Pharmacy Provider Notice #271– March 2022 PDL Changes

May 2, 2022

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 March 28, 2022.

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

On <u>June 2, 2022</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):
Antibiotics: Inhaled	Bethkis® QL Kitabis™ Pak QL	tobramycin inhalation solution QL (generic for TOBI®) .		*Arikayce® CC, QL* *Cayston® QL* *tobramycin inhalation solution QL (generic for Bethkis® and Kitabis™ Pak)* *TOBI® QL* *TOBI Podhaler® QL*
Antibiotics: Vaginal	Cleocin® Ovules Clindesse® Nuvessa®	metronidazole vaginal 0.75% gel	*Vandazole®*	*Cleocin® cream* *clindamycin vaginal 2% cream* *MetroGel Vaginal®*
Antiretrovirals: HIV/AIDS	abacavir QL abacavir-lamivudine atazanavir QL Biktarvy® QL Cimduo™ QL Complera® QL Delstrigo™ QL Descovy® CC, QL Edurant® efavirenz efavirenz/emtricitabine/tenofovir disoproxil fumarate QL emtricitabine/tenofovir disoproxil fumarate CC, QL	Dovato QL Juluca QL Symtuza™ QL		*abacavir-lamivudine-zidovudine* *Aptivus®* *Combivir®* *Crixivan®* *didanosine DR QL* *efavirenz/lamivudine/tenofovir disoproxil fumarate QL* *emtricitabine QL* *Epivir® QL* *Epzicom®* *etravirine* *fosamprenavir* *Fuzeon®*

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):
	Emtriva® QL Evotaz™ QL Genvoya® QL Intelence® Isentress® lamivudine QL lamivudine-zidovudine lopinavir-ritonavir tablets, solution Odefsey® QL Pifeltro™ QL Prezista® ritonavir tablets Selzentry® stavudine capsules QL stavudine solution Stribild® QL Symfi™ QL Symfi Lo™ QL tenofovir disoproxil fumarate tablets QL Tivicay® tablets QL Triumeq® QL Trizivir® Tybost® zidovudine syrup, tablets			*Invirase®* Kaletra® tablets, solution *Lexiva®* *maraviroc* *nevirapine QL* *nevirapine ER QL* *Norvir® tablets, solution QL* *, powder packets* *Prezcobix® QL* *Retrovir®* *Reyataz® QL* *Rukobia® CC, QL* *Sustiva®* *Temixys™ QL* *Tivicay® suspension* *Truvada® QL* *Viracept®* *Viramune® QL* *Viramune XR® QL* *Viread® powder packets* *Viread® tablets QL* *Vocabria™ CC, AE, QL* *Ziagen® QL* *zidovudine capsules*
Antibiotics: Oxazolidinones	linezolid tablets CC, QL, MD	Zyvox® Suspension QL, MD		*linezolid suspension QL, MD* *Sivextro™ QL* *Zyvox® Tablets QL, MD*
Antibiotics: Tetracyclines	demeclocycline doxycycline hyclate doxycycline monohydrate 50 mg, 100 mg capsules doxycycline monohydrate suspension, tablets minocycline capsules Morgidox®	tetracycline capsules		*Doryx®* *Doryx® DR* *Doryx® MPC* *doxycycline hyclate DR* *doxycycline IR-DR* *doxycycline monohydrate 40, 75, 150 mg capsules* *doxycycline "kits" or "packs"* *minocycline tablets* *minocycline ER* *Minolira™ ER* *Morgidox® Kit* *Nuzyra™ CC, QL* *Oracea™* *Solodyn®* *Targadox™* *Vibramycin®*

