Notice of PDL Changes

Kentucky Medicaid

Pharmacy Provider Notice – November 2023 P&T PDL Changes

January 18,2024,

Please be advised that the Department for Medicaid Services (DMS) is making changes to the Kentucky Medicaid Pharmacy Preferred Drug List (PDL) based on recommendations and guidance from the Kentucky Medicaid Pharmacy and Therapeutics Advisory Committee (P&T Committee), that have subsequently been adopted by the Commissioner of DMS of the Cabinet for Health and Family Services by order dated December 1, 2023.

The Kentucky Medicaid P&T Committee met on November 16, 2023. The expertise, vote, and recommendations were captured within the P&T Committee's official recommendations and submitted to the Commissioner for review. After the review of the Commissioner, DMS has rendered the below final decisions.

On February 9, 2024 the following changes will be effective:

EXISTING DRUG CLASSES (**agents changing status will be denoted in ***bold and italics***)

Drug Class	Preferred Agents	Non-Preferred Agents
Anti-Emetics: Other	Bonjesta® ***Diclegis™ CC, QL*** meclizine metoclopramide oral solution, tablets prochlorperazine tablets promethazine syrup, tablets promethazine 12.5, 25 mg suppositories Promethegan 12.5, 25 mg suppositories scopolamine patches	Antivert® Compro® doxylamine/pyridoxine CC, QL Gimoti™ CC, QL metoclopramide ODT prochlorperazine suppositories Promethegan 50 mg suppositories Reglan® Transderm-Scop® trimethobenzamide
Cytokine and CAM Antagonists	Cosentyx® CC, QL Enbrel® CC, QL Humira® CC, QL Otezla® CC, QL ***Xeljanz® CC, QL***	Abrilada CC, QL Actemra® (syringe, Actpen) CC, QL adalimumab-adaz CC, QL adalimumab-adbm CC, QL adalimumab-fjkp CC, QL Amjevita™ CC, QL Cibinqo™ CC, QL Cimzia® CC, QL Cyltezo® CC, QL Enspryng™ CC, AE, QL Entyvio Pen CC, QL Hadlima™ CC, QL Hulio® CC, QL Hyrimoz® CC, QL

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Drug Class	Preferred Agents	Non-Preferred Agents
		Idacio® CC, QL Ilaris® CC, QL Ilumya™ CC, AE, QL Kevzara® CC, AE, QL Kineret® CC, QL Olumiant®CC, AE, QL Orencia® CC, QL Rinvoq™ CC, AE, QL Siliq™ CC, AE, QL Simponi™ CC, QL Skyrizi™ CC, AE, QL Sotyktu® AE, CC, QL Stelara™ CC, QL Taltz® CC, QL Tremfya™CC, AE, QL Xeljanz® XR CC, QL Yuflyma ® CC, QL
Ophthalmic Quinolones	ciprofloxacin ***moxifloxacin (generic Vigamox™)*** ofloxacin	Besivance™ Ciloxan® gatifloxacin levofloxacin moxifloxacin (generic Moxeza™) Ocuflox® ***Vigamox™*** Zymaxid™
Antipsychotics: Injectable	***Abilify Asimtufii® CC, AE, 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® Hafyera CC, QL Invega® Sustenna® CC, QL Invega Trinza™ CC, QL olanzapine CC, QL Perseris ER™ CC Risperdal® Consta® CC, QL ***Uzedy CC, AE, QL***	Haldol® Decanoate QL ziprasidone injection QL Zyprexa® QL Zyprexa® Relprevv QL
COPD Agents	albuterol-ipratropium inhalation solution QL Anoro Ellipta® QL Atrovent® HFA QL Combivent Respimat® QL ipratropium inhalation solution QL Spiriva HandiHaler® QL Stiolto Respimat® QL	***Bevespi Aerosphere™ QL*** Breztri Aerosphere™ QL Daliresp™ CC, QL Duaklir® Pressair® Incruse Ellipta® QL Lonhala™ Magnair™ CC, QL roflumilast CC, QL

