Pharmacy Provider Notice #288 November 2022 P&T PDL Changes

January 9th, 2023

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 as adopted by the Commissioner of DMS of the Cabinet for Health and Family Services by order dated December 1st, 2022.

The Kentucky Medicaid Pharmacy and Therapeutics Advisory Committee (Committee) met on November 17, 2022. The necessary quorum was attained, and the expertise, vote, and recommendations were captured within the Committee's official recommendations. DMS, through the Commissioner, reviewed the recommendations and in consultation rendered these final decisions.

On February 9th, 2023 the following changes will be effective:

Existing Drug Classes

Drug Class	The following products will **remain preferred** products:	The following products will **become preferred** products:	The following products will **become non-preferred** products and **require prior authorization (PA):**	The following products will **remain non-preferred** products and **require prior authorization (PA):**
Anticonvulsants: First Generation	Celontin® clobazam QL clonazepam tablets QL diazepam rectal gel QL divalproex delayed-release divalproex sodium ER divalproex sprinkle ethosuximide felbamate Peganone® phenobarbital CC phenytoin IR/ER primidone CC valproate valproic acid Valtoco® QL	Nayzilam® QL	*N/A*	*clonazepam ODT* *Depakene®* *Depakote®* *Depakote ER®* *Depakote® Sprinkle* *Diastat® QL* *Dilantin®* *Felbatol®* *Klonopin® QL* *Mysoline®* *Onfi™ QL* *Phenytek®* *Sympazan™ CC, QL* *Zarontin®*
Topical Antifungal Agents	clotrimazole cream, solution clotrimazole/betamethasone cream ketoconazole cream QL ketoconazole shampoo Nyamyc® nystatin cream, ointment, powder QL nystatin/triamcinolone cream, ointment	ciclopirox cream, solution	*N/A*	*Ciclodan® cream, kit, solution* *ciclopirox suspension, shampoo, gel, kit* *clotrimazole/betamethasone lotion* *econazole* *Ertaczo®* *Exelderm®* *Extina®* *Jublia® CC*

Drug Class	The following products will **remain preferred** products:	The following products will **become preferred** products:	The following products will **become non-preferred** products and **require prior authorization (PA):**	The following products will **remain non-preferred** products and **require prior authorization (PA):**
	Nystop®			*Kerydin™ CC* *ketoconazole foam* *Ketodan™* *Loprox®* *luliconazole* *Luzu®* *Mentax®* *miconazole/zinc oxide/petrolatum* *naftifine* *Naftin®* *Oxiconazole QL* *Oxistat® QL* *sulconazole nitrate cream, solution* *tavaborole* *Triamazole™ CC, QL* *Vusion®*
Anti-Emetics: Other	meclizine metoclopramide oral solution, tablets prochlorperazine tablets promethazine syrup, tablets promethazine/Promethegan 12.5, 25 mg suppositories scopolamine patches	Bonjesta®	*N/A*	*Antivert®* *Compro®* *Diclegis™ CC, QL* *doxylamine/pyridoxine CC, QL* *Gimoti™ CC, QL* *metoclopramide ODT* *prochlorperazine suppositories* *promethazine/Promethegan 50 mg suppositories* *Reglan®* *Transderm-Scop®* *trimethobenzamide*
Topical Antiviral Agents	acyclovir ointment	acyclovir cream	*Zovirax® cream*	*Denavir®* *Xerese™* *Zovirax® ointment*
GI Motility Agents	Amitiza® CC, AE, QL Linzess® CC, AE, QL Movantik® CC, AE, QL	Trulance™ CC, AE, QL	*N/A*	*alosetron CC, AE, QL* *Ibsrela® CC, AE, QL* *Lotronex® CC, AE, QL* *lubiprostone AE, QL* *Motegrity™ AE, QL* *Relistor® CC, AE, QL* *Symproic® CC, AE, QL* *Viberzi® CC, AE, QL*
Immunomodulators, Atopic Dermatitis	Elidel® Eucrisa® CC, QL	Dupixent® CC, QL Protopic®	*N/A*	*Adbry™ CC, AE, QL* *Opzelura™ CC, AE* *pimecrolimus* *tacrolimus ointment*
Multiple Sclerosis Agents	Avonex® CC, QL Betaseron® CC, QL Copaxone® 20 mg CC, QL dimethyl fumarate CC, QL Gilenya™ CC, QL Rebif® CC, QL	dalfampridine ER QL	*N/A*	Ampyra™ QL Aubagio® QL Bafiertam™ AE, QL Copaxone® 40 mg QL Extavia® QL fingolimod QL glatiramer acetate QL