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):
				Ximino™ ER
Intranasal Corticosteroids	fluticasone propionate QL	Dymista® QL		*azelastine/fluticasone* QL *Beconase AQ®* QL *budesonide* *Children's Qnasl™* QL *flunisolide* QL *mometasone* QL *Nasonex®* QL *Omnaris™* QL *Qnasl™* QL *Xhance™* CC *Zetonna™* QL *carteolol* *Istalol ®* *metipranolol* *timolol maleate once daily (generic Istalol®)* *timolol PF (preservative-free)* *Timoptic®* *Timoptic XE®*

New Products to Market

Drugs Requiring PA	Criteria for Prior Authorization
Qulipta™	**Non-prefer in the PDL class:** Anti-Migraine: CGRP Inhibitors **Length of Authorization:** 3 months initial; 1 year renewal • Atogepant (Qulipta) is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the preventive treatment of episodic migraine in adults. **Criteria for Approval** • 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 • 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**

Drugs Requiring PA	Criteria for Prior Authorization
	• 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

Lybalvi™	**Non-prefer in the PDL class:** *Second-Generation Antipsychotics*
	Length of Authorization: 1 year
	• Lybalvi™ (Olanzapine/samidorphan) is a combination of the atypical antipsychotic olanzapine and the opioid antagonist samidorphan (new molecular entity). It is indicated for the treatment of schizophrenia and bipolar I disorder in adults.
	Criteria for Approval:
	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
	Quantity Limit: 30 tablets/30 days

Winlevi®	**Non-prefer in PDL Class:** *Topical Acne Agents* **Length of Authorization:** 1 year • Clascoterone (Winlevi) topical cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients ≥ 12 years of age. **Criteria for Approval:** **Initial Approval Criteria**

Drugs Requiring PA	Criteria for Prior Authorization
	• Patient has had a trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of ≥ 4 preferred or covered over-the-counter (OTC) agents. **Age Limit:** ≥12 years
Azstarys™	**Non-prefer in the PDL class:** *Central Nervous System: Stimulants And Related Agents* **Length of Authorization:** 1 year • Serdexmethylphenidate/dexmethylphenidate (Azstarys) is a central nervous system (CNS) stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients aged ≥ 6 years old. **Criteria for Approval:** **Initial Approval Criteria** • Patient has a diagnosis of ADHD • Patient has a history of trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to 1 preferred agent, unless otherwise specified. **Therapeutic duplication limit:** • Patient is limited to one long-acting and one short-acting CNS agent for ADHD at a time within the quantity/dosing limits. **Age Limit:** none **Quantity Limit:** 1 per day
Bylvay™	**Non-prefer in the PDL class:** *Bile Salts* **Length of Authorization:** 1 year • Odevixibat (Bylvay) is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of pruritus in patients ≥ 3 months of age with progressive familial intrahepatic cholestasis (PFIC). **Criteria for Approval:** **Initial Approval Criteria** • 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).

Drugs Requiring PA	Criteria for Prior Authorization
	Note: use of these agents is off-label. **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 **Quantity Limit:** Maximum daily dose = 6 mg • 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: 5 per day; 150 per 30 days

Livmarli™	**Non-prefer in the PDL class:** *Bile Salts*
	Length of Authorization: 1 year
	• Maralixibat (Livmarli), an ileal bile acid transporter (IBAT) inhibitor, is indicated for the treatment of cholestatic pruritus in patients ≥ 1 year of age with Alagille syndrome (ALGS).
	Criteria for Approval:
	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
	• 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 are 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

