Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

November 16, 2017

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **November 16, 2017** meeting.

Although the Committee met on November 16, 2017, the necessary quorum was not achieved; however, the expertise, vote and recommendations of the Committee members in attendance were captured and the Committee delivered the unofficial recommendations reflected below for review.

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	**Sedative Hypnotics Maximum Duration Edit Addition** • Preferred sedative hypnotic agents shall be available for up to 60 days' supply per 365-day period without a prior authorization. • For therapy beyond 60 days with any sedative hypnotic agent, with the exception of Hetlioz® (tasimelteon), a prior authorization is required.	**Passed** 4 For 0 Against
2	**New Product to Market: Nerlynx™** Non-prefer in the PDL class: *Oral Oncology Agents, Breast Cancer* **Length of Authorization:** 1 year • Nerlynx™ (neratinib) is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage human epidermal growth factor receptor 2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy. **Criteria for Approval**: • Diagnosis of early stage, human epidermal growth factor receptor 2 (HER2)-positive breast cancer; AND • Previous treatment with Herceptin® (trastuzumab) within the past 2 years. **Age Limit**: ≥ 18 years **Quantity Limit**: 6 tablets per day	**Passed** 4 For 0 Against
3	**Antiemetics & Antivertigo Agents** **Anti-Emetics: Other** • DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA.	**Passed** 4 For 0 Against

	Description of Recommendation	P & T Vote
	• For any new chemical entity in the *Anti-Emetics: Other* class, require PA until reviewed by the P&T Committee. **Oral Anti-Emetics: 5-HT3 Antagonists** • 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 will require PA. • For any new chemical entity in the *Oral Anti-Emetics: 5-HT3 Antagonists* class, require PA until reviewed by the P&T Committee. **Oral Anti-Emetics: Delta-9-THC Derivatives** • 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 will require PA. • For any new chemical entity in the *Oral Anti-Emetics: Delta-9-THC Derivatives* class, require PA until reviewed by the P&T Committee. **New Agent in the Class: Syndros™** Non-prefer in this class. **Length of Authorization:** 6 months • Syndros™ (dronabinol) oral solution is a cannabinoid indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS as well as nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. It is available as a 5 mg/mL oral solution in 30 mL bottles. • NOTE: The DEA has classified Syndros™ as C- II, indicating that this liquid formulation may have a higher potential for addiction, abuse and/or misuse than dronabinol capsules, which are C-III. **Criteria for Approval:** • Clinically valid reason (e.g., feeding tube, swallow study) that dronabinol capsules cannot be used; AND • No history of hypersensitivity to, or abuse of, alcohol; AND • Diagnosis of nausea and vomiting associated with cancer chemotherapy; AND • Have failed to respond adequately to at least 1 other anti-emetic therapy; OR • Diagnosis of anorexia associated with weight loss in a patient with AIDS. **Age Limit**: ≥ 18 years **Quantity Limits**: *AIDS Anorexia*: 3 mL per day *Chemotherapy Nausea and Vomiting*: 8 mL per day **Oral Anti-Emetics: NK-1 Antagonists** • DMS to select preferred agent(s) based on economic evaluation; however, at	

	Description of Recommendation	P & T Vote
	least 1 unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Oral Anti-Emetics: NK-1 Antagonists* class, require PA until reviewed by the P&T Committee.	
4	**Antipsychotics** **First-Generation Antipsychotics** • DMS to select preferred agent(s) based on economic evaluation; however, at least 6 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 *First-Generation Antipsychotics* class, require PA until reviewed by the P&T Committee. **Second-Generation Antipsychotics** • DMS to select preferred agent(s) based on economic evaluation; however, at least 6 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 *Second-Generation Antipsychotics* class, require PA until reviewed by the P&T Committee. **Antipsychotics: Injectable** • DMS to select preferred agent(s) based on economic evaluation; however, at least 4 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 *Antipsychotics: Injectable* class, require PA until reviewed by the P&T Committee. **Atypical Antipsychotic and SSRI Combinations** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Atypical Antipsychotic and SSRI Combinations* class, require PA until reviewed by the P&T Committee.	**Passed** 4 For 0 Against
5	**BPH Agents** **Alpha Blockers for BPH** • 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 *Alpha Blockers for BPH* class, require PA until reviewed by the P&T Committee.	**Passed** 4 For 0 Against