Drug Class	The following products will **remain preferred** products:	The following products will **become preferred** products:	The following products will **become non-preferred** products and **require prior authorization (PA):**	The following products will **remain non-preferred** products and **require prior authorization (PA):**
				Glatopa™ QL Kesimpta® CC, AE, QL Mavenclad® CC, AE, QL Mayzent® CC, AE, QL Plegridy® QL Ponvory™ CC, AE, QL Tascenso ODT™ Tecfidera™ QL Vumerity™ AE, QL Zeposia® CC, AE, QL
Topical Steroids	alclometasone dipropionate Anusol® HC betamethasone dipropionate cream, lotion betamethasone dipropionate (augmented) cream betamethasone valerate cream, ointment clobetasol propionate cream, ointment, shampoo, solution Clodan® shampoo Derma-Smoothe/FS® desonide cream, ointment fluocinonide solution fluticasone propionate cream, ointment halobetasol propionate cream, ointment hydrocortisone cream, lotion, ointment mometasone furoate cream, ointment, solution Procto-Med HC™ Procto-Pak™ Proctosol-HC® Proctozone-HC™ triamcinolone acetonide cream, lotion, ointment	fluocinonide ointment	*clobetasol propionate gel*	*amcinonide* *Ana-Lex™* *Aqua Glycolic HC®* *Beser™* *betamethasone dipropionate ointment* *betamethasone dipropionate augmented ointment, lotion, gel* *betamethasone valerate foam, lotion* *Bryhali™* *Capex® Shampoo* *clobetasol emollient* *clobetasol propionate foam, lotion, spray* *Clobex®* *clocortolone* *Clodan® kit* *Cloderm®* *desonide lotion* *desoximetasone* *diflorasone diacetate* *Diprolene®* *fluocinolone acetonide oil, cream, ointment, solution* *fluocinonide emollient* *fluocinonide cream, gel* *flurandrenolide* *fluticasone propionate lotion* *halcinonide cream* *halobetasol propionate foam* *Halog®* *hydrocortisone butyrate* *hydrocortisone butyrate/emollient* *hydrocortisone valerate cream, ointment* *Impeklo™* *Kenalog®* *Lexette* *Lidocort™* *Locoid®*

Drug Class	The following products will **remain preferred** products:	The following products will **become preferred** products:	The following products will **become non-preferred** products and **require prior authorization (PA):**	The following products will **remain non-preferred** products and **require prior authorization (PA):**
				Locoid Lipocream® *Luxiq®* *Olux®, Olux-E®* *Pandel®* *prednicarbate* *Proctocort®* *Sanaderm™ Rx* *Synalar®, Synalar® TS* *Temovate®* *Texacort®* *Topicort®* *Tovet™* *triamcinolone acetonide spray* *Ultravate®* *Vanos™*

New Products to Market

Drugs Requiring PA	Criteria for Prior Authorization
Ztalmy®	**Non-prefer in the PDL class:** *Anticonvulsants: Second Generation* **Length of Authorization:** 1 year • Ganaxolone (Ztalmy) is a neuroactive steroid gamma-aminobutyric acid (GABA). A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients ≥ 2 years of age. **Criteria for Approval:** **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

Drugs Requiring PA	Criteria for Prior Authorization
Zoryve®	**Non-prefer in the PDL class:** *Topical Psoriasis Agents* **Length of Authorization:** 1 year • Phosphodiesterase 4 (PDE-4) inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas (e.g., groin folds, axillae, gluteal cleft), in patients ≥ 12 years old. **Criteria for Approval:** **Initial Approval Criteria** • Patient must have an adequate trial and failure, contraindication or intolerance, of at least two preferred medications within the last 90 days. **Age Limit**: ≥ 12 years **Quantity Limit**: 1 tube per 30 days
Vivjoa®	**Non-preferred in the PDL class:** *Antifungals, Oral* **Length of Authorization:** 1 year • Oteseconazole (Vivjoa) is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential. **Criteria for Approval:** **Initial Approval Criteria** • Patient has diagnosis of recurrent vulvovaginal candidiasis with ≥3 episodes of vulvovaginal candidiasis (VVC) in a 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 x 6 months **Age Limit:** none **Quantity Limit:** 18 tablets per treatment course