Opzelura™	**Non-prefer in the PDL class:** *Immunomodulators, Atopic Dermatitis*

Drugs Requiring PA	Criteria for Prior Authorization
	Length of Authorization: 1 year • Ruxolitinib (Opzelura) is a Janus kinase (JAK) inhibitor that targets the JAK and signal transducer and activator of transcription (STAT) pathway, indicated for short-term and non-continuous chronic treat immunocompromised patients ≥ 12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. **Criteria for Approval:** **Initial Approval Criteria** • Patient has a diagnosis of mild to moderate atopic dermatitis; AND • Patient is NOT immunocompromised; 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: o Prescription topical corticosteroids o Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus) o Topical phosphodiesterase-4 inhibitor (e.g., crisaborole) **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
Rezurock™	**Non-prefer in the PDL class:** *Immunosuppressants* **Length of Authorization:** 1 year • Belumosudil (Rezurock), a kinase inhibitor that targets Rho-associated coiled-coil kinase (ROCK2), is indicated for the treatment of patients ≥ 12 years of age with chronic graft-versushost disease (cGVHD) following failure of ≥ 2 prior lines of systemic therapy. **Criteria for Approval:** **Initial Approval Criteria** • Patient is post-allogenic stem cell transplant (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

Drugs Requiring PA	Criteria for Prior Authorization
	• Belumosudil will not be used in combination with ibrutinib (subsequent therapy is allowed). **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
Tyrvaya™	**Non-prefer in the PDL class:** *Ophthalmic Immunomodulators* **Length of Authorization:** 1 year • Varenicline (Tyrvaya) is a partial nicotinic acetylcholine receptor agonist indicated for treatment of the signs and symptoms of dry eye disease (DED) in adults. **Criteria for Approval:** **Initial Approval Criteria** • Patient has diagnosis of dry eye disease (DED); AND • Prescribed by or in consultation with an ophthalmologist or optometrist; AND • 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. • 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
Skytrofa™	**Non-prefer in the PDL class:** *Growth Hormones* **Length of Authorization:** 1 year

Drugs Requiring PA	Criteria for Prior Authorization
	• Lonapegsomatropin-tcgd (Skytrofa) is a long-acting prodrug of a human GH (HGH; somatropin) made through recombinant DNA technology using Escherichia coli. It contains somatropin conjugated to a methoxypolyethylene glycol carrier via a proprietary TransCon™ linker; this results in a pegylated form of human GH, indicated for the treatment of pediatric patients ≥ 1 year old who weigh ≥ 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH). **Criteria for Approval:** **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 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
Livtencity™	**Non-PDL Medication** **Length of Authorization:** 6 month initial, 6 month renewal • Maribavir (Livtencity) is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients (≥ 12 years of age and weighing ≥ 35 kg) with posttransplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir, or foscarnet. **Criteria for Approval:** **Initial Approval Criteria** • Patient is a recipient of a hematopoietic stem cell or solid organ transplant; AND

Drugs Requiring PA	Criteria for Prior Authorization
	• Patient has documented cytomegalovirus (CMV) infection in whole blood or plasma (screening value ≥ 2,730 IU/mL in whole blood or ≥ 910 IU/mL in plasma) in 2 consecutive assessments separated by ≥ 1 day; AND • Patient has current CMV infection that is refractory to anti-CMV treatment agents (ganciclovir, valganciclovir, cidofovir, or foscarnet); AND • Maribavir will NOT be co-administered with ganciclovir or valganciclovir; AND • Patient will be monitored for clinically important drug interactions that could result in decreased therapeutic effect of maribavir. **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient must have disease improvement and/or stabilization OR improvement in the slope of decline (> 1 log10 decrease in CMV DNA level in whole blood or plasma after 14 days or longer treatment); AND • Patient has NOT experienced any treatment-restricting adverse effects; AND • Patient is NOT a non-responder (resistant) to maribavir. **Age Limit:** 12 years old **Quantity Limit:** none
Exkivity™	**Non-PDL Class:** *Oral Oncology, Lung* **Length of Authorization:** 1 year • Mobocertinib (Exkivity), is a kinase inhibitor indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion (ex20ins) mutations, as detected by a United States (US) Food and Drug Administration (FDA)-approved test, whose disease has progressed on or after platinum-based chemotherapy. **Criteria for Approval:** **Initial Approval Criteria** • Patient has a diagnosis of non-small cell lung cancer (NSCLC); AND • Patient has locally advanced or metastatic NSCLC; AND • Patient's disease has epidermal growth factor receptor (EGFR) exon 20 insertion mutations as detected by a FDA or Clinical Laboratory Improvement Amendments (CLIA)-compliant test; AND • Patient has disease progression on or subsequent to platinum-based chemotherapy; AND • Patient does NOT have untreated brain metastases (clinically stable, treated, asymptomatic brain metastases are allowed); AND • Patient does NOT have a history of interstitial lung disease (ILD), radiation pneumonitis that required steroid treatment, or drug related pneumonitis; AND

