



# Kentucky Department for Medicaid Services

## Drug Review and Options for Consideration



The following tables list the Agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the **November 16, 2017** meeting of the Pharmacy and Therapeutics Advisory Committee.

Maximum Duration Edit	Options for Consideration
<b>Sedative Hypnotics</b>	<p><b>Committee Recommendation</b></p> <ul style="list-style-type: none"> <li>Institute a maximum duration edit for each agent as stated in the package insert (PI).</li> </ul> <p><b>Recommended Changes:</b> Note: Some labels do not clearly define a duration of use.</p> <p><i>Option 1:</i></p> <ul style="list-style-type: none"> <li>Adopt a standard maximum duration for all agents in the class.</li> <li>Recommended duration edit: 60 days per year</li> </ul> <p><i>Option 2:</i></p> <ul style="list-style-type: none"> <li>Adopt a maximum duration for each sub-class within the class.</li> <li>Recommended duration edits:               <ul style="list-style-type: none"> <li>Benzodiazepines: 30 days per year</li> <li>Non-benzodiazepines: 60 days per year</li> </ul> </li> </ul> <p><i>Option 3:</i></p> <ul style="list-style-type: none"> <li>Adopt a separate maximum duration for each active ingredient based on the PI.</li> <li>See table on next page.</li> </ul>

**Maximum Duration Edit - Sedative Hypnotics**

Generic Name (DEA schedule)	Benzo- diazepine  No/Yes	Brand Name  <i>generics</i>	PDL Status	Paid Claims (10/16- 9/17)	PI Language	Suggested Duration Edit
estazolam (C-IV)	Yes	<i>estazolam</i>	Non-preferred	0	<ul style="list-style-type: none"> <li>“...indicated for the short-term management of insomnia...”</li> <li>“...prolonged administration of estazolam is generally neither necessary nor recommended.”</li> </ul>	14 days
eszopiclone (C-IV)	No	Lunesta®	Non-preferred	0	<ul style="list-style-type: none"> <li>“...indicated for the treatment of insomnia.”</li> <li>“...clinical trials performed in support of efficacy were up to 6 months in duration.”</li> </ul>	180 days
		<i>eszopiclone</i>	Non-preferred	52		
flurazepam (C-IV)	Yes	<i>flurazepam</i>	Non-preferred	11	<ul style="list-style-type: none"> <li>“...effective for at least 28 consecutive nights of drug administration...”</li> <li>“...short-term use is usually sufficient. Prolonged use of hypnotics is usually not indicated and should only be undertaken concomitantly with appropriate evaluation of the patient.”</li> </ul>	30 days
quazepam (C-IV)	Yes	Doral®	Non-preferred	0	<ul style="list-style-type: none"> <li>“...indicated for the treatment of insomnia...”</li> <li>“The sustained effectiveness of DORAL has been established in chronic insomnia in a sleep lab (polysomnographic) study of 28 nights duration...”</li> <li>“prolonged administration of DORAL Tablets is generally not necessary or recommended”</li> </ul>	30 days
ramelteon (N/A)	No	Rozerem®	Non-preferred	26	<ul style="list-style-type: none"> <li>“...indicated for the treatment of insomnia characterized by difficulty with sleep onset.”</li> <li>“...clinical trials performed in support of efficacy were up to 6 months in duration.”</li> </ul>	180 days
suvorexant (C-IV)	No	Belsomra®	Non-preferred	13	<ul style="list-style-type: none"> <li>“...indicated for the treatment of insomnia...”</li> <li>“...3-month placebo-controlled trials...”</li> </ul>	90 days

