Notice of PDL Changes

Kentucky Medicaid

Pharmacy Provider Notice – January 2025 P&T PDL Changes

March 14, 2025

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 **February 7, 2025.**

The Kentucky Medicaid P&T Committee met on January 28, 2025. 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 April 15, 2025, the following changes will be effective:

EXISTING DRUG CLASSES

Agents with status changes will be shown in ***bold, italicized text***.

Agents ***moving from preferred to non-preferred status are highlighted in yellow.*** These agents will now require prior authorization for continued use. Please refer to the full PDL table below for a list of preferred alternatives for possible adjustment to therapy.

Agents ***moving from non-preferred to preferred status are highlighted in green***.

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics: Gastrointestinal	metronidazole 250 mg, 500 mg tablet neomycin tinidazole ***vancomycin*** capsule, ***solution*** CC Xifaxan CC, QL	Aemcolo Dificid suspension, tablet CC, QL ***Firvanq*** CC Flagyl Likmez metronidazole capsule metronidazole 125 mg tablet nitazoxanide paromomycin Solosec AE, CC, QL Vancocin Vowst AE, CC, QL
Antibiotics: Vaginal	Cleocin Ovule ***clindamycin vaginal 2% cream*** metronidazole vaginal 0.75% gel	Cleocin cream ***Clindesse vaginal cream*** metronidazole vaginal 1.30% gel

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Drug Class	Preferred Agents	Non-Preferred Agents
	Nuvessa gel	Vandazole gel Xaciato gel
Antibiotics: Penicillins	amoxicillin ***amoxicillin/clavulanate chewable tablet***, tablet, suspension Ampicillin capsule Dicloxacillin capsule penicillin V potassium tablet, suspension	amoxicillin/clavulanate ER Augmentin Augmentin XR
Antibiotics: Sulfonamides, Folate Antagonists	sulfamethoxazole/trimethoprim ***Sulfatrim suspension*** trimethoprim	Bactrim Bactrim DS sulfadiazine
Antifungal, Oral	clotrimazole troche fluconazole suspension, tablet griseofulvin suspension itraconazole capsule CC, QL ***ketoconazole*** nystatin suspension, tablets terbinafine	Ancobon Brexafemme CC, QL Cresemba Diflucan flucytosine griseofulvin microsize tablet, ultramicrosize tablet itraconazole solution Noxafil Oravig posaconazole Sporanox QL Tolsura Vfend Vivjoa CC, QL voriconazole
Hepatitis C Agents: Interferons and Ribavirins	***PEGASYS*** syringe, ***vial*** CC, QL ribavirin capsule, tablet CC	
Chronic Obstructive Pulmonary Disease (COPD) Agents	albuterol-ipratropium inhalation solution QL Anoro Ellipta QL Atrovent HFA QL ***Breztri Aerosphere CC, QL*** Combivent Respimat QL ipratropium inhalation solution QL ***roflumilast tablet CC, QL*** Spiriva Handihaler QL Stiolto Respimat QL	Bevespi Aerosphere QL Daliresp tablet CC, QL Duaklir Pressair Incruse Ellipta QL Ohtuvayre AE, CC, QL Spiriva Respimat QL Tiotropium QL Trelegy Ellipta CC, QL Tudorza Pressair QL Yupelri solution CC, QL

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Drug Class	Preferred Agents	Non-Preferred Agents
Epinephrine, Self-Injectable	***epinephrine 0.3 mg autoinjector (all manufacturers)*** QL ***epinephrine 0.15 mg autoinjector (all manufacturers)*** QL EpiPen QL EpiPen Jr. QL	Auvi-Q autoinjector QL Neffy QL Symjepi QL
Glucocorticoids, Inhaled	Asmanex Twisthaler QL budesonide inhalation suspension AE, QL Flovent HFA QL fluticasone propionate HFA QL ***Pulmicort Flexhaler*** QL	Alvesco QL ArmonAir Digihaler QL Arnuity Ellipta QL Asmanex HFA QL Flovent Diskus QL Pulmicort Respules QL Qvar Redihaler

NEW PRODUCTS TO MARKET

Drugs Requiring PA	Criteria for Prior Authorization
Cobenfy™	**Central Nervous System – Antipsychotics, Second Generation (Atypical) and Injectable: Non-Preferred** **Approval Duration: 1 year** **Initial Approval Criteria:** • Diagnosis of schizophrenia; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to one preferred agent; **AND** • Prescriber attests that liver enzymes and bilirubin were measured prior to initiation; **AND** • Patient meets the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms. **Age Limit:** 18 years of age or older **Quantity Limit:** 2 capsules per day

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Drugs Requiring PA	Criteria for Prior Authorization