	Description of Recommendation	P & T Vote
	5-Alpha Reductase (5AR) Inhibitors • 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 will require PA. • For any new chemical entity in the *5-Alpha Reductase (5AR) Inhibitors* class, require PA until reviewed by the P&T Committee.	
6	**Immunomodulators** • 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 *Immunomodulators* class, require PA until reviewed by the P&T Committee. **New Agent in the Class: Tremfya™** Non-prefer in this class. **Length of Authorization**: 1 year • Tremfya™ (guselkumab) is a monoclonal antibody that functions as an interleukin-23 (IL-23) antagonist; it is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is available as a 100 mg/mL pre-filled syringe for subcutaneous injection. **Criteria for Approval:** • Diagnosis of moderate to severe plaque psoriasis; AND • Symptoms persistent for ≥ 6 months with at least 1 of the following: o Involvement of at least 10% of body surface area (BSA); OR o Psoriasis Area and Severity Index (PASI) score of 12 or greater; OR o Incapacitation due to plaque location (i.e., head and neck, palms, soles or genitalia); AND • Negative tuberculosis (TB) screening prior to initiating treatment; AND • Trial and failure of **two** of the following therapies: o Methotrexate o Cyclosporine o Oral retinoid (e.g., Soriatane®, acitretin) o Topical corticosteroids o Phototherapy/UV light o Coal tar preparations; AND • Trial and failure of, or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®). **Renewal Criteria:** • Patient continues to meet criteria identified above; AND • Ongoing monitoring for TB; AND • Disease response as indicated by improvement in signs and symptoms compared to baseline, such as redness, thickness, scaliness, and/or the amount of surface area involvement.	**Passed** 4 For 0 Against

	Description of Recommendation	P & T Vote
	Age Limit: ≥18 years **Quantity Limit:** *Loading Dose*: 2 syringes per 56 days *Maintenance Dose*: 1 syringe per 56 days	
7	**H. Pylori Treatment** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *H. Pylori Treatment class*, require PA until reviewed by the P&T Committee.	**Passed** 4 For 0 Against
8	**Hepatitis C Agents** **Hepatitis C: Direct-Acting Antivirals** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 treatment regimen with coverage for each genotype should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Hepatitis C: Direct-Acting Antivirals* class, require PA until reviewed by the P&T Committee. **Clinical Criteria for All Hepatitis C Virus (HCV) Direct-Acting Antiviral (DAA) Requests** For approval of any Hepatitis C virus (HCV) DAA treatment regimen: • Patient must have a diagnosis of chronic Hepatitis C infection; AND • Patient does not have a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy; AND • Patient is NOT pregnant; AND • Treatment must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease provider; AND • Prescribed treatment course and duration must be supported by an FDA-approved indication and/or AASLD HCV treatment guidelines; AND • Must provide documentation of the following clinical data: o Date of Hepatitis C diagnosis or earliest record of HCV infection; AND o Genotype and, if known, subtype; AND o Recent (within 3 months) quantitative HCV RNA level (HCV viral load); AND o HCV treatment status and, if applicable, prior treatment regimen(s); AND o Assessment of liver disease severity (e.g., cirrhosis status) using the Child-Pugh score; AND o Hepatitis B virus (HBV) screening results; AND • If newly diagnosed with Hepatitis C infection within the past year, MUST submit 2 HCV RNA levels taken at least 6 months apart to demonstrate a chronic HCV infection; AND • If a non-preferred regimen is requested, justification as to why a preferred	**Passed** 5 For 0 Against

	Description of Recommendation	P & T Vote

	product cannot be used.
	• Requests for repeat treatment with DAA therapy are subject to additional criteria.
	
	Additional Clinical Criteria for Patients Previously Treated with DAAs.
	
	Requests for repeat DAA therapy will be considered on a case-by-case basis; the following additional criteria shall apply:
	• Prescriber must answer the following questions:
	  o Is retreatment necessary due to treatment failure or reinfection?
	  o Was the patient compliant (e.g., few to no missed doses) with previous DAA therapy? If not, why?
	• Were there any additional factors that led to DAA treatment failure? If so, describe these factors and how they have been addressed or are no longer relevant.
	• Patient must be evaluated for alcohol and substance abuse using a validated screening tool; AND
	• If the patient has a recent history (within the past 6 months) of alcohol or substance abuse, the following is required:
	  o Documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND
	  o Documentation that the patient is not actively participating in illicit substance use or alcohol abuse with confirmatory laboratory testing (e.g., urine drug screen); AND
	• Provider attests that:
	  o Patient is willing and able to comply with the requirements of the proposed retreatment plan; AND
	  o Any factors that may have led to noncompliance with previous treatment(s) have been addressed; AND
	  o Patient has received education regarding risk behaviors (e.g., IV drug use) associated with HCV infection.
	
