

Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the November 20, 2014 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
<u>New Products to Market:</u> <u>Adempas[®]</u>	Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension; however, approve riociguat (Adempas [®]) if one of the following is true: <ul style="list-style-type: none"> • Diagnosis of PAH (WHO Group I) after trial and failure of two preferred products; OR • Diagnosis of CTEPH (WHO Group 4) functional class II or III deemed inoperable or with residual PH after undergoing pulmonary endarterectomy.
<u>New Products to Market:</u> <u>Orenitram[™]</u>	Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension.
<u>New Products to Market:</u> <u>Zontivity[™]</u>	Place this product non preferred in the PDL class titled Platelet Inhibitors; however, approve Zontivity [™] for a diagnosis of history of myocardial infarction (MI) or peripheral artery disease (PAD) WITHOUT a history of stroke, transient ischemic attack (TIA), acute coronary syndrome (ACS), gastrointestinal (GI) bleed, or peptic ulcer. Patients must also be taking aspirin and/or clopidogrel concomitantly.
<u>New Products to Market:</u> <u>Velphoro[®]</u>	Place this product non preferred in the PDL class titled Phosphate Binders.
<u>New Products to Market:</u> <u>Tanzeum[™]</u>	Place this product non preferred in the PDL class titled GLP-1 Receptor Agonists.
<u>New Products to Market:</u> <u>Jardiance[®]</u>	Empagliflozin (Jardiance [®]) should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
<u>New Products to Market:</u> <u>Invokamet[™]</u>	Invokamet [™] (canagliflozin/metformin) should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
<u>New Products to Market:</u> <u>Otezla[®]</u>	Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Immunomodulators.
<u>New Products to Market:</u> <u>Entyvio[™]</u>	Place this product non preferred with appropriate quantity limits and similar approval criteria in the PDL class titled Immunomodulators.
<u>New Products to Market:</u> <u>Zohydro ER[™]</u>	Place this product non preferred with appropriate quantity limits in the PDL class titled Narcotics: Long-Acting.

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<p><u>New Products to Market:</u> <u>Evzio™</u></p>	<p>Evzio™ will be limited to 4 auto injectors per prescription and will only be approved in the following circumstances:</p> <ul style="list-style-type: none"> • Patient or care-giver is administering medication outside of a healthcare facility (such as a personal residence or school); AND • Patient or active care-giver is unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension; AND • The prescriber has completed and submitted with the prior approval request the Opioid Overdose Risk Assessment Checklist Form. The form can be found at: http://evzio.com/pdfs/Evzio-Opioid-Overdose-Risk-Assessment-Checklist.pdf; AND • If the diagnosis is substance abuse, dependence and/or addiction, the patient is receiving addiction counseling services; such as psychosocial therapy from a Substance Abuse provider. Documentation must be provided to include provider name, type of provider, and provider phone number.
<p><u>New Products to Market:</u> <u>Aptiom®</u></p>	<p>Place this product non preferred in the PDL class titled Anticonvulsants: Carbamazepine Derivatives.</p>
<p><u>New Products to Market:</u> <u>Hetlioz®</u></p>	<p>Place this product non preferred with appropriate quantity limits in the PDL class titled Sedative Hypnotics; however, only approve tasimelteon (Hetlioz®) for a diagnosis of Non-24-hour sleep-wake disorder (“non-24”) in patients who are totally blind.</p>
<p><u>New Products to Market:</u> <u>Anoro™ Ellipta™</u></p>	<p>Place this product non preferred with similar quantity limits in the PDL class titled COPD Agents; however, approve Anoro™ Ellipta™ for a diagnosis of COPD after trial and failure of an inhaled long-acting bronchodilator (a LABA or an anticholinergic).</p>
<p><u>New Products to Market:</u> <u>Striverdi® Respimat®</u></p>	<p>Place this product non preferred with similar quantity limits in the PDL class titled Long-Acting Beta Agonists.</p>
<p><u>New Products to Market:</u> <u>Sivextro™</u></p>	<p>Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Oxazolidinones.</p>
<p><u>New Products to Market:</u> <u>Luzu®</u></p>	<p>Place this product non preferred in the PDL class titled Topical Antifungal Agents.</p>
<p><u>New Products to Market:</u> <u>Jublia®</u></p>	<p>Place this product non preferred in the PDL class titled Topical Antifungal Agents; however, only approve efinaconazole (Jublia®) for a diagnosis of toenail onychomycosis after trial and failure of one other agent indicated for the treatment of onychomycosis.</p>

