerance, or contraindication to metformin; **OR** • Diagnosis of chronic kidney disease (ICD-10 Group N18) AND trial and failure of, intolerance or contraindication to ≥ 1 SGLT2 inhibitor plus metformin; **OR** • Diagnosis of atherosclerotic cardiovascular disease (ASCVD); **OR** • Diagnosis of heart failure with reduced ejection fraction AND trial and failure or, intolerance or contraindication to ≥ 1 SGLT2 inhibitor; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of at least 3-month therapy with 1 preferred GLP-1 agent, unless otherwise specified. **Age Limit**: ≥ 18 years **Quantity Limit:** 4 pens per 28 days

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Byetta CC, QL	Bydureon BCise QL
Ozempic AE, CC, QL	Mounjaro AE, CC, QL
Trulicity CC, QL	Rybelsus AE, QL
Victoza 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: 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

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
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

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
Nesina CC, QL	Kombiglyze XR QL
Tradjenta CC, QL	Onglyza QL
	Oseni QL
	Qtern QL
	saxagliptin QL
	saxagliptin/metformin ER QL
	Steglujan AE, QL
	Trijardy XR QL
	Zituvio QL

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

DIABETES: 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.

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
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

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

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

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

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 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	

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

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.*

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.

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

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**
	• Patient does NOT have a hypersensitivity to somatropin-ghla 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**
	• 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.
	
	Age Limit: ≥ 3 years

Skytrofa [CC]	**Initial Approval Criteria** • Patient has growth failure secondary to growth hormone deficiency (GHD); **AND** • Patient does NOT have a hypersensitivity to any somatropin product or any of the excipients; **AND** • Pediatric patient must NOT have closed epiphyses; **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, 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

Agent(s) Subject to Criteria	Criteria for Approval
	following risk factors: severe obesity, have a history of upper airway obstruction or sleep apnea or have severe respiratory impairment, or unidentified respiratory infection; **AND** • Patient must have tried and failed 2 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 not had unacceptable toxicity from the drug; **AND** • Patient has a positive response compared to pre-treatment baseline.

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**
	• 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

Prior Authorization Criteria

Kentucky Medicaid

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

CURRENT PDL STATUS

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

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

Agent(s) Subject to Criteria	Criteria for Approval
Emflaza AE, CC, QL	• 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).

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 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. **Quantity Limits:** 2 tablets per day **Age Limit:** ≥ 2 years

CURRENT PDL STATUS

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

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

ENDOCRINE AND METABOLIC AGENTS: BONE RESORPTION SUPRESSION 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 **≥ 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 osteoporosis; **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 (to allow for repeat DXA) on previous therapy with:

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

Agent(s) Subject to Criteria	Criteria for Approval
	○ 1 bisphosphonate drug (oral or intravenous [IV]) such as alendronate, ibandronate, or risedronate; **AND** ○ Raloxifene or calcitonin. **Renewal Criteria** • Documentation of disease response (e.g., absence of fractures); **AND** • Total length of therapy will not exceed 24 months (lifetime cumulative).
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 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
	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

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

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	

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

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**
	  ○ Minimal use of glucocorticoids (e.g., < 5 mg of prednisone or equivalent); **AND**

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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); **AND** • Patient has NOT experienced any treatment-restricting adverse effects (e.g., hepatoxicity, severe hypersensitivity reactions, serious infections). **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	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

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

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 Gilenya CC, QL	• Diagnosis of multiple sclerosis (ICD-10 Disease Group G35).

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 **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
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**

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

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

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

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

Agent(s) Subject to Criteria	Criteria for Approval

	secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); **AND**
	• Patient has had an inadequate response to, or is unable to tolerate, 1 or more preferred MS agent; **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**
	• 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, 1 or more preferred MS agent; **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;

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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 consulation with a neurologist or multiple sclerosis specialists; **AND** • Patient has a diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); **AND** • Patient has had an inadequate response to, or is unable to tolerate, 1 or more preferred MS agent; **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**

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. **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** • 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).