Maximum Duration Edit - Sedative Hypnotics

Generic Name (DEA schedule)	Benzo-diazepine No/Yes	Brand Name <i>generics</i>	PDL Status	Paid Claims (10/16-9/17)	PI Language	Suggested Duration Edit
temazepam (C-IV)	Yes	Restoril™	Non-preferred	0	<ul style="list-style-type: none"> <li>• "...indicated for the short-term treatment of insomnia (generally 7 to 10 days)."</li> <li>• "...clinical trials performed in support of efficacy were 2 weeks in duration..."</li> </ul>	14 days
		temazepam 15 and 30 mg	Preferred	437		
		temazepam 7.5 and 22.5 mg	Non-preferred	8		
triazolam (C-IV)	Yes	Halcion®	Non-preferred	0	<ul style="list-style-type: none"> <li>• "...indicated for the short-term treatment of insomnia (generally 7–10 days). Use for more than 2–3 weeks requires complete reevaluation of the patient"</li> <li>• "Prescriptions for triazolam should be written for short-term use (7–10 days) and it should not be prescribed in quantities exceeding a 1-month supply."</li> </ul>	14 days
		triazolam	Non-preferred	9		
zaleplon (C-IV)	No	Sonata®	Non-preferred	0	<ul style="list-style-type: none"> <li>• "...indicated for the short-term treatment of insomnia."</li> <li>• "...shown to decrease the time to sleep onset for up to 30 days in controlled clinical studies."</li> <li>• "...clinical trials performed in support of efficacy ranged from a single night to 5 weeks in duration."</li> </ul>	30 days
		zaleplon	Non-preferred	7		
zolpidem (C-IV)	No	Ambien®	Non-preferred	0	<ul style="list-style-type: none"> <li>• "...indicated for the short-term treatment of insomnia..."</li> <li>• "...shown to decrease sleep latency for up to 35 days in controlled clinical studies."</li> <li>• "...clinical trials performed in support of efficacy were 4-5 weeks in duration."</li> </ul>	30 days
		Edluar™	Non-preferred	0		
		Intermezzo®	Non-preferred	0		
		Zolpimist®	Non-preferred	0		
		zolpidem	Preferred	1145		
zolpidem ER (C-IV)	No	Ambien CR®	Non-preferred	10	<ul style="list-style-type: none"> <li>• "...indicated for the treatment of insomnia..."</li> <li>• "...clinical trials performed in support of efficacy were up to 24 weeks in duration."</li> </ul>	180 days
		zolpidem ER	Non-preferred	5		

Single Agent Review	Options for Consideration
New Product to Market: <b>Nerlynx™</b>	Non-prefer in the PDL class: <i>Oral Oncology Agents, Breast Cancer (Oncology, Oral – Breast Cancer)</i> <b>Length of Authorization:</b> 1 year <ul style="list-style-type: none"> <li>• 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.</li> </ul> <b>Criteria for Approval:</b> <ul style="list-style-type: none"> <li>• Diagnosis of early stage, human epidermal growth factor receptor 2 (HER2)-positive breast cancer; AND</li> <li>• Previous treatment with Herceptin® (trastuzumab) within the past 2 years.</li> </ul> <b>Age Limit:</b> ≥ 18 years <b>Quantity Limit:</b> 6 tablets per day

*Note: The following new agents will be reviewed along with their respective classes.*

- Syndros™ – Antiemetics and Antivertigo Agents (Delta-9-THC Derivatives)
- Tremfya™ – Cytokine and CAM Antagonists
- Mavyret™ – Hepatitis C Agents (Direct-Acting Antivirals)
- Vosevi™ – Hepatitis C Agents (Direct-Acting Antivirals)
- Idhifa® – Oncology Oral, Hematologic
- Cotempla XR-ODT™ – Stimulants and Related Agents
- Mydayis™ – Stimulants and Related Agents