Livdelzi®	**Gastrointestinal, Bile Salts: Non-Preferred**
	
	Approval Duration: 1 year
	
	Initial Approval Criteria:
	
	• Diagnosis of primary biliary cholangitis (PBC); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or other disease state specialist; **AND**
	• Patient meets one of the following:
	  ○ Patient has had a 12-month trial and failure of ursodiol, and will take Livdelzi in addition to current therapy; **OR**
	  ○ Patient has a contraindication or intolerance to ursodiol and will take Livdelzi as monotherapy; **AND**
	• Patient has an alkaline phosphatase (ALP) level greater than 200 IU/L; **AND**
	• Patient does not have decompensated cirrhosis; **AND**
	• Patient meets the minimum age recommended by the package insert for the provided indication.
	
	Renewal Criteria:
	
	• Documentation (e.g., progress notes, labs) of improvement or stabilization in alkaline phosphatase (ALP); **AND**
	• Patient meets one of the following:
	  ○ Patient has had a 12-month trial and failure of ursodiol and will take Livdelzi in addition to current therapy; **OR**
	  ○ Patient has a contraindication or intolerance to ursodiol and will take Livdelzi as monotherapy.
	
	Age Limit: 18 years of age or older
	Quantity Limit: 1 capsule per day

Vyalev™	**Central Nervous System – Parkinson's Disease (Antiparkinson's Agents): Non-Preferred** **Approval Duration: 1 year**

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Drugs Requiring PA	Criteria for Prior Authorization

	Initial Approval Criteria:
	
	• Diagnosis of Parkinson's disease (PD); AND
	• Receiving PD therapy with carbidopa/levodopa; AND
	• Experiencing "off" episodes with carbidopa/levodopa for at least 2 hours per day; AND
	• Trial and failure of at least 2 adjunctive therapies, such as:
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole)
	  ○ Monoamine oxidase-B inhibitors (e.g., selegiline)
	  ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); **AND**
	• Patient will not take within two weeks of a non-selective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, isocarboxazid, tranylcypromine); **AND**
	• Patient meets the minimum age recommended by the package insert for the provided indication.
	
	Renewal Criteria:
	
	• Patient has clinically meaningful response of treatment (e.g., patient shows a reduction in time of "off" episodes).
	
	Age Limit: 18 years of age or older
	Quantity Limit: 2 vials (20 mL) per day

Ebglyss™	**Immunomodulators – Atopic Dermatitis: Non-Preferred**
	
	Approval Duration: 4 months initial, 1 year renewal
	
	Initial Approval Criteria:
	
	• Diagnosis of moderate-to-severe atopic dermatitis (AD) with ≥ 1 of the following:
	  ○ Involvement of at least 10% of body surface area (BSA); **OR**
	  ○ Scoring Atopic Dermatitis (SCORAD) score of 25 or more; **OR**
	  ○ Investigator's Global Assessment (IGA) with a score ≥ 3; **OR**
	  ○ Eczema Area and Severity Index (EASI) score of ≥ 16; **OR**

Drugs Requiring PA	Criteria for Prior Authorization
	○ Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); **AND** • Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND** • Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days): ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **AND** ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **OR** ○ Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil); **AND** • Trial and failure, contraindication, or intolerance to at least one preferred injectable agent (Adbry or Dupixent); **AND** • Patient must meet the minimum age and weight recommended by the package insert for the provided indication. **Renewal Criteria:** • Patient must continue to meet initial approval criteria; **AND** • Patient must have disease improvement and/or stabilization based on an objective measure. **Age Limit:** 12 years of age or older **Quantity Limit:** 1 pen/syringe (2 mL) per 28 days
Xdemvy™	**Non-PDL** **Approval Duration: 3 months initial, 1 year renewal** **Initial Approval Criteria:** • Diagnosis of Demodex Blepharitis; **AND** • Prescribed by, or in consultation with, an ophthalmologist or other specialist for the requested condition; **AND**

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Drugs Requiring PA	Criteria for Prior Authorization
	• Prescriber attests that the patient currently has active disease. **Renewal Criteria:** • Patient has a diagnosis of Demodex Blepharitis [H01.00]; **AND** • Prescribed by, or in consultation with, an ophthalmologist or other specialist for the requested condition; **AND** • Prescriber attests patient has experienced a response to previous therapy. **Age Limit:** 18 years of age or older **Quantity Limit:** 1 bottle (10 mL) per month

Yorvipath™	**Non-PDL**
	
	Approval Duration: 6 months initial, 1 year renewal
	
	Initial Approval Criteria:
	
	• Diagnosis of hypoparathyroidism; **AND**
	• Prescriber attests that this medication is NOT being prescribed for acute hypoparathyroidism post-surgery; **AND**
	• Patient has not received therapy with parathyroid hormone analogs (e.g. abaloparatide, teriparatide) for 24 months or more (lifetime cumulative); **AND**
	• Documentation that the following labs are within normal limits:
	  ○ **Corrected Serum Calcium:** 7.8-10.2 mg/dL; **AND**
	  ○ **Serum Phosphate:** 2.5-4.5 mg/dL; **AND**
	• Prescriber attestation that the patient is not well-controlled despite appropriate utilization (trial and failure of 3 months) of calcium and active forms of vitamin D; **AND**
	• Prescribed by, or in consultation with, an endocrinologist or other specialist for the requested condition.
	
