** Fee-For-Service Pharmacy Provider Notice #240 – November 2019 PDL Changes **

January 31, 2020

Please be advised that the Department for Medicaid Services (DMS) is making changes to the Kentucky Medicaid Fee-For-Service (FFS) Pharmacy Preferred Drug List (PDL) based on recommendations and guidance as adopted by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services by order dated November 26, 2019.

The Kentucky Medicaid FFS Pharmacy and Therapeutics Advisory Committee (Committee) met on November 21, 2019. The Committee did not attain the necessary quorum; the expertise, vote, and recommendations of the Committee members in attendance were captured within the Committee's official recommendations delivered for review. DMS, through its Commissioner, reviewed the recommendations and in consultation rendered its final decisions.

On <u>March 2, 2020</u> 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):
Topical Acne Agents	adapalene gel (except pump) clindamycin solution clindamycin/benzoyl peroxide (generic for BenzaClin® or Duac®; except pump) erythromycin solution Retin-A® cream, gel		*adapalene gel pump* *Differin® cream*	*Acanya™* *Aczone™* *adapalene cream, solution, swab* *adapalene/benzoyl peroxide* *Altreno™* *Atralin™* *Avar™/Avar E™/Avar E LS™/Avar LS™* *Avita®* *BenzaClin®* *Benzamycin®* *BenzePro™* *benzoyl peroxide cleanser, kit, microspheres, gel, foam, medicated pad, towlette* *BP 10-1®* *BPO®/BPO-5®/BPO-10®* *BP Wash™* *Brevoxyl®* *Cleocin-T®* *Clindacin PAC™* *Clindagel®* *clindamycin gel, foam, lotion, medicated swab* *clindamycin/benzoyl peroxide gel*

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):
				pump *clindamycin/tretinoin* *dapsone gel* *DermaPak Plus Kit* *Differin® lotion, gel* *Duac®* *Effaclar Duo®* *Epiduo™/Epiduo Forte™* *Erygel®* *erythromycin gel, medicated swab* *erythromycin/benzoyl peroxide* *Fabior®* *Inova™/Inova™ 4-1/Inova™ 8-2* *Klaron®* *Neuac®* *Pacnex®* *Panoxyl®* *Persa-Gel®* *Plixda™* *PR benzoyl peroxide* *OC8®* *Onexton™* *Ovace®/Ovace Plus®* *Retin-A Micro®* *Rosula®* *sodium sulfacetamide 10% CLNSG* *sodium sulfacetamide/sulfur 10-4% pad* *sodium sulfacetamide/sulfur cleanser* *sodium sulfacetamide/sulfur/urea* *SSS 10-5®* *sulfacetamide cleanser* *sulfacetamide/urea* *Sumadan™* *Sumadan™ XLT* *Sumaxin®* *Tazorac®* *tazarotene* *Tretin-X™* *tretinoin* *tretinoin microsphere* *Vanoxide-HC®* *Ziana™*