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		Spiriva Respimat® QL tiotropium QL Trelegy Ellipta CC, QL Tudorza Pressair™ QL Yupelri® CC, QL
Diabetes: GLP-1 Receptor Agonists	Byetta® CC, QL Ozempic® CC, AE, QL ***Trulicity™ CC, QL*** Victoza® CC, QL	Adlyxin™ AE, QL Bydureon BCise™ QL Mounjaro™ CC, AE, QL Rybelsus® AE, QL Soliqua™ CC, AE, QL Xultophy® CC, AE, QL
Glucagon Agents	Baqsimi™ CC glucagon emergency kit (Eli Lilly, Amphastar, ***Fresenius***) Proglycem®	diazoxide glucagon HCl Gvoke™ ***Zegalogue® autoinjector AE*** Zegalogue® syringe AE
Growth Hormones	Genotropin® CC Norditropin FlexPro® CC ***Nutropin AQ NuSpin® CC***	Humatrope® CC Ngenla™ CC, AE Nutropin AQ NuSpin® CC Omnitrope® CC Saizen® CC Serostim® CC Skytrofa™ CC Sogroya® CC, QL Zomacton® CC
Immunomodulators, Atopic Dermatitis	***Adbry™ CC, AE, QL*** Dupixent® CC, QL Elidel® Eucrisa® CC, QL	Opzelura™ CC, AE pimecrolimus Protopic® tacrolimus ointment
Multiple Sclerosis	Avonex® CC, QL Betaseron® CC, QL Copaxone® 20 mg CC, QL dalfampridine ER QL dimethyl fumarate CC, QL Gilenya™ CC, QL ***teriflunomide QL***	Ampyra™ QL Aubagio® QL Bafiertam™ AE, QL Copaxone® 40 mg QL Extavia® QL fingolimod QL glatiramer acetate QL Glatopa™ QL Kesimpta® CC, AE, QL
Ophthalmic Immunomodulators	Restasis® CC Xiidra™ CC, AE, QL	Cequa™ cyclosporine 0.05% Eysuvis™ ***Restasis® Multidose CC*** Tyrvaya™ CC, AE, QL Verkazia®

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NEW PRODUCTS TO MARKET

Drugs Requiring PA	Criteria for Prior Authorization

Filspari™	**Non-PDL Class**
	
	Length of Authorization: 6 months initial, 1 year renewal
	
	Initial Approval Criteria
	
	• Biopsy-proven primary immunoglobulin A nephropathy (IgAN); **AND**
	• Presence of proteinuria; **AND**
	• Patient is at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g; **AND**
	• Patient must not have hypersensitivity to any component of the product; **AND**
	• Patient must have had an adequate trial of an angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) at ≥ 50% of the maximum labeled dose; **AND**
	• Patient will avoid concomitant therapy with major interacting drugs, including:
	  ○ Coadministration with strong and moderate CYP3A4 inducers; **AND**
	  ○ Renin-angiotensin-aldosterone (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren; **AND**
	  ○ Strong CYP3A inhibitors; **AND**
	  ○ Strong CYP3A inducers; **AND**
	  ○ Histamine H2 receptor antagonists; **AND**
	  ○ Proton pump inhibitors; **AND**
	  ○ Sensitive substrates of P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP); **AND**
	• Prescriber has confirmed aminotransferases (ALT, AST) are < 3x upper limit of normal (ULN)
	• Prescriber will monitor ALT, AST and total bilirubin monthly for the first 12 months after initiation, or when restarting therapy following an interruption due to elevated aminotransferases, then every 3 months for the duration of treatment; **AND**
	• Prescriber will monitor renal function and serum potassium regularly during treatment; **AND**
	• Female patients have a negative pregnancy test prior to the start of therapy; **AND**
	• Patients of reproductive potential have been advised to use an effective contraceptive method during treatment; **AND**
	• Prescriber has assessed the patient's risk for hypotension and has discontinued or adjusted other antihypertensive medications as needed.

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Drugs Requiring PA	Criteria for Prior Authorization
	Renewal Criteria • Patient must continue to meet the above criteria; **AND** • Patient must have reduction or stabilization in proteinuria; **AND** • Patient has not experienced any treatment-restricting adverse effects (e.g., hepatotoxicity, acute kidney injury, severe hypotension, hyperkalemia). **Quantity Limit:** 1 per day **Age Limit:** 18 years of age