Prior Authorization Criteria

Kentucky Medicaid

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	fingolimod capsule QL
dimethyl fumarate DR capsule CC, QL	glatiramer acetate syringe QL
Gilenya capsule CC, QL	Glatopa syringe QL
teriflunomide tablet QL	Kesimpta pen AE, CC, QL
	Mavenclad tablet AE, CC, 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

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

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 spondyloarthritis (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 • 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

Agent(s) Subject to Criteria	Criteria for Approval
Humira (and 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 spondyloarthritis (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

Agent(s) Subject to Criteria	Criteria for Approval
	○ Sulfasalazine ○ Colchicine ○ Topical or oral steroids (e.g., triamcinolone, prednisone) **Renewal Criteria** • Documentation (e.g., progress note) of response to therapy compared to baseline.
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. Prescribed by, or in consultation with, a gastroenterologist or other specialist in the treatment of CD/UC; **OR**

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

d. 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**

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.

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; **AND** • Patient has NOT experienced any treatment-restricting adverse effects **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 • 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:

Agent(s) Subject to Criteria	Criteria for Approval
	○ Seropositive for aquaporin-4 (AQP4) IgG antibodies; **AND** ○ Presence of ≥ 1 core clinical characteristic (e.g., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem 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	• The Ulcerative Colitis Clinical Criteria or compendia-supported indication has been met. **Quantity Limit:** 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**

Agent(s) Subject to Criteria	Criteria for Approval
	• Patient has chronic or recurrent disease (defined as > 6 flares per year); **AND** • Other causes for recurrent fever have been excluded (e.g. recurrent bacterial/viral infection, other autoinflammatory diseases, cancer, cyclic neutropenia, interferonpathies). **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:

Agent(s) Subject to Criteria	Criteria for Approval
	○ Patient continues to have one or more attacks monthly after a six-month compliant trial of colchicine at maximum tolerated doses.; **OR** ○ Patient has AA amyloidosis while on maximum tolerated doses of colchicine; **OR** ○ Patient has an intolerance or contraindication to colchicine therapy.; **AND** • Other causes for recurrent fever have been excluded (e.g. bacterial/viral infection, other autoinflammatory diseases, cancer, other causes of abdominal pain). Documentation 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:

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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** • 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	• Plaque Psoriasis Clinical Criteria must be met.
Kevzara AE, CC, QL	The following diagnosis-based clinical criteria for an FDA-approved or compendia-supported indication has been met: • Rheumatoid Arthritis (RA) Clinical Criteria **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**

Agent(s) Subject to Criteria	Criteria for Approval
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
Kineret CC, QL	• 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	• Rheumatoid Arthritis (RA) Clinical Criteria must be met.
Orencia 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 • Rheumatoid Arthritis (RA) Clinical Criteria **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
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 spondyloarthritis (nr-axSpA) Clinical Criteria • Crohn's Disease (CD) 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**

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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** • Documentation (e.g., progress note) of response to therapy relative to baseline measure(s) (e.g., BSA involvement, EASI, IGA, SCORAD).
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 • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria
Stelara [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

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

Agent(s) Subject to Criteria	Criteria for Approval
	• 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: • Plaque Psoriasis Clinical Criteria • Psoriatic Arthritis (PsA) Clinical Criteria
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

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Cosentyx CC, QL	Abrilada CC, QL
Enbrel CC, QL	Actemra CC, QL
Humira CC, QL	adalimumab-aacf CC, QL
Otezla CC, QL	adalimumab-adaz CC, QL
Xeljanz CC, QL	adalimumab-adbm CC, QL
	adalimumab-fjkp CC, QL
	Amjevita CC, QL
	Cibinqo CC, QL
	Cimzia CC, QL
	Cyltezo CC, QL
	Enspryng AE, CC, QL
	Hadlima CC, QL
	Hulio CC, QL
	Hyrimoz CC, QL
	Idacio CC, QL
	Ilaris CC, QL
	Ilumya AE, CC, QL
	Kevzara AE, CC, QL
	Kineret CC, QL
	Olumiant AE, CC, QL
	Orencia CC, QL
	Rinvoq AE, CC, 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
	Siliq AE, CC, QL
	Simponi CC, QL
	Skyrizi AE, CC, QL
	Sotyktu AE, CC, QL
	Stelara CC, QL
	Taltz CC, QL
	Tremfya AE, CC, QL
	Xeljanz XR CC, QL
	Yuflyma CC, QL
	Yusimry 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