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):
Antidiarrheals	diphenoxylate with atropine tablets loperamide		*diphenoxylate with atropine liquid*	*Fulyzaq™ CC, QL* *Lomotil®* *Motofen®* *opium* *paregoric* *Restora®*
Anti-Emetics: Other	meclizine metoclopramide oral solution, tablets prochlorperazine tablets promethazine syrup, tablets promethazine 12.5, 25 mg suppositories Transderm-Scop®		*prochlorperazine suppositories*	*Compazine®* *Compro®* *Bonjesta® CC, QL* *Diclegis™ CC, QL* *doxylamine/pyridoxine CC, QL* *metoclopramide ODT* *Phenadoz®* *Phenergan®* *promethazine 50 mg suppositories* *Reglan®* *scopolamine transdermal system* *Tigan®* *trimethobenzamide*
Oral Anti-Emetics: 5-HT3 Antagonists	ondansetron			*Aloxi® QL* *Anzemet®* *granisetron* *Sancuso® CC, QL* *Zofran®* *Zuplenz®*
Oral Anti-Emetics: NK-1 Antagonists	Emend® capsules QL			*Akynzeo® QL* *aprepitant QL* *Emend® powder packet QL* *Varubi® CC, QL*
Oral Anti-Emetics: Δ-9-THC Derivatives	dronabinol CC, QL			*Cesamet® CC, QL* *Marinol® CC, QL*
Topical Antiparasitic Agents	Natroba® permethrin 5% cream		*Sklice®*	*Crotan™* *Elimite™* *Eurax®* *lindane* *malathion* *Ovide®* *spinosad* *Ulesfia®*
Immunomodulators	Cosentyx® CC, QL Enbrel® CC QL Humira® CC, QL		*Rinvoq™ CC, QL*	*Actemra® CC, QL* *Cimzia® CC, QL* *Entyvio™ CC, QL* *Ilumya™ CC, QL* *Kevzara® CC, QL* *Kineret® CC, QL* *Olumiant® CC, QL* *Orencia® CC, 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):
				Otezla® CC, QL *Siliq™ CC, QL* *Simponi™ CC, QL* *Skyrizi™ CC, QL* *Stelara™ CC, QL* *Taltz® CC, QL* *Tremfya™ CC, QL* *Xeljanz® CC, QL* *Xeljanz® XR CC, QL*
Multiple Sclerosis Agents	Avonex® CC, QL Betaseron® CC, QL Copaxone® 20 mg CC, QL Gilenya™ CC, QL Rebif® CC, QL	Tecfidera™ CC, QL		*Ampyra™ QL, CC* *Aubagio® QL* *Copaxone® 40 mg QL* *dalfampredine ER CC, QL* *Extavia® QL* *glatiramer acetate QL* *Glatopa™ QL* *Mavenclad® CC, QL* *Mayzent® CC, QL* *Plegridy®* *Vumerity™ QL*
Ophthalmic Beta Blockers	levobunolol timolol maleate			*Betagan®* *betaxolol* *Betimol®* *Betoptic S®* *carteolol* *Istalol®* *metipranolol* *Optipranolol®* *timolol maleate once daily (generic Istalol®)* *Timoptic®* *Timoptic XE®*
Ophthalmic Carbonic Anhydrase Inhibitors	dorzolamide		*Azopt®*	*Trusopt®*
Ophthalmic Combinations for Glaucoma	Combigan™ dorzolamide/timolol Simbrinza™			*Cosopt®* *Cosopt PF®*
Ophthalmic Glaucoma Direct Acting Miotics	N/A			*Isopto Carpine®* *pilocarpine* *Pilopine HS® 4%*
Ophthalmic Prostaglandin Agonists	latanoprost QL			*bimatoprost QL* *Lumigan® QL* *Rescula® QL* *Travatan Z®* *travoprost* *Vyzulta™ CC, 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):
				Xalatan® QL *Xelpros™* *Zioptan® QL*
Ophthalmic Sympathomimetics	Alphagan P® 0.15% brimonidine 0.2%			*Alphagan P® 0.1%* *apraclonidine* *brimonidine 0.15%*
Ophthalmics, Glaucoma Agents (Other)		Rhopressa® ST, QL Rocklatan™ ST, QL		*N/A*
Otic Antibiotics	CiproDex® Otic hydrocortisone/neomycin/polymyxin ofloxacin		*ciprofloxacin*	*ciprofloxacin/fluocinolone* *Cipro HC® Otic* *Coly-mycin® S* *Floxin™* *Otovel™*
Proton Pump Inhibitors	esomeprazole magnesium capsules QL Nexium® suspension QL omeprazole capsules QL pantoprazole QL	lansoprazole QL		*Aciphex® QL* *Dexilant™ QL* *esomeprazole strontium QL* *Nexium® capsules QL* *omeprazole suspension QL* *omeprazole/sodium bicarbonate QL* *Prevacid® QL* *Prilosec® QL* *Protonix® QL* *rabeprazole QL* *Zegerid® QL*
Spinal Muscular Atrophy	N/A		*Zolgensma® CC*	
Ulcerative Colitis Agents	Apriso™ balsalazide mesalamine enema (generic Rowasa®) mesalamine suppository (generic Canasa®) sulfasalazine sulfasalazine EC		*Delzicol®*	*Asacol® HD* *Azulfidine®* *Azulfidine EN-tabs®* *budesonide ER (generic Uceris®)* *Canasa®* *Colazal®* *Dipentum®* *Giazo®* *Lialda™* *mesalamine 400 mg capsule (generic Delzicol®)* *mesalamine 1.2 gm tablet (generic Lialda™)* *Pentasa®* *Rowasa®* *Uceris®*

Criteria Review

Clinical Criteria Review: Multiple Sclerosis Agents

Current criteria: Preferred agents do not require a prior authorization.

Recommended criteria: Preferred agents require a diagnosis code of multiple sclerosis (ICD-10 = G35) or a history of use of another MS agent. This requirement can be fulfilled automatically by drug history lookback, and/or medical diagnosis lookback/submission.

Clinical Criteria Review: Ophthalmics, Glaucoma Agents (Other)

Current criteria: Preferred agents do not require a prior authorization (PA).

Recommended criteria: Preferred agents require PA consisting of a step edit through generic latanoprost. An electronic 90-day lookback for a paid pharmacy claim for latanoprost will be established to allow an automated PA.