	Kentucky Medicaid Pharmacy Program Requests the Following Clinical Data as Informational Only
	Requests will not be denied in absence of this information.
	• Fibrosis score via biopsy, elastography (e.g., Fibroscan), ultrasound or laboratory measures.
	  o Note: Patients with fibrosis score F0-F4 are eligible for HCV treatment.
	• HIV infection status and/or screening results.
	• Severe renal impairment (e.g., CrCl <30 mL/min) and dialysis status.
	• Organ transplantation status.	

	Description of Recommendation	P & T Vote
	New Agent in the Class: Mavyret™ Prefer with Clinical Criteria in this class. **Length of Authorization**: Duration of treatment course (8, 12, or 16 weeks) • Mavyret™ (glecaprevir/pibrentasvir) is a fixed-dose combination product containing glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor (PI), and pibrentasvir, an HCV NS5A inhibitor. It is indicated for the treatment of HCV genotypes 1 to 6 in adult patients without cirrhosis or with compensated cirrhosis (Child-Pugh A). It is also indicated to treat HCV in patients who have genotype 1 and have been treated previously with regimens containing either an HCV NS5A inhibitor or an HCV NS3/4A PI, but not both. Mavyret™ is available as tablets for oral administration containing 100 mg glecaprevir and 40 mg pibrentasvir; the recommended dosing is 3 tablets once daily. **Criteria for Approval:** • Diagnosis of chronic hepatitis C virus (HCV) infection; AND • Patient does not have a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy; AND • Patient is NOT pregnant; AND • Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease provider; AND • Must be evaluated for liver disease severity and have no cirrhosis or compensated cirrhosis (Child-Pugh A); AND • Must be screened for Hepatitis B Virus (HBV) infection prior to treatment; AND • Must be prescribed for an FDA-labeled and/or AASLD-recommended treatment course regarding cirrhosis status, genotype, and prior treatment experience. • Requests for repeat treatment are subject to additional criteria. **Age Limit**: ≥18 years **Quantity Limit**: 3 tablets per day **New Agent in the Class: Vosevi™** Prefer with Clinical Criteria in this class. **Length of Authorization**: 12 weeks • Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir), a fixed-dose combination product containing sofosbuvir, a hepatitis C virus (HCV) NS5B polymerase inhibitor, velpatasvir, an HCV NS5A inhibitor, and voxilaprevir, an HCV NS3/4A protease inhibitor, is indicated for the treatment of chronic HCV infection in patients without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have genotypes 1-6 infection and previously received treatment with an NS5A inhibitor, or who have genotype 1a or 3 HCV infection and have been treated previously with sofosbuvir without an NS5A inhibitor. Vosevi™ is available as a fixed-dose combination tablet containing 400 mg sofosbuvir, 100 mg velpatasvir, and 100 mg voxilaprevir; the recommended dosing is 1 tablet daily. **Criteria for Approval:** • Diagnosis of chronic hepatitis C virus (HCV) infection; AND • Patient does not have a short life expectancy that cannot be remediated by	

	Description of Recommendation	P & T Vote
	HCV therapy, liver transplantation, or another directed therapy; AND • Patient is NOT pregnant; AND • Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease provider; AND • Must be evaluated for liver disease severity and have no cirrhosis or compensated cirrhosis (Child-Pugh A); AND • Must be screened for Hepatitis B Virus (HBV) infection prior to treatment; AND • Patient must be evaluated for alcohol and substance abuse using a validated screening tool with appropriate follow up to address addiction as part of HCV treatment; AND • Abstinence from alcohol and illicit substances confirmed by laboratory testing; AND • Treatment-experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir); OR • Genotype 1a or 3 and treatment-experienced with sofosbuvir without an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir). **Age Limit**: ≥18 years **Quantity Limit**: 1 tablet per day **Hepatitis C: Interferons** • 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 will require PA. • For any new chemical entity in the *Hepatitis C: Interferons* class, require PA until reviewed by the P&T Committee. **Hepatitis C: Ribavirins** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 generic version of ribavirin should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Hepatitis C: Ribavirins* class, require PA until reviewed by the P&T Committee.	
9	**Neuropathic Pain** **Anticonvulsants: Second Generation** • 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 will require PA. • For any new chemical entity in the *Anticonvulsants: Second Generation* class, require PA until reviewed by the P&T Committee. **Antidepressants: SNRIs** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.	**Passed** 5 For 0 Against