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 **≥ 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**

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

Agent(s) Subject to Criteria	Criteria for Approval
	○ 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** • 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** ○ Patient has not experienced any treatment-restricting adverse effects. **Age Limit:** ≥ 12 years old **Quantity Limit:** 1 prefilled syringe per 28 days (0.07 mL per day)

6. THERAPEUTIC DUPLICATON

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 AE, QL	Tezspire pen CC, AE, QL
Fasenra syringe AE, QL	Tezspire syringe CC, AE, QL
Nucala autoinjector AE, QL	
Nucala syringe AE, QL	
Nucala vial AE, QL	
Xolair syringe AE, QL	
Xolair vial AE, 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 [CC, AE, 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; **AND**
	• Patient has NOT experienced serious treatment-related adverse events.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 4 syringes per 28 days (0.143 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

Eucrisa [CC, QL]	• Patient is ≥ 3 months of age; **AND**
	• 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).

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 ≥ 18 years of age; **AND**

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

Agent(s) Subject to Criteria	Criteria for Approval

	• Prescribed by or in consultation with an allergist; immunologist; ear, nose, and throat (ENT), or other applicable specialist; **AND**
	• Trial and failure (and continued use of) ≥ 1 intranasal corticosteroid, unless intolerant or otherwise ineligible.
	
	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 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 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; **AND**
	• Patient has NOT experienced serious treatment-related adverse events.

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
Opzelura [CC, AE]	**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 ≥ 2 of the following classes: ○ Prescription topical corticosteroids ○ Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus) ○ Topical phosphodiesterase-4 inhibitor (e.g., crisaborole) **OR** • Patient has a diagnosis of nonsegmental vitiligo; **AND** • Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to mid- to high-potency topical corticosteroids or topical calcineurin inhibitors. **Renewal Criteria:** • Patient must continue to meet the above criteria; **AND** • Patient must have disease improvement and/or stabilization; **AND** • Patient has NOT experienced serious treatment-related adverse events. **Age Limit:** ≥ 12 years old

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
Adbry syringe CC, AE, QL	Opzelura cream CC, AE
Dupixent pen CC, QL	pimecrolimus cream
Dupixent syringe CC, QL	Protopic cream
Elidel	tacrolimus ointment
Eucrisa CC, QL	

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

Not applicable. All preferred agents are preferred without PA.

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

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
allopurinol tablet	colchicine capsule CC
colchicine tablet CC	febuxostat tablet QL
Colcrys tablet CC	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
Neupogen CC, QL Nyvepria 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
Fulphila CC, QL Fylnetra CC, QL Neulasta CC, QL Neulasta Onpro CC, QL Simufend 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
Neupogen CC, QL	Fulphila CC, QL
Nyvepria CC,QL	Fylnetra QL
	Granix QL
	Leukine QL
	Neulasta CC, QL
	Neulasta Onpro CC, QL
	Nivestym 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.

*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

Reblozyl CC, AE	• 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**
	• Member has required 2 or more RBC units over an 8-week period; **AND**
	  ○ Failure of an erythropoiesis stimulating agent (e.g., epoetin alfa); **OR**
	  ○ Serum erythropoietin (EPO) > 500 mU/mL.
	
	Renewal Criteria:
	• Attestation or documentation (e.g., progress note) of a reduction in transfusion burden or other clinical benefit.
	