	Renewal Criteria:
	
	• Patient continues to have the above listed diagnosis; **AND**

Drugs Requiring PA	Criteria for Prior Authorization
	• Prescribed by, or in consultation with, an endocrinologist or other specialist for the requested condition; **AND** • Documentation (e.g., progress note) of response to therapy. **Age Limit:** 18 years of age or older **Quantity Limit:** 2 pens per month
Duvyzat™	**Muscular Dystrophy Agents: Non-Preferred** **Approval Duration: 6 months initial, 1 year renewal** **Initial Approval Criteria:** • Diagnosis of Duchenne muscular dystrophy (DMD) [G71.01]; **AND** • Platelet count within the last 30 days equals to or is greater than 150 x 10^9/L; **AND** • Prescribed by, or in consultation with, a neuromuscular specialist with expertise in the treatment of DMD; **AND** • Patient is ambulatory (e.g., ability to walk with or without assistive devices, not wheelchair dependent); **AND** • Patient's baseline ambulatory function has been or will be assessed prior to therapy initiation; **AND** • Patient has been on a stable systemic corticosteroid therapy for at least 6 months and will continue to be on the systemic corticosteroid therapy unless contraindicated or clinically significant adverse effects are experienced; **AND** • Prescriber provides a patient weight obtained within the past 3 months; **AND** • The requested dose meets the FDA-approved dosing recommendation. **Renewal Criteria:** • Documentation (e.g., progress note) of stabilized or improved ambulatory function from baseline; **AND** • Patient will continue systemic corticosteroid therapy unless contraindicated or clinically significant adverse effects are experienced; **AND**

Drugs Requiring PA	Criteria for Prior Authorization
	• Prescriber provides a patient weight obtained within the past 3 months; **AND** • The requested dose meets the FDA-approved dosing recommendation. **Age Limit:** 6 years of age or older **Quantity Limit:** 12 mL per day

Nemluvio®	**Immunomodulators, Atopic Dermatitis Class: Non-Preferred**
	
	Approval Duration: 4 months initial, 1 year renewal
	
	Initial Approval Criteria:
	
	Atopic Dermatitis:
	• Diagnosis of moderate-to-severe atopic dermatitis (AD) with ≥ 1 of the following:
	  ○ Involvement of at least 10% of body surface area (BSA); **OR**
	  ○ Investigator's Global Assessment (IGA) with a score ≥ 3; **OR**
	  ○ Eczema Area and Severity Index (EASI) score of ≥ 16; **OR**
	  ○ Peak Pruritis Numeric Rating Scale (PP-NRS) score ≥ 4; **OR**
	  ○ Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); **AND**
	• Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND**
	• Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days):
	  ○ 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**

Drugs Requiring PA	Criteria for Prior Authorization
	○ Immunosuppressive systemic agents (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.); **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 1 preferred injectable (Adbry, Dupixent) agent; **AND** • Nemluvio will be taken with topical corticosteroids and/or calcineurin inhibitors (e.g., pimecrolimus, tacrolimus); **AND** • Patient must meet the minimum age recommended by the package insert for this FDA approved indication. **Prurigo Nodularis:** • Diagnosis of prurigo nodularis; **AND** • At least 20 nodular lesions; **AND** • Other causes of pruritis have been ruled out; **AND** • Trial and failure, contraindication, or intolerance to one of the following: ○ Moderate to super potent topical corticosteroids [e.g., betamethasone dipropionate, (augmented), fluocinonide 0.1%, flurandrenolide, betamethasone dipropionate 0.05%, clobetasol propionate 0.025%, or desoximetasone 0.05%] for a minimum of 2 weeks; **OR** ○ Narrowband ultraviolet B (NBUVB) phototherapy or psoralen plus ultraviolet A (PUVA) phototherapy; **AND** • Trial and failure, contraindication, or intolerance to Dupixent; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Renewal Criteria:** • Patient must continue to meet initial approval criteria; **AND** • Patient must have disease improvement and/or stabilization based on an objective measure.