Joenja®	**Non-PDL Class**
	
	Length of Authorization: 1 year
	
	Initial Approval Criteria
	
	• Patient has a confirmed diagnosis by the presence of an activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)-associated genetic PI3Kδ mutation with a documented variant in either PIK3CD or PIK3R1; **AND**
	• Patient has nodal and/or extra-nodal lymphoproliferation, with the presence of ≥ 1 measurable nodal lesion, as measured on computed tomography (CT) or magnetic resonance imaging (MRI); **OR**
	• Patient has clinical findings and manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, organ dysfunction [e.g., lung, liver]); **AND**
	• Pregnancy status will be confirmed in female patients of reproductive potential prior to initiating therapy and highly effective methods of contraception will be used during treatment; **AND**
	• Patient will avoid concomitant therapy with all the following:
	  ○ Coadministration with strong and moderate CYP3A4 inducers
	  ○ Coadministration with strong CYP3A4 inhibitors
	
	Renewal Criteria
	
	• Patient must continue to meet the above criteria; **AND**
	• Patient must have disease response with treatment as defined by stabilization of or improvement of disease signs and symptoms (e.g., decrease in the frequency and/or severity of infections, decreased lymphadenopathy, increased percentage of naïve B cells, decrease in disease-related hospitalizations); **AND**
	• Patient has NOT experienced any treatment-restricting adverse effects (e.g., severe neutropenia: absolute neutrophil count [ANC] < 500 cells/µL).

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Drugs Requiring PA	Criteria for Prior Authorization
	Age Limit: ≥ 12 years **Quantity Limit:** 2 per day
Miebo™	**Non-preferred in the PDL class:** *Ophthalmic Immunomodulators* **Length of Authorization:** 1 year **Criteria for Approval:** • 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. **Age Limit:** none **Quantity Limit:** 0.4 mL (8 drops) per day

Ngenla™	**Non-preferred in the PDL class:** *Growth Hormones*
	
	Length of Authorization: 1 year
	
	Initial Approval Criteria
	
	• Diagnosis of growth hormone deficiency; **AND**
	• Patient does NOT have a hypersensitivity to somatrogon-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**

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Drugs Requiring PA	Criteria for Prior Authorization
	• Patient has not had unacceptable toxicity from the drug; **AND** • Patient has a positive response compared to pre-treatment baseline. **Age Limit:** ≥ 3 years **Quantity Limit:** none
Olpruva™	**Non-PDL Class** **Length of Authorization:** 1 year **Initial Approval Criteria** • Patient is diagnosed with a urea cycle disorder involving deficiency of CPS, OTC, or AS.; **AND** • Patient weighs 20 kg or greater with a body surface area ≥ 1.2 m2; **AND** • Prescribed by, or in consultation with, a specialist experienced in the treatment of urea cycle disorders; **AND** • Requested drug is not being used for acute hyperammonemia. **Renewal Criteria** • Patient has a documented response to therapy; **AND** • Patient has not experienced any treatment limiting adverse effects
Skyclarys™	**Non-PDL Class** **Length of Authorization:** 1 year **Initial Approval Criteria** • Patient has a diagnosis of Friedreich's ataxia as confirmed by molecular genetic testing and detection of biallelic pathogenic variant in the FXN gene and clinical signs and symptoms (e.g., ataxia, speech disturbance, sensory dysfunction, etc.) that is consistent with Friedreich's ataxia; **AND** • Patient retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulates); **AND** • Patient does not have pes cavus defined as having a loss of lateral support and was determined if light from a flashlight could be seen under the patient's arch when barefoot and weight bearing; **AND** • Patient does not have a history of clinically significant left-sided heart disease and/or clinically significant cardiac disease (Note: excludes mild to moderate cardiomyopathy associated with Friedreich's ataxia); **AND**

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Drugs Requiring PA	Criteria for Prior Authorization

	• Patient does not have signs of very advanced disease (e.g., cardiomyopathy by transthoracic echocardiogram); **AND**
	• Patient B-Type Natriuretic Peptide (BNP) is ≤ 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment; **AND**
	• Prescriber will assess the following prior to therapy initiation and periodically during therapy as recommended in the product label:
	  ○ Liver function (alanine transaminase [ALT], aspartate transaminase [AST], bilirubin); **AND**
	  ○ Lipid parameters; **AND**
	• Patient does not have severe hepatic impairment (Child-Pugh C); **AND**
	• Patient has the ability to swallow capsules; **AND**
	• Patient will avoid concomitant therapy with any of the following:
	  ○ Moderate or strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
	  ○ Moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's wort); **AND**
	• Patients of reproductive potential have been advised to use nonhormonal contraceptive method (e.g., non-hormonal intrauterine system, condoms) during omaveloxolone therapy and for 28 days after discontinuation.
	