Drugs Requiring PA	Criteria for Prior Authorization
	• Left ventricular ejection fraction (LVEF) is measured prior to initiating therapy and will be assessed at regular intervals during treatment; AND • Patient does NOT have prolonged QTc interval; AND • NOT used in combination with amivantamab-vmjw (Rybrevant); AND • Prescriber attestation QTc and electrolytes will be monitored at baseline and periodically during treatment; • Abnormalities in sodium, potassium, calcium, and magnesium will be corrected prior to initiating therapy; AND • Patient is not pregnant; AND • Females of reproductive potential will use nonhormonal contraception during treatment and for 1 month following the last dose; OR • Males with female partners of reproductive potential will use effective contraception during treatment and for 1 week after the last dose. **Renewal Criteria** • Patient must continue to meet above criteria; AND • Patient must have disease stabilization and/or decrease in size of tumor or tumor spread; AND • Patient has NOT experienced any unacceptable toxicity. **Age Limit:** ≥ 18 years old **Quantity Limit:** 4 per day

Scemblix®	**Non-PDL Class:** *Oral Oncology*
	Length of Authorization: 1 year
	• Scemblix (asciminib) is an ABL/BCR-ABL1 tyrosine kinase inhibitor (TKI) indicated for the treatment of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more TKIs or with T315I mutation.
	Criteria for Approval:
	Initial Approval Criteria
	• Patient has a diagnosis of chronic myeloid leukemia (CML); AND
	• Patient's disease is Philadelphia chromosome-positive (Ph+); AND
	• Patient has chronic phase disease; AND
	  ○ Patient is resistant, or intolerant, or had an inadequate response to prior therapy consisting of a 3 month trial or longer, with ≥ 2 tyrosine kinase inhibitors (e.g., imatinib, bosutinib, dasatinib, nilotinib, ponatinib); OR
	  ○ Patient has the T315I mutation; AND
	• Patient does NOT have uncontrolled hypertension; AND
	• Patient's serum lipase and amylase levels will be measured periodically during treatment; AND

Drugs Requiring PA	Criteria for Prior Authorization
	• Patient will be monitored and managed according to the prescribing information for myelosuppression, cardiovascular toxicities, and hypersensitivity; AND • Female patients of reproductive potential have a negative pregnancy test prior to starting asciminib therapy and have been counselled to use effective contraception during therapy and for 1 week after the last dose. **Renewal Criteria** • Patient continues to meet initial approval criteria; AND • Patient has NOT experienced unacceptable toxicity from the drug. (Examples of unacceptable toxicity include myelosuppression, pancreatic toxicity, hypertension, hypersensitivity, cardiovascular toxicity, etc.); AND • Physician attestation that patient has been adherent to therapy; AND • Patient has had a positive response to treatment **Age Limit:** ≥ 18 years old **Quantity Limit:** Maximum dose is 400 mg/day • 20 mg (2 tablets/day): 60 tablets/30 days • 40 mg (10 tablets/day): 300 tablets/30 days

Welireg®	**Non-PDL Class:** *Oral Oncology*
	Length of Authorization: 1 year
	• Belzutifan (Welireg), a hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, indicated for the treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery.
	Criteria for Approval:
	Initial Approval Criteria
	• Patient has a diagnosis of Von Hippel-Lindau Disease (VHL) based on a germline VHL-alteration; AND
	• Patient has ≥ 1 of the following associated tumors:
	  ○ Renal cell carcinoma (RCC) [note: may be confirmed radiologically only]; OR
	  ○ CNS hemangioblastomas; OR
	  ○ Pancreatic neuroendocrine tumors (pNET); AND
	• Patient does not have an immediate need for surgical intervention for tumor treatment OR have evidence of metastatic disease; AND
	• Patient has a serum hemoglobin level of at least 9 mg/dL: AN
	Renewal Criteria
	• Patient must continue to meet the above criteria; AND
	• Patient has not had unacceptable toxicity from the drug; AND

Drugs Requiring PA	Criteria for Prior Authorization
	• Treatment has resulted in disease response, as defined by stabilization of disease or decrease in size of tumor or tumor spread. **Age Limit:** ≥ 18 years old **Quantity Limit:** 90 tablets/ 30 days
Tukysa®	**Non-PDL Class:** *Oral Oncology, Breast* **Length of Authorization:** 1 year • Tucatinib is an oral tyrosine kinase inhibitor (TKI) that is highly selective for human epidermal growth factor receptor 2 (HER2) and has minimal inhibition of epidermal growth factor receptor (EGFR). Tucatinib is indicated in combination with capecitabine and trastuzumab in adult patients for the treatment of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received 1 or more prior anti-HER2-based regimens in the metastatic setting. **Criteria for Approval:** **Initial Approval Criteria** • Patient is ≥ 18 years old; AND • Patient has a diagnosis of breast cancer; AND • Patient's disease is human epidermal growth factor receptor (HER2-positive); AND • Patient's disease is unresectable, locally advanced, or metastatic; AND • Used as subsequent therapy in combination with trastuzumab and capecitabine; AND • Patient has been previously treated with the following antiHER2 directed therapies: trastuzumab, pertuzumab, and adotrastuzumab emtansine; alone or in combination with at least 1 in the metastatic setting; OR • Patient has neurologically stable brain metastases related to breast cancer; AND • Patient does NOT have leptomeningeal disease; AND • Used as subsequent therapy in combination with trastuzumab and capecitabine; AND • Patient has been previously treated with the following antiHER2 directed therapies: trastuzumab, pertuzumab, and adotrastuzumab emtansine; alone or in combination with at least 1 in the metastatic setting **Renewal Criteria** • Patient must continue to meet the above initial criteria, such as concomitant therapy requirements (not including prerequisite therapy); AND • Disease response with treatment, as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND • Absence of unacceptable toxicity from the drug (e.g., hepatotoxicity [severe changes in liverfunction tests], severe diarrhea). **Quantity Limit:** 120 tablets/ 30 days
Pemazyre™	**Non-PDL Class:** *Oral Oncology*

Drugs Requiring PA	Criteria for Prior Authorization
	Length of Authorization: 1 year • Pemigatinib (Pemazyre) is a kinase inhibitor indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor (FGFR) 2 fusion or other rearrangement as detected by an FDA-approved test. **Criteria for Approval:** **Initial Approval Criteria** • Patient has a diagnosis of cholangiocarcinoma; AND • Disease is unresectable locally advanced or metastatic disease; AND • Patient has a susceptible gene mutation rearrangement or fusion in the fibroblast growth factor receptor 2 (FGFR2) gene, as determined by an FDA-approved or CLIA-compliant test; AND • Patient has previously been treated with at least 1 systemic therapy; AND • Pemigatinib will be used as a single agent; AND • Patient will receive ophthalmological examinations (e.g., assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography) at baseline and periodically throughout therapy; AND • Patient has a diagnosis of cholangiocarcinoma; AND • Disease is unresectable locally advanced or metastatic disease; AND • Patient has a susceptible gene mutation rearrangement or fusion in the fibroblast growth factor receptor 2 (FGFR2) gene, as determined by an FDA-approved or CLIA-compliant test; AND • Patient has previously been treated with at least 1 systemic therapy; AND • Pemigatinib will be used as a single agent; AND • Patient will receive ophthalmological examinations (e.g., assessment of visual acuity, slit lamp examination, fundoscopy, and optical coherence tomography) at baseline and periodically throughout therapy; AND • Patient serum phosphate level is measured at baseline and periodically throughout therapy; AND • Therapy will not be used concomitantly with other selective FGFR-inhibitors (e.g., erdafitinib) **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient has not had unacceptable toxicity from the drug; AND • Treatment has resulted in disease response, as defined by stabilization of disease or decrease in size of tumor or tumor spread. **Age Limit:** ≥ 18 years old