Full Class Reviews	Options for Consideration
<p><b>Antiemetics &amp; Antivertigo Agents</b></p> <p><b>(Anti-Emetics: Other, Oral Anti-Emetics: 5-HT3 Antagonists, Oral Anti-Emetics: Delta-9-THC Derivatives, Oral Anti-Emetics: NK-1 Antagonists)</b></p>	<p><b>Anti-Emetics: Other</b></p> <ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>For any new chemical entity in the <i>Anti-Emetics: Other</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b>Oral Anti-Emetics: 5-HT3 Antagonists</b></p> <ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>For any new chemical entity in the <i>Oral Anti-Emetics: 5-HT3 Antagonists</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b>Oral Anti-Emetics: Delta-9-THC Derivatives</b></p> <ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>For any new chemical entity in the <i>Oral Anti-Emetics: Delta-9-THC Derivatives</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b><u>New agent in the class: Syndros™</u></b>  Non-prefer in this class.  <b>Length of Authorization:</b> 6 months</p> <ul style="list-style-type: none"> <li>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.</li> <li>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.</li> </ul> <p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>Clinically valid reason (e.g., feeding tube, swallow study) that dronabinol capsules cannot be used; AND</li> <li>No history of hypersensitivity to, or abuse of, alcohol; AND</li> <li>Diagnosis of nausea and vomiting associated with cancer chemotherapy; AND</li> <li>Have failed to respond adequately to at least 1 other anti-emetic therapy; OR</li> <li>Diagnosis of anorexia associated with weight loss in a patient with AIDS.</li> </ul> <p><b>Age Limit:</b> ≥ 18 years  <b>Quantity Limits:</b>  <i>AIDS Anorexia:</i> 3 mL per day  <i>Chemotherapy Nausea and Vomiting:</i> 8 mL per day</p> <p><b>Oral Anti-Emetics: NK-1 Antagonists</b></p> <ul style="list-style-type: none"> <li>DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.</li> <li>Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>For any new chemical entity in the <i>Oral Anti-Emetics: NK-1 Antagonists</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul>

Full Class Reviews	Options for Consideration
<p><b>Antipsychotics</b></p> <p><b>(First-Generation Antipsychotics, Second-Generation Antipsychotics, Antipsychotics: Injectable, Atypical Antipsychotic and SSRI Combinations)</b></p>	<p><b>First-Generation Antipsychotics</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>First-Generation Antipsychotics</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b>Second-Generation Antipsychotics</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Second-Generation Antipsychotics</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b>Antipsychotics: Injectable</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 4 unique chemical entities should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Antipsychotics: Injectable</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b>Atypical Antipsychotic and SSRI Combinations</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Atypical Antipsychotic and SSRI Combinations</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul>
<p><b>BPH Agents</b></p> <p><b>(Alpha Blockers for BPH, 5-Alpha Reductase (5AR) Inhibitors)</b></p>	<p><b>Alpha Blockers for BPH</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Alpha Blockers for BPH</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b>5-Alpha Reductase (5AR) Inhibitors</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>5-Alpha Reductase (5AR) Inhibitors</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul>

Full Class Reviews	Options for Consideration
<p><b>Cytokine and CAM Antagonists</b></p> <p><b>(Immunomodulators)</b></p>	<p><b>Immunomodulators</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Immunomodulators</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b><u>New agent in the class: Tremfya™</u></b>  Non-prefer in this class.</p> <p><b>Length of Authorization:</b> 1 year</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of moderate to severe plaque psoriasis; AND</li> <li>• Symptoms persistent for ≥ 6 months with at least 1 of the following: <ul style="list-style-type: none"> <li>○ Involvement of at least 10% of body surface area (BSA); OR</li> <li>○ Psoriasis Area and Severity Index (PASI) score of 12 or greater; OR</li> <li>○ Incapacitation due to plaque location (i.e., head and neck, palms, soles or genitalia); AND</li> </ul> </li> <li>• Negative tuberculosis (TB) screening prior to initiating treatment; AND</li> <li>• Trial and failure of <b>two</b> of the following therapies: <ul style="list-style-type: none"> <li>○ Methotrexate</li> <li>○ Cyclosporine</li> <li>○ Oral retinoid (e.g., Soriatane®, acitretin)</li> <li>○ Topical corticosteroids</li> <li>○ Phototherapy/UV light</li> <li>○ Coal tar preparations; AND</li> </ul> </li> <li>• Trial and failure of, or contraindication to, a preferred immunomodulator (i.e., Enbrel® or Humira®).</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>• Patient continues to meet criteria identified above; AND</li> <li>• Ongoing monitoring for TB; AND</li> <li>• 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.</li> </ul> <p><b>Age Limit:</b> ≥18 years</p> <p><b>Quantity Limit:</b>  <i>Loading Dose:</i> 2 syringes per 56 days  <i>Maintenance Dose:</i> 1 syringe per 56 days</p>
<p><b>H. Pylori Treatment</b></p>	<p><b>H. Pylori Treatment</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>H. Pylori Treatment</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul>