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
- Antibiotics, Topical
- Anticholinergics/Antispasmodics
- Antifungals, Topical
- Antipsoriatics, Oral
- Antipsoriatics, Topical
- Anti-Ulcer Protectants
- Antivirals, Topical
- Bile Salts
- GI Motility, Chronic
- H. Pylori Treatment
- Histamine II Receptor Blockers
- Immunomodulators, Atopic Dermatitis
- Immunosuppressives, Oral
- Laxatives & Cathartics
- Ophthalmic Antibiotic-Steroid Combinations
- Ophthalmic Antibiotics
- Ophthalmics, Anti-Inflammatories
- Ophthalmics, Anti-Inflammatories-Immunomodulators
- Ophthalmics, Antiviral
- Ophthalmics for Allergic Conjunctivitis
- Ophthalmics, Mydriatic
- Ophthalmics, Vasoconstrictor
- Otic Anti-Infectives & Anesthetics
- Otics, Anti-Inflammatory
- Rosacea Agents, Topical
- Steroids, Topical (High, Low, Medium, Very High)

New Products to Market

Drugs Requiring PA	Criteria for Prior Authorization
Inrebic®	Prefer with clinical criteria in the PDL class: *Oral Oncology, Hematologic Cancer* **Length of Authorization:** 1 year • Inrebic® (fedratinib) is a Janus kinase 2 (JAK2) inhibitor indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). **Criteria for Approval**: • Diagnosis of intermediate-2 or high-risk myelofibrosis (MF), including secondary post-polycythemia vera or post-essential thrombocythemia MF; AND • NOT to be used in combination with rituximab. **Renewal Criteria:** • Continue to meet initial approval criteria; AND • Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread). **Age Limit**: ≥ 18 years **Quantity Limit**: 4 per day

Xpovio™	Non-prefer in the PDL class: *Oral Oncology, Hematologic Cancer*
	Length of Authorization: 1 year
	• Xpovio™ (selinexor) is a nuclear export inhibitor indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received ≥ 4 prior therapies and whose disease is refractory to ≥ 2 proteasome inhibitors, ≥ 2 immunomodulatory agents, and an anti-CD38 monoclonal antibody.
	Criteria for Approval:
	• Diagnosis of relapsed or refractory multiple myeloma; AND
	• Patient does NOT have smoldering myeloma, central nervous system myeloma, systemic amyloid light chain amyloidosis or plasma cell leukemia; AND
	• Trial and failure (inadequate response; progression during or within 60 days of therapy) of ≥ 4 prior therapies that must include:
	  ○ 2 proteasome inhibitors (e.g., bortezomib, ixazomib, or carfilzomib); AND
	  ○ 2 immunomodulatory agents (e.g., lenalidomide, pomalidomide, thalidomide); AND
	  ○ An anti-CD38 antibody (e.g., daratumumab)
	Renewal Criteria
	• Continue to meet initial approval criteria; AND
	• Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread).
	Age Limit: ≥ 18 years
	Quantity Limit: 32 tablets per 28 days

Drugs Requiring PA	Criteria for Prior Authorization

Rozlytrek™	Prefer with clinical criteria in the PDL class: *Oral Oncology, Lung Cancer*
	Length of Authorization: 35 days initial; one 35-day renewal
	• Rozlytrek™ (entrectinib) is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive. Patients should be selected based on the presence of ROS1 rearrangement(s) in tumor specimens. An FDA-approved test for detection of these mutations in NSCLC for selecting patients is not available; however, a companion diagnostic test is planned to be submitted to the FDA for approval.
	• Entrectinib is also indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that:
	  ○ Have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation;
	  ○ Are metastatic or where surgical resection is likely to result in severe morbidity; and
	  ○ Have either progressed following treatment or have no satisfactory alternative therapy.
	• Patients should be selected for treatment of locally advanced or metastatic solid tumors based on the presence of a NTRK gene fusion. An FDA-approved test for the detection of NTRK gene fusion in solid tumors is not available; however, a companion diagnostic test is planned to be submitted to the FDA for approval.
	Criteria for Approval:
	• Diagnosis of metastatic non-small cell lung cancer (NSCLC) that is:
	  ○ ALK- and EGFR-negative; AND
	  ○ ROS1-positive as determined by laboratory testing (e.g., next generation sequencing [NGS] or fluorescence in situ hybridization [FISH]); OR
	• Diagnosis of solid tumor (e.g., soft tissue sarcoma, salivary gland, infantile fibrosarcoma, thyroid, lung, or gastrointestinal stromal tumors); AND
	  ○ Tumor has a positive NTRK gene fusion status, without a known acquired resistance mutation, as determined by laboratory testing (e.g., NGS or FISH); AND
	  ○ Disease is metastatic or surgical resection is likely to result in severe morbidity; AND
	  ○ Patient has no satisfactory alternative treatments or has progressed following treatment.
	Renewal Criteria
	• Continue to meet initial approval criteria; AND
	• Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread).
	Age Limit: ≥ 12 years
	Quantity Limit: 100 mg: 5 per day; 200 mg: 3 per day