Sotyktu®	**Non-preferred in the PDL class:** *Cytokine and CAM Antagonists*
	Length of Authorization: 1 year
	• Deucravacitinib (Sotyktu) is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is not recommended for use in combination with other potent immunosuppressants.
	Criteria for Approval:
	• Diagnosis of moderate to severe plaque psoriasis; AND
	• Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of psoriasis; AND
	• Symptoms persistent for ≥ 6 months with at least 1 of the following:
	  ○ Involvement of at least 3% of body surface area (BSA); OR
	  ○ Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR
	  ○ Incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia); AND
	• Trial and failure (at least 3 months) of ≥ 1 conventional therapy:
	  ○ Disease-modifying anti-rheumatic drug (DMARD), such as methotrexate

Drugs Requiring PA	Criteria for Prior Authorization
	○ Immunosuppressant (e.g., cyclosporine) ○ Oral retinoid (e.g., acitretin); AND • NOT used in combination with any other biologic agent; AND • Trial and failure (at least 3 months) unless contraindication or intolerance to, ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; AND • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Renewal Criteria:** • Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day

Existing Product to be reviewed as a Single Product

Drugs Requiring PA	Criteria for Prior Authorization
Tyvaso® Tyvaso DPI™	**Non-preferred in the PDL class:** *Pulmonary Arterial Hypertension (PAH) Agents* **Length of Authorization:** 1 year • Treprostinil (Tyvaso® Tyvaso DPI™) is a prostacyclin mimetic indicated for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability and pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. **Criteria for Approval:** *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 therapeutic 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 has 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

Consent Agenda

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

- Acne Agents, Oral
- Acne Agents, Topical
- Antibiotics, Topical
- Anticholinergics/Antispasmodics
- Antidiarrheals
- Antiemetics & Antivertigo Agents
  - Oral Anti-Emetics: 5-HT3 Antagonists
  - Oral Anti-Emetics: NK-1 Antagonists
  - Oral Anti-Emetics: Δ-9-THC Derivatives
- Antiparasitic, Topical
- Antipsoriatic, Oral
- Antipsoriatics, Topical
- Anti-Ulcer Protectants
- Bile Salts
- Cytokine and CAM Antagonists
- Histamine II Receptor Blockers (H2 Receptor Antagonists)
- *H. pylori* Treatment
- Immunomodulators, Asthma
- Immunosuppressives, Oral (Immunosuppressants)
- Laxatives and Cathartics
- Ophthalmics, Allergic Conjunctivitis
  - Ophthalmic Antihistamines
  - Ophthalmic Mast Cells Stabilizers
- Ophthalmics, Antibiotics
  - Ophthalmic Quinolones
  - Ophthalmic Antibiotics, Non-Quinolones
- Ophthalmics, Antibiotics-Steroid Combinations
- Ophthalmics, Anti-inflammatories
  - Ophthalmic NSAIDs
  - Ophthalmic Anti-inflammatory Steroids
- Ophthalmics, Antivirals
- Ophthalmics, Glaucoma Agents
  - Ophthalmic Beta Blockers
  - Ophthalmic Carbonic Anhydrase Inhibitors
  - Ophthalmic Combinations for Glaucoma
  - Ophthalmic Prostaglandin Agonists
  - Ophthalmic Sympathomimetics
  - Ophthalmic Glaucoma Agents, Other
- Ophthalmic Immunomodulators
- Ophthalmics, Mydriatics & Mydriatic Combinations
- Ophthalmic Vasoconstrictors
- Otic Antibiotics
- Otic Anesthetic and Anti-Inflammatories
- Proton Pump Inhibitors
- Rosacea Agents, 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 November 17, 2022 posted on the provider web portal at: https://kentucky.magellanmedicaid.com (by clicking the Provider/Resources/Documents/Committees/P&T tabs).

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 Magellan Medicaid Administration at kyproviders@magellanhealth.com for Fee-for-Service members or the Kentucky MedImpact team at KYMCOPBM@medimpact.com for Managed Care Organization (MCO) members.

Sincerely,

ShaLeigh Hammons, CPhT

ShaLeigh Hammons, CPhT
Account Manager I
kyproviders@magellanhealth.com

Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information		
Clinical Support Center	1-800-477-3071 Sunday – Saturday 24 hours a day	Please contact the Clinical Support Center to request a prior authorization (PA) or to check the status of a request. **NOTE: The only drugs that are now required to be submitted via fax are Brand Medically Necessary.**
Pharmacy Support Center	1-800-432-7005 Sunday – Saturday 24 hours a day	Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this Call Center.
Provider Services	1-877-838-5085 Monday – Friday 8:00 a.m. – 4:30 p.m.	Please contact Provider Services if you have questions about enrollment or when updating your license or bank information.
Member Services	1-800-635-2570 Monday – Friday 8:00 a.m. – 5:00 p.m.	Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates.