Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

The following chart provides a summary of the official recommendations made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **March 17th, 2022,** meeting.

Pending is the review by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services of these recommendations and final decisions.

	Description of Recommendation	P & T Vote
1	**New Product to Market: 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** • 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	**Passed** 10 For 0 Against
2	**New Product to Market: Lybalvi™** **Non-prefer in the PDL class:** *Second-Generation Antipsychotics* **Length of Authorization:** 1 year • Olanzapine/samidorphan (Lybalvi) 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**	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	○ 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	
3	**New Products to Market – 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** • 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 old	**Passed** 10 For 0 Against
4	**New Products to Market – Azstarys™** **Non-prefer in 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	**Passed** 10 For 0 Against
5	**New Products to Market – Bylvay™** **Non-prefer in 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	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	• 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 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	

6	**New Product to Market- Livmarli™**
	Non-prefer in 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 is off-label.
	Renewal Criteria
	• Patient must continue to meet the above criteria; AND
	• 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
		Passed
		10 For
		0 Against

7	**New Product to Market- Opzelura™** **Non-prefer in PDL Class:** *Immunomodulators, Atopic Dermatitis* **Length of Authorization:** 1 year • Ruxolitinib 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 treatment of mild to moderate atopic dermatitis (AD) in non-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**	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote

	• 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:
	  ○ Prescription topical corticosteroids
	  ○ Topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus)
	  ○ 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	

8	**New Product to Market: Rezurock™** **Non-prefer in PDL Class:** *Immunosuppressants* • 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-versus-host disease (cGVHD) following failure of ≥ 2 prior lines of systemic therapy. **Criteria for Approval:** **Initial Approval Criteria** • Patient is post-allogeneic 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 • Belumosudil 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 • 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 **Quantity Limit:** 1 per day	**Passed** 10 For 0 Against
9	**New Product to Market: Tyrvaya™** **Non-prefer in 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	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote

	(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
	Quantity Limit: 1 carton (2 bottles)/30 days	

10	**New Product to Market: Skytrofa™** **Non-prefer in PDL Class:** *Growth Hormones* **Length of Authorization:** 1 year • 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	**Passed** 10 For 0 Against
11	**New Product to Market: 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 post-transplant 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**	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	• Patient is a recipient of a hematopoietic stem cell or solid organ transplant; AND • 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	
12	**New Product to Market: 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 disease 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 (progression of disease due to inability to tolerate platinum therapy is acceptable); 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 • 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	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	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 **Quantity Limit:** 4 per day	

13	**New Product to Market: Scemblix®**
	Non-PDL Class: *Oral Oncology*
	Length of Authorization: 1 year
	• Scemblix (asciminib) is a 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
	• 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
	• Patient has been adherent to therapy; AND
	• Patient has had a positive response to treatment
	Age Limit: ≥ 18 years
	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
		Passed
		10 For
		0 Against

14	**New Product to Market: 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	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote

	• 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: AND
	• Patient's oxygen saturation will be monitored prior to initiation of therapy and periodically throughout therapy; AND
	• Patient has not received prior treatment with another HIF-2a inhibitor; AND
	• Will not be used in combination with erythropoiesis stimulating agents (ESAs); AND
	• Patient is not pregnant; AND
	• Females of reproductive potential will use nonhormonal contraception during treatment; OR
	• Males with female partners of reproductive potential will use effective contraception during treatment.
	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
	Quantity Limit: 90 tablets/30 days	

15	**Existing Product in Market: 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; 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 anti-HER2 directed therapies: trastuzumab, pertuzumab, and ado-trastuzumab 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	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	in size of tumor or tumor spread; AND • Absence of unacceptable toxicity from the drug (e.g., hepatotoxicity [severe changes in liver function tests], severe diarrhea). **Quantity Limit:** 120 tablets per 30 days	
16	**Existing Product in Market: Pemazyre™** **Non-PDL Class:** *Oral Oncology* **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 serum phosphate level is measured at baseline and periodically throughout therapy; AND • Therapy will not be used concomitantly with other selective FGFR-inhibitor (e.g., erdafitinib) **Renewal Criteria** • Patient must continue to meet the above criteria; **AND**	**Passed** 10 For 0 Against
17	**Existing Product in Market: Qinlock™** **Non-PDL Class: Oral Oncology** **Length of Authorization: 1 year** • Ripretinib (Qinlock) is a tyrosine kinase inhibitor (TKI) with activity against KIT proto-oncogene 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 must NOT have had a surgical procedure within the preceding 14 days or have a surgical wound that has not fully healed; AND • Patient does NOT have active CNS metastases **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient must demonstrate disease response with treatment as defined by	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	stabilization of disease or decrease in size of tumor or tumor spread; AND • Patient has NOT experienced any treatment-restricting adverse effects; AND • 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 **Quantity Limit:** 90 tablets/30 days	
18	**Antibiotics: Inhaled** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antibiotics: Inhaled* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
19	**Antibiotics: Vaginal** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antibiotics: Vaginal class*, require PA until reviewed by the P&T Advisory Committee	**Passed** 10 For 0 Against
20	**Antiretrovirals: HIV/AIDS** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 first-line treatment regimens should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antiretrovirals: HIV/AIDS* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
21	**Antibiotics: Oxazolidinones** • DMS to select preferred agent(s) based on economic evaluation; however, at least one unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antibiotics: Oxazolidinones* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
22	**Antibiotics: Tetracyclines** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antibiotics: Tetracyclines* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
23	**Intranasal Corticosteroids** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Intranasal Corticosteroids* class, require PA until reviewed by the P&T Advisory Committee	**Passed** 10 For 0 Against

Consent Agenda

For the following therapeutic classes, the P&T Committee had no recommended changes to the currently posted Preferred Drug List (PDL) status.

	Therapeutic Classes	P & T Vote
24	• 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	**Passed** 10 For 0 Against