	Renewal Criteria
	
	• Patient must continue to meet the above criteria; **AND**
	• Patient must have disease improvement as defined by stabilization OR slowed progression of disease signs and symptoms (e.g., bulbar function, upper/lower limb coordination, upright stability) from pretreatment baseline; **AND**
	• Patient has not experienced any treatment-restricting adverse effects (e.g., fluid overload, heart failure; ALT or AST >5x the ULN or >3x the ULN with signs of liver dysfunction).
	
	Age Limit: ≥ 16 years old
	Quantity Limits: 90 capsules per 30 days

Vyjuvek™	**Non-PDL Class** **Length of Authorization:** 6 months initial, 1 year renewal **Initial Approval Criteria** • Age ≥ 6 months; **AND**

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Drugs Requiring PA	Criteria for Prior Authorization
	• Patient has not received a skin graft within the past 3 months; **AND** • Prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB**; AND** • Patient has a genetically confirmed diagnosis of dystrophic epidermolysis bullosa with mutation in the COL7A1 gene (documentation required); **AND** • Patient has cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected; **AND** • Patient is receiving standard-of-care wound therapy; **AND** • Patient has not received or is being considered for other gene therapy, or investigational cellular therapy. **Renewal Criteria** • Patient must continue to meet the above criteria; **AND** • Patient has not experienced any unacceptable toxicity from the drug (e.g., severe medication reactions resulting in discontinuation of therapy); **AND** • Patient must have disease response as defined by improvement (healing) of treated wound(s), reduction in skin infections, etc.; **AND** • Patient requires continued treatment for new and/or existing open wounds. **Age Limit:** none **Quantity Limit:** 4 vials per 28 days

CONSENT AGENDA ITEMS

The therapeutic classes listed in the table below were reviewed; no changes were made to the currently posted status for agents in these classes.

Drug Classes With No Changes	

• Acne Agents, Oral
• Acne Agents, Topical
• Antibiotics, Topical
• Anticholinergics/Antispasmodics
• Antidiarrheals
• Antiemetics & Antivertigo Agents
  ○ Oral Anti-Emetics: 5-HT3 Antagonists
	• Ophthalmic, Allergic Conjunctivitis
	  ○ Ophthalmic Antihistamines
	  ○ Ophthalmic Mast Cells Stabilizers
	• Ophthalmic, Antibiotics
	• Ophthalmic, Quinolones
	• Ophthalmic, Antibiotics, Non-Quinolones
	• Ophthalmic, Anti-Inflammatories
	  ○ Ophthalmic NSAIDs

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Drug Classes With No Changes	
○ Oral Anti-Emetics: NK-1 Antagonists ○ Oral Anti-Emetics: Δ-9-THC Derivatives • Antifungals, Topical • Antiparasitic, Topical • Antipsoriatic, Oral • Antipsoriatic, Topical • Anti-Ulcer Protectants • Antivirals, Topical • Bile Salts • GI Motility, Chronic • Histamine II Receptor Blockers (H2 Receptor Antagonists) • H. Pylori Treatment • Immunomodulators, Asthma • Immunosuppressives, Oral (Immunosuppressants) • Laxatives and Cathartics	○ Ophthalmic Anti-inflammatory Steroids • Ophthalmic, Antivirals • Ophthalmic, Glaucoma Agents ○ Ophthalmic Beta Blockers ○ Ophthalmic Carbonic Anhydrase Inhibitors ○ Ophthalmic Combinations for Glaucoma ○ Ophthalmic Prostaglandin Agonists ○ Ophthalmic Sympathomimetics ○ Ophthalmic Glaucoma Agents, Other • Ophthalmic, Mydriatics & Mydriatic Combinations • Ophthalmic Vasoconstrictors • Otic Antibiotics • Otic Anesthetic and Anti-Inflammatories • Proton Pump Inhibitors • Rosacea Agents, Topical • Steroids, Topical • Spinal Muscular Atrophy • Ulcerative Colitis Agents

To review the complete summary of the final PDL selections and new products to market updates and changes, please refer to the “Commissioner’s Final Decisions” from December 1, 2023, posted on the provider portal at: https://kyportal.medimpact.com/provider-documents/pt-committee

Thank you for helping Kentucky Medicaid members maintain access to cost effective medications by selecting drugs on the preferred drug list whenever possible. For any additional information or questions that you may have, please contact the Kentucky MedImpact team at KYMFFS@medimpact.com for Fee-for-Service members or at KYMCOPBM@medimpact.com for Managed Care Organization (MCO) members.

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