	Age Limit: ≥ 18 years

CURRENT PDL STATUS

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

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

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
calcium acetate capsule, tablet	Auryxia
Renvela powder packet, tablet	Fosrenol chewable tablet, powder packet
	lanthanum carbonate chewable tablet
	Renagel
	sevelamer carbonate powder packet, tablet
	Velphoro

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); **AND** • Patient has not experienced any treatment-restricting adverse effects. **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.

4. GENERIC MEDICALLY NECESSARY CRITERIA

Not applicable.

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
Oxbryta CC, AE, QL	**Initial Approval Criteria:** • Diagnosis of sickle cell disease; **AND** • Patient does not have a history of serious drug hypersensitivity reaction to voxelotor or excipients; **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 one vaso-occlusive crises within the past 6 months; **AND** • Patient has tried at least 2 preferred agents for ≥ 3-months, unless allergic, contraindicated or intolerant. **Renewal Criteria:** • Patient must have disease improvement (decrease in the number of sickle cell crises); **AND** • Patient has not experienced any treatment-restricting adverse effects. **Age Limit:** ≥ 4 years old **Quantity Limit:** • 300 mg tablets (90 count), 500mg tablets: 3 tablets per day • 300 mg tablets for suspension: 3 tablets per day • 300 mg tablets (60 count): 2 tablets per day

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
Droxia	Oxbryta CC, AE, QL
Endari CC, AE, QL	
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

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 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)

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

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
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	Doptelet CC, AE, QL
	Mulpleta CC, AE, QL
	Nplate
	Promacta powder packet QL
	Tavalisse CC, AE, QL

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

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 drops	Besivance
Ofloxacin drops	Ciloxan
moxifloxacin (generic Vigamox)	gatifloxacin
	moxifloxacin (generic Moxeza)
	Ocuflox
	Vigamox

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

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	hydrocortisone/neomycin sulfate/polymyxin B suspension
hydrocortisone/bacitracin zinc/neomycin sulfate/polymyxin B ointment, suspension	Maxitrol ointment, suspension
Neo-Polycin hydrocortisone ointment	prednisolone sodium phosphate/sulfacetamide sodium
Tobradex ointment, suspension	Tobradex ST
tobramycin/dexamethasone suspension	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
olopatadine 0.1% (generic Patanol)	azelastine
olopatadine 0.2% (generic Pataday)	bepotastine besilate
	Bepreve
	epinastine
	Zerviate

OPHTHALMIC MAST CELL STABILIZERS

Preferred Agents	Non-Preferred Agents
cromolyn sodium	Alocril
	Alomide

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

OPHTHALMICS: GLAUCOMA AGENTS

GUIDELINES FOR USE

Approval Duration: 1 year

1. PREFERRED WITH PA (PDP) CRITERIA

Agent(s) Subject to Criteria	Criteria for Approval
Rhopressa CC, AE, QL Rocklatan CC, AE, QL	• Trial and failure of ≥ 1 preferred agent. **Age Limit:** ≥ 18 years **Quantity Limit:** 5 mL per 30 days

2. NON-PREFERRED (NPD) CRITERIA

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

3. BRAND MEDICALLY NECESSARY CRITERIA

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

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

Preferred Agents	Non-Preferred Agents
	Xalatan QL
	Xelpros
	Zioptan QL

OPHTHALMIC BETA BLOCKERS

Preferred Agents	Non-Preferred Agents
levobunolol	betaxolol
timolol maleate (except preservative free)	Betimol
	Betoptic S
	Carteolol
	Istalol
	timolol maleate once daily (generic Istalol)
	timolol PF (preservative-free)
	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 CC, AE, QL	phospholine iodide
Rocklatan CC, AE, QL	pilocarpine
	Vuity

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

OPHTHALMICS: 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
prednisolone acetate suspension	Flarex
prednisolone sodium phosphate drops	FML suspension, FML Forte suspension
	Inveltys
	Lotemax gel, ointment, suspension
	Lotemax SM gel
	loteprednol etabonate gel, suspension
	Maxidex
	Pred Forte
	Pred Mild