Full Class Reviews	Options for Consideration
<p><b>Hepatitis C Agents</b></p> <p><b>(Direct-Acting Antivirals, Interferons, Ribavirins)</b></p>	<p><b>Hepatitis C: Direct-Acting Antivirals</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 treatment regimen with coverage for each genotype should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Hepatitis C: Direct-Acting Antivirals</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b><u>New agent in the class: Mavyret™</u></b>  Prefer with Clinical Criteria in this class.</p> <p><b>Length of Authorization:</b> 8 weeks initial, renewal criteria for 12- and 16-week courses</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>General Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of chronic hepatitis C virus (HCV) infection; AND</li> <li>• Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician; AND</li> <li>• Prescribed for an FDA-labeled and/or AASLD-recommended treatment course regarding cirrhosis status, genotype, and prior treatment experience; AND</li> <li>• No cirrhosis or compensated cirrhosis (Child-Pugh A); AND</li> <li>• Metavir score of F3 or greater; AND/OR</li> <li>• Documentation showing high risk for severe complications; AND</li> <li>• Screening for Hepatitis B Virus (HBV) infection prior to treatment; AND</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>• Not applicable to 8 week regimens</li> <li>• If HCV RNA &lt; 25 IU/mL at treatment week 4, then approve for an additional 4 or 8 weeks of therapy.</li> </ul> <p><b>Age Limit:</b> ≥18 years</p> <p><b>Quantity Limit:</b> 3 tablets per day</p>



Full Class Reviews	Options for Consideration
	<p><b><u>New agent in the class: Vosevi™</u></b>  Prefer with Clinical Criteria in this class.  <b>Length of Authorization:</b> 12 weeks (8 weeks initial with a 4 week renewal)</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>General Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of chronic hepatitis C virus (HCV) infection; AND</li> <li>• Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician; AND</li> <li>• No cirrhosis or compensated cirrhosis (Child-Pugh A); AND</li> <li>• Documentation showing Metavir score of F3 or greater; AND/OR</li> <li>• Documentation showing high risk for severe complications; AND</li> <li>• Screening for Hepatitis B Virus (HBV) infection prior to treatment; AND</li> <li>• Patient must be treatment-experienced with an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir); OR</li> <li>• Patient must be genotype 1a or 3 and treatment-experienced with sofosbuvir without an NS5A inhibitor (e.g., daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir).</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>• If HCV RNA &lt; 25 IU/mL at treatment week 4, then approve for an additional 4 weeks of therapy.</li> </ul> <p><b>Age Limit:</b> ≥18 years  <b>Quantity Limit:</b> 1 tablet per day</p> <p><b>Hepatitis C: Interferons</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Hepatitis C: Interferons</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b>Hepatitis C: Ribavirins</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 generic version of ribavirin should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Hepatitis C: Ribavirins</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul>