Drugs Requiring PA	Criteria for Prior Authorization

Turalio™	Prefer with clinical criteria in the PDL class: *Oral Oncology, Other*
	Length of Authorization: 1 year
	• Turalio™ (pexidartinib) is indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.
	Criteria for Approval:
	• Histologically confirmed diagnosis of tenosynovial giant cell tumor (TGCT) – also referred to as giant cell tumor of the tendon sheath (GCT-TS) or pigmented villonodular synovitis (PVNS); AND
	  ○ NOT metastatic; AND
	  ○ Symptomatic and/or associated with severe morbidity or functional limitations; AND
	  ○ NOT amenable to improvement with surgery or patient is not a surgery candidate.
	Renewal Criteria
	• Continue to meet initial approval criteria; AND
	• Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread).
	Age Limit: ≥ 18 years
	Quantity Limit: 4 per day

Nubeqa®	Prefer with criteria in the PDL class: *Oral Oncology, Prostate* **Length of Authorization:** 1 year • Nubeqa® (darolutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer **Criteria for Approval** • Diagnosis of non-metastatic castration-resistant disease (nmCRPC); AND • Patient will also receive a gonadotropin-releasing hormone (GnRH)-analog or has had a bilateral orchiectomy; AND • NOT used with another androgen receptor inhibitor (e.g., apalutamide, enzalutamide). **Renewal Criteria** • Continue to meet initial approval criteria; AND • Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread). **Age Limit:** ≥ 18 years **Quantity Limit:** 4 per day

Drugs Requiring PA	Criteria for Prior Authorization
Sunosi™	Non-prefer in the PDL class: *Narcolepsy Agents* **Length of Authorization:** 1 year • Sunosi™ (solriamfetol) is a dopamine and norepinephrine reuptake inhibitor (DNRI) approved for improving wakefulness in adults with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA). **Criteria for Approval** • Diagnosis of excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA); 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, a preferred agent (e.g., modafinil). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day
Rinvoq™	Non-prefer in the PDL class: *Immunomodulators* **Length of Authorization:** 1 year • Rinvoq™ (upadacitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate (MTX). • Use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended. **Criteria for Approval** • Diagnosis of moderately to severely active rheumatoid arthritis (RA) using an objective measure/tool; AND • Trial and failure (at least 3 months) or intolerance to methotrexate (MTX); AND • Trial and failure (at least 3 months), or contraindication to, a preferred immunomodulator (e.g., Enbrel®or Humira®); AND • Used for treatment of RA as a single agent or in combination with MTX or similar non-biologic DMARD; AND • Negative tuberculosis (TB) screening and no signs of clinically significant infection prior to treatment initiation. **Renewal Criteria** • Meet initial approval criteria; AND • Ongoing monitoring for TB or other active infection; AND • Disease response as indicated by improvement in signs and symptoms compared to baseline objective measurements, such as the number of tender and swollen joints. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day

Drugs Requiring PA	Criteria for Prior Authorization

Zolgensma®	Non-prefer in the PDL class: *Spinal Muscular Atrophy*
	Length of Authorization: Date of service: once per lifetime
	• Zolgensma® (onasemnogene abeparvovec-xioi) is an adeno-associated virus vector-based gene therapy indicated for the treatment of pediatric patients < 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene.
	• The safety and effectiveness of repeat administration and use in patients with advanced SMA (e.g., complete paralysis of limbs, permanent ventilator dependence) have not been evaluated.
	Criteria for Approval
	• Prescribed by, or in consultation with, a pediatric neurologist or other specialist in the diagnosis and treatment of spinal muscular atrophy (SMA); AND
	• Diagnosis of SMA confirmed by either bi-allelic deletion or dysfunctional point mutation of the SMN1 gene; AND
	• Must have SMA phenotype 1 confirmed by:
	  ○ 1 or 2 copies of the SMN2 gene; OR
	  ○ 3 copies of the SMN2 gene WITHOUT the c.859G>C single base substitution modification in exon 7; 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 nusinersen; AND
	• Therapy to be administered prior to recipient's 2nd birthday.

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 21, 2019 posted on the provider web portal at: https://kyportal.magellanhealth.com (by clicking the Resources/Documents/Committees/P&T tabs).

Thank you for helping Kentucky Medicaid members maintain access to prescription coverage by selecting drugs on the preferred drug list whenever possible. Please contact Magellan Medicaid Administration at kyproviders@magellanhealth.com for any additional information or questions you may have.

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, Buprenorphine products, Synagis®, and Zyvox®.**
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.