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Drugs Requiring PA	Criteria for Prior Authorization
	Quantity Limit: 2 pens (60 mg) per 28 days
Neffy®	**Self-injectable Epinephrine: Non-Preferred** **Approval Duration: 6 months initial, 1 year renewal** **Approval Criteria:** • Patient has had a trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 1 preferred agent. **Quantity Limit:** 2 bottles per fill

Miplyffa ™	**Non-PDL**
	
	Approval Duration: 6 months initial, 1 year renewal
	
	Initial Approval Criteria:
	
	• Diagnosis of Niemann-Pick Disease Type C (NPC); **AND**
	• Confirmed diagnosis of NPC by ≥ 1 of the following:
	  ○ Positive genetic test for mutations on both alleles of NPC1 or NPC2; **OR**
	  ○ Positive genetic test for mutations on one allele NPC1 or NPC2; **AND**
	  ▪ Elevated biomarker; **OR**
	  ▪ Positive filipin staining; **AND**
	• Prescribed by, or in consultation with, a neurologist or geneticist or other specialist in the treatment of Niemann-Pick Disease Type C; **AND**
	• Prescriber attests patient presents with at least one neurological symptom of the disease (e.g., hearing loss, ataxia, dystonia, seizures, speech delay); **AND**
	• Prescriber attests medication will be used in combination with miglustat; **AND**
	• Patient must meet the minimum age recommended by the package insert.
	
	Renewal Criteria:
	
	• Prescriber provides documentation (i.e., NPC Neurologic Severity Scale, cognitive function tests,

Drugs Requiring PA	Criteria for Prior Authorization
	motor function assessment, etc.) that patient has experienced disease improvement or stabilization or a reduction in disease progression/ **Age Limit:** 2 years of age or older **Quantity Limit:** 3 capsules per day

Aqneursa ™	**Non-PDL**
	
	Approval Duration: 3 months initial, 1 year renewal
	
	Initial Approval Criteria:
	
	• Diagnosis of Niemann-Pick Disease Type C (NPC); **AND**
	• Confirmed diagnosis of NPC by ≥ 1 of the following:
	  ○ Positive genetic test for mutations on both alleles of NPC1 or NPC2; **OR**
	  ○ Positive genetic test for mutations on one allele NPC1 or NPC2; **AND**
	  ▪ Elevated biomarker; **OR**
	  ▪ Positive filipin staining; **AND**
	• Prescribed by, or in consultation with, a neurologist or geneticist or other specialist in the treatment of Niemann-Pick Disease Type C; **AND**
	• Prescriber attests patient presents with at least one neurological symptom of the disease (e.g., hearing loss, ataxia, dystonia, seizures, speech delay); **AND**
	• Patient must meet the minimum age and weight recommended by the package insert for the provided indication
	  ○ ≥ 4 years of age
	  ○ ≥ 15 kg
	
	Renewal Criteria:
	
	• Prescriber provides documentation (i.e., NPC Neurologic Severity Scale, cognitive function tests, motor function assessment, etc.) that patient has experienced disease improvement or stabilization or a reduction in disease progression.
	
	Age Limit: 4 years of age or older
	Quantity Limit: 4 packets (4 grams) per day

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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	
• **Antibiotics, Cephalosporins 1st Generation** • **Antibiotics, Cephalosporins 2nd Generation** • **Antibiotics, Cephalosporins 3rd Generation** • **Antibiotics, Inhaled** • **Antibiotics, Macrolides** • **Antibiotics, Oxazolidinones** • **Antibiotics, Quinolones** • **Antibiotics, Tetracyclines**	• **Antihistamines, Minimally Sedating** • **Antiretrovirals, HIV/AIDS** • **Antivirals, Oral** • **Bronchodilators, Beta Agonist** • **Hepatitis B Agents** • **Hepatitis C Agents: Direct-Acting Antivirals** • **Intranasal Rhinitis Agents** • **Leukotriene Modifiers**

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 January 28, 2025, 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.

KY MCO Contact Information

Program Questions	KYMCOPBM@MedImpact.com
Pharmacy Help Desk	(800) 210-7628 [24 hours per day/ 7 days per week]
Prior Authorizations	Phone (844) 336-2676 [8:00AM - 7:00PM EST/ 7 days per week] Fax (858) 357-2612
Pharmacy Portal	https://kyportal.medimpact.com/
BIN: 023880 / PCN: KYPROD1 / GROUP: KYM01	

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KY FFS Contact Information

Program Questions	KYMFFS@MedImpact.com
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Prior Authorizations	Phone (877) 403-6034 [8:00AM - 7:00PM EST/ 7 days per week] Fax (858) 357-2612
Pharmacy Portal	https://kyportal.medimpact.com/
BIN: 026309 / PCN: KYPROD1 / GROUP: KYF01	

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