	Description of Recommendation	P & T Vote
	• Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antidepressants: SNRIs* class, require PA until reviewed by the P&T Committee.	
10	**Oral Oncology Agents, Hematologic Cancer** • DMS to select preferred agent(s) based on economic evaluation; however, at least 6 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 *Oral Oncology, Hematologic Cancer* class, require PA until reviewed by the P&T Committee. **New Agent in the Class: Idhifa®** Non-prefer in this class. **Length of Authorization**: 1 year • Idhifa® (enasidenib) is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2 mutation as detected by an FDA-approved test. It is available as 50 mg and 100 mg tablets for oral administration. **Criteria for Approval**: • Diagnosis of relapsed or refractory acute myeloid leukemia (AML); AND • Presence of an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test; AND • Not pregnant. **Renewal Criteria:** • Continue to meet above criteria; AND • Clinical response or lack of disease progression. **Age Limit**: ≥18 years **Quantity Limit**: 1 tablet per day	**Passed** 5 For 0 Against
11	**Stimulants and Related Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique stimulants and 2 unique non-stimulant 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 *Stimulants and Related Agents* class, require PA until reviewed by the P&T Committee. **New Agent in the Class: Cotempla XR-ODT™** Non-prefer in this class. **Length of Authorization**: 1 year • Cotempla XR-ODT™ (methylphenidate) is a central nervous system stimulant indicated for the treatment of attention deficit hyperactivity disorder in pediatric patients 6 to 17 years of age. It is available as 8.6 mg, 17.3 mg, and 25.9 mg extended-release orally dissolving tablets for oral	**Passed** 5 For 0 Against

	Description of Recommendation	P & T Vote

	administration.
	Criteria for Approval:
	• Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
	  o Allergy to medications not requiring prior approval
	  o Contraindication to or drug-to-drug interaction with medications not requiring prior approval
	  o History of unacceptable/toxic side effects to medications not requiring prior approval
	• The requested non-preferred medication may be approved if both of the following are true:
	  o If there has been a therapeutic failure of at least one preferred medication; AND
	  o The requested medication's corresponding generic (if covered by the state) has been attempted with multiple manufacturers (if available) and failed or is contraindicated.
	Age Limit: ≥6 years AND ≤17 years
	Quantity Limits:
	8.6 mg and 17.3 mg tablets: 1 per day
	25.9 mg tablets: 2 per day
	Maximum Daily Dosage: 51.8 mg
	
	New Agent in the Class: Mydayis™
	Non-prefer in this class.
	Length of Authorization: 1 year
	• Mydayis™ (mixed amphetamine salts) is a central nervous system stimulant indicated for the treatment of attention deficit hyperactivity disorder in patients 13 years of age and older. It is available as 12.5 mg, 25 mg, 37.5 mg, and 50 mg extended-release capsules for oral administration.
	Criteria for Approval:
	• Is there any reason that the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
	  o Allergy to medications not requiring prior approval
	  o Contraindication to or drug-to-drug interaction with medications not requiring prior approval
	  o History of unacceptable/toxic side effects to medications not requiring prior approval
	• The requested non-preferred medication may be approved if both of the following are true:
	  o If there has been a therapeutic failure of at least one preferred medication; AND
	  o The requested medication's corresponding generic (if covered by the state) has been attempted with multiple manufacturers (if available) and failed or is contraindicated.
	Age Limit: ≥13 years
	Quantity Limits: 1 capsule per day
	Maximum Daily Dosage: 50 mg	

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
12	• Antianginal & Anti-Ischemic • Antibiotics, Topical • Anticoagulants • Bronchodilators, Beta-Agonists • Calcium Channel Blockers • Laxatives & Cathartics • Oncology Oral - Other • Ophthalmics, Allergic Conjunctivitis • Ophthalmics, Anti-inflammatories • Ophthalmics, Antibiotic-Steroid Combinations • Ophthalmics, Antibiotics • Ophthalmics, Antivirals • Ophthalmics, Glaucoma • Ophthalmics, Mydriatics • Platelet Aggregation Inhibitors • Proton Pump Inhibitors • Thrombopoiesis Stimulating Proteins	**Passed** 5 For 0 Against

Consent Agenda: Brand/Generic Switches Only

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

	Therapeutic Classes	P & T Vote
13	• Antiarrythmics, Oral • Lipotropics, Other	**Passed** 5 For 0 Against