Drugs Requiring PA	Criteria for Prior Authorization
	Quantity Limit: • 4.5 mg tablet: 14 tablets/21-day cycle • 9 mg tablet: 14 tablets/21-day cycle • 13.5 mg tablet: 14 tablets/21-day cycle
Qinlock™	**Non-PDL Class: Oral Oncology** **Length of Authorization: 1 year** • Ripretinib (Qinlock) is a tyrosine kinase inhibitor (TKI) with activity against KIT protooncogene receptor tyrosine kinase (KIT) and platelet derived growth factor receptor (PDGFR) alpha (PDGFRA) kinases, including those with wild-type, primary, and secondary mutations. It is indicated for the treatment of adults with advanced gastrointestinal stromal tumors (GIST) who have received prior treatment with ≥ 3 kinase inhibitors, including imatinib. **Criteria for Approval:** **Initial Approval Criteria** • Patient has unresectable, locally advanced, or metastatic gastrointestinal stromal tumors (GIST); AND • Patient's disease progressed after an adequate trial or intolerance to ≥ 3 prior therapies (e.g., imatinib, sunitinib, regorafenib), with 1 being imatinib; AND • Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; AND • Patient will have a dermatologic evaluation prior to initiating therapy and routinely during treatment; AND • Patient does NOT have uncontrolled hypertension; AND • Patient has unresectable, locally advanced, or metastatic gastrointestinal stromal tumors (GIST); AND • Patient's disease progressed after an adequate trial or intolerance to ≥ 3 prior therapies (e.g., imatinib, sunitinib, regorafenib), with 1 being imatinib; AND • Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals during treatment; AND • Patient will have a dermatologic evaluation prior to initiating therapy and routinely during treatment; AND • Patient does NOT have uncontrolled hypertension; AND **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient must demonstrate disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND • Patient has NOT experienced any treatment-restricting adverse effects; AND

Drugs Requiring PA	Criteria for Prior Authorization
	• Patient does NOT have grade 3 or 4 left-ventricular systolic dysfunction (e.g., symptomatic due to a resting ejection fraction ≤ 39% or > 20% decrease from baseline). **Age Limit:** ≥ 18 years old **Quantity Limit:** 90 tablets/ 30 days

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.

• Antibiotics: Cephalosporins 1st Generation • Antibiotics: Cephalosporins 2nd Generation • Antibiotics: Cephalosporins 3rd Generation • Antibiotics: Gastrointestinal (GI) • Antibiotics: Macrolides/Ketolides • Antibiotics: Penicillins • Antibiotics: Pleuromutilins • Antibiotics: Quinolones • Antibiotics: Sulfonamides, Folate Antagonists • Antifungals: Oral • Anti-Infectives: Hepatitis B • Antivirals: Herpes • Antivirals: Influenza	• Beta Agonists: Combination Products • COPD Agents • Hepatitis C: Direct-Acting Antiviral Agents • Hepatitis C: Interferons • Hepatitis C: Ribavirins • Inhaled Corticosteroids • Intranasal Antihistamines and Anticholinergics • Leukotriene Modifiers • Long-Acting Beta2 Adrenergic Agonists • Minimally Sedating Antihistamines • Self-Injectable Epinephrine • Short-Acting Beta2 Adrenergic Agonists

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 March 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

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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.