Full Class Reviews	Options for Consideration
<p><b>Neuropathic Pain</b></p> <p><b>(Anticonvulsants: Second Generation, Antidepressants: SNRIs)</b></p>	<p><b>Anticonvulsants: Second Generation</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Anticonvulsants: Second Generation</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b>Antidepressants: SNRIs</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Antidepressants: SNRIs</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul>
<p><b>Oncology, Oral – Hematologic</b></p> <p><b>(Oral Oncology Agents, Hematologic Cancer)</b></p>	<p><b>Oral Oncology Agents, Hematologic Cancer</b></p> <ul style="list-style-type: none"> <li>• DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities should be preferred.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Oral Oncology, Hematologic Cancer</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b><u>New agent in the class: Idhifa®</u></b> Non-prefer in this class.</p> <p><b>Length of Authorization:</b> 1 year</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>• Diagnosis of relapsed or refractory acute myeloid leukemia (AML); AND</li> <li>• Presence of an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test; AND</li> <li>• Not pregnant.</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>• Continue to meet above criteria; AND</li> <li>• Clinical response or lack of disease progression.</li> </ul> <p><b>Age Limit:</b> ≥18 years</p> <p><b>Quantity Limit:</b> 1 tablet per day</p>

Full Class Reviews	Options for Consideration
<b>Stimulants and Related Agents</b>	<p><b>Stimulants and Related Agents</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Agents not selected as preferred will be considered non-preferred and will require PA.</li> <li>• For any new chemical entity in the <i>Stimulants and Related Agents</i> class, require PA until reviewed by the P&amp;T Committee.</li> </ul> <p><b><u>New agent in the class: Cotelpla XR-ODT™</u></b>  Non-prefer in this class.</p> <p><b>Length of Authorization:</b> 1 year</p> <ul style="list-style-type: none"> <li>• Cotelpla 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 administration.</li> </ul> <p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>• Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: <ul style="list-style-type: none"> <li>○ Allergy to medications not requiring prior approval</li> <li>○ Contraindication to or drug-to-drug interaction with medications not requiring prior approval</li> <li>○ History of unacceptable/toxic side effects to medications not requiring prior approval</li> </ul> </li> <li>• The requested non-preferred medication may be approved if both of the following are true: <ul style="list-style-type: none"> <li>○ If there has been a therapeutic failure of at least one preferred medication; AND</li> <li>○ The requested medication's corresponding generic (if covered by the state) has been attempted with multiple manufacturers (if available) and failed or is contraindicated.</li> </ul> </li> </ul> <p><b>Age Limit:</b> ≥6 years AND ≤17 years</p> <p><b>Quantity Limits:</b>  8.6 mg and 17.3 mg tablets: 1 per day  25.9 mg tablets: 2 per day</p> <p><b>Maximum Daily Dosage:</b> 51.8 mg</p>

Full Class Reviews	Options for Consideration
	<p><b><u>New agent in the class: Mydayis™</u></b>  Non-prefer in this class.</p> <p><b>Length of Authorization:</b> 1 year</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Criteria for Approval:</b></p> <ul style="list-style-type: none"> <li>• Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: <ul style="list-style-type: none"> <li>○ Allergy to medications not requiring prior approval</li> <li>○ Contraindication to or drug-to-drug interaction with medications not requiring prior approval</li> <li>○ History of unacceptable/toxic side effects to medications not requiring prior approval</li> </ul> </li> <li>• The requested non-preferred medication may be approved if both of the following are true: <ul style="list-style-type: none"> <li>○ If there has been a therapeutic failure of at least one preferred medication; AND</li> <li>○ The requested medication's corresponding generic (if covered by the state) has been attempted with multiple manufacturers (if available) and failed or is contraindicated.</li> </ul> </li> </ul> <p><b>Age Limit:</b> ≥13 years  <b>Quantity Limits:</b> 1 capsule per day  <b>Maximum Daily Dosage:</b> 50 mg</p>

Consent Agenda	Options for Consideration
<p>A. For the following therapeutic classes, there are <b>no recommended changes to the currently posted Preferred Drug List (PDL) status</b>; these may be voted on as a group:</p>	
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
<p>B. The following therapeutic classes have <b>recommended brand/generic switches</b> and may be voted on as a group:</p>	
Antiarrhythmics, Oral	Lipotropics, Other