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

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).
Tyvaya [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

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 not had treatment-limiting adverse effects from the drug; 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	

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

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
	Flac Otic Oil
	fluocinolone acetonide 0.01% 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

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

5-ALPHA REDUCTASE (5AR) INHIBITORS

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

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
	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	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
isotretinoin capsule	
Zenatane	

DERMATOLOGICS: TOPICAL ACNE

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% (Teva and Mayne Pharma)	Acanya
Clindacin P	adapalene cream, gel, gel pump
clindamycin gel, medicated swab (pledget), solution	adapalene/benzoyl peroxide gel
clindamycin/benzoyl peroxide (generic BenzaClin or Duac; excluding pumps)	Altreno
erythromycin solution	Arazlo
erythromycin/benzoyl peroxide	Atralin
Neuac gel	Avar, Avar E, Avar E LS, Avar LS
Retin-A cream, gel	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 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
	Ery medicated swab
	Erygel
	erythromycin gel
	Evoclin
	Fabior
	Klaron
	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
	Winlevi AE
	Ziana
	Zma Clear suspension

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

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
Finacea gel	azelaic acid gel
metronidazole cream, gel, gel pump	brimonidine tartrate 0.33% gel pump
	Finacea foam
	ivermectin 1% cream
	metronidazole lotion
	Noritate

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
	Rhofade CC, AE, QL
	Rosadan

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

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

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-betamethsone 1%-0.05% cream • ketaconazole 2% cream • nystatin cream, ointment, powder • nystatin-triamcinolone cream, ointment • Nystop powder • Miconazole 2% cream (OTC) • Terbinafine 1% cream (OTC) • Tolnafate 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
ketoconazole cream [QL], shampoo	econazole
Nyamyc	Ertazczo
nystatin cream, ointment, powder [QL]	Extina
nystatin/triamcinolone cream, ointment	Jublia [CC]
Nystop	Kerydin [CC]

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
	ketoconazole foam
	Ketodan
	Loprox cream, kit, suspension, suspension kit
	luliconazole
	Luzu
	miconazole/zinc oxide/petrolatum
	naftifine cream, gel
	Naftin
	oxiconazole QL
	Oxistat QL
	tavaborole
	Vusion

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

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 ointment, solution	Bensal HP
salicylic acid cream, gel, liquid film, lotion	calcipotriene cream, foam
urea cream [QL], foam, lotion	calcipotriene/betamethasone ointment, suspension
	calcitriol ointment
	Duobrii
	Enstilar [MD, AE]
	salicylic acid ointment
	Sorilux
	Taclonex ointment, suspension
	Uramaxin
	Uramaxin GT
	Vtama [AE, QL]
	Zoryve [AE, QL]

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

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

Not applicable.

5. DRUG-SPECIFIC CLINICAL CRITERIA

Not applicable.

CURRENT PDL STATUS

Preferred Agents	Non-Preferred Agents
alclometasone dipropionate	Ana-Lex [QL]
Anusol HC	Apexicon E
betamethasone dipropionate cream, lotion	Beser
betamethasone dipropionate (augmented) cream	betamethasone dipropionate augmented ointment, lotion, gel
betamethasone valerate cream, ointment	betamethasone dipropionate ointment
clobetasol propionate cream, ointment, shampoo, solution	betamethasone valerate foam, lotion
Clodan shampoo	Bryhali
Derma-Smoothe/FS	clobetasol emollient
desonide cream, ointment	clobetasol propionate foam, gel, lotion, spray
fluocinonide ointment, solution	clocortolone cream
fluticasone propionate cream, ointment	Clodan shampoo kit
halobetasol propionate cream, ointment	Cloderm

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

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

MedImpact Healthcare Systems, Inc.

10181 Scripps Gateway Ct. San Diego, CA 92131
Phone: 800.788.2949

MedImpact.com

MedImpact