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<p><u>New Products to Market:</u> <u>Rasuvo™</u></p>	<p>Rasuvo™ (methotrexate) will only be approved for the following diagnoses:</p> <ul style="list-style-type: none"> • Rheumatoid arthritis (RA) after trial and failure of: <ul style="list-style-type: none"> ○ NSAID; and ○ Corticosteroid; and ○ Oral methotrexate; OR • Polyarticular juvenile idiopathic arthritis (pJIA) after trial and failure of: <ul style="list-style-type: none"> ○ NSAID; and ○ Corticosteroid; and ○ Oral methotrexate; OR • Psoriasis after trial and failure of: <ul style="list-style-type: none"> ○ Topical agents for the treatment of psoriasis (e.g., emollients, corticosteroids, retinoids, vitamin D analogs, and/or topical tacrolimus, pimecrolimus); AND ○ Oral methotrexate.
<p><u>New Products to Market:</u> <u>Zykadia™</u></p>	<p>Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology, Lung Cancer.</p>
<p><u>New Products to Market:</u> <u>Zydelig®</u></p>	<p>Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology, Hematologic Cancer; however, only approve idelalisib (Zydelig®) for one of the following diagnoses:</p> <ul style="list-style-type: none"> • Chronic lymphocytic leukemia (CLL), in combination with rituximab; OR • Follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies; OR • Small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.
<p><u>Omalizumab (Xolair®)</u> <u>Clinical Criteria</u></p>	<p>Initial Therapy (6 months): Xolair® (omalizumab) will be approved initially for the following diagnoses:</p> <ul style="list-style-type: none"> • Moderate to severe asthma (step 5 or higher) if ALL of the following are true: <ul style="list-style-type: none"> ○ 12 years of age or older; AND ○ Positive skin test or in vitro reactivity to a perennial aeroallergen; AND ○ FEV1 of <80% while on asthma controller medication; AND ○ Has had failure of or contraindication to inhaled corticosteroid in combination with a second controller agent (such as a long-acting inhaled beta2-agonist, ipratropium, leukotriene modifier, or theophylline) for a 60-day trial. • Chronic idiopathic urticaria if ALL of the following are true: <ul style="list-style-type: none"> ○ 12 years of age or older; AND ○ The underlying cause of the patient’s condition has been ruled out and is NOT considered to be any other allergic condition(s) or other form(s) of urticaria; AND ○ One of the following: <ul style="list-style-type: none"> ▪ 3-month trial and failure of two (2) H1 antihistamines at maximally tolerated doses and patient has documented ongoing symptoms of chronic idiopathic urticaria; or ▪ 3-month trial and failure of one antihistamine products and one (1) of

	<p>the following leukotriene antagonists: montelukast OR zafirlukast and patient has documented ongoing symptoms of chronic idiopathic urticaria; AND</p> <ul style="list-style-type: none"> ○ A baseline urticaria activity score (UAS7) is required before approval. Renewals will require submission of a new UAS7 (within previous 30 days of renewal). <p>Continuation of Therapy: Xolair[®] (omalizumab) will be approved for continuation of therapy for the following diagnoses:</p> <ul style="list-style-type: none"> ● Moderate to severe asthma (step 5 or higher) if one of the following is true: <ul style="list-style-type: none"> ○ During previous treatment with omalizumab, the patient experienced a reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-omalizumab baseline, OR ○ The patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of omalizumab and the patient has been able to reduce their oral corticosteroid dose to less than their pre-omalizumab baseline or to ≤ 5 mg daily, OR ○ The patient was receiving maintenance therapy with an inhaled corticosteroid prior to initiation of omalizumab and the patient has been able to reduce their inhaled corticosteroid dose to less than their pre-omalizumab baseline. ● Chronic idiopathic urticaria if ALL of the following are true: <ul style="list-style-type: none"> ○ Treatment with omalizumab has resulted in clinical improvement as documented by improvement (decrease) in urticaria activity score (UAS7) from baseline; AND ○ Submitted current UAS7 was recorded within the past 30 days.
<p><u>Oral Oncology, Lung Cancer</u></p>	<ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology, Lung Cancer class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
<p align="center"><u>Oral Oncology, Renal Cell Carcinoma</u></p>	<ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology, Renal Cell Carcinoma class, require a PA until reviewed by the P&T Advisory Committee.
<p align="center"><u>Oral Oncology, Breast Cancer</u></p>	<ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least tamoxifen and one Aromatase Inhibitor should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology, Breast Cancer class, require a PA until reviewed by the P&T Advisory Committee.
<p align="center"><u>Oral Oncology, Prostate Cancer</u></p>	<ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology, Prostate Cancer class, require a PA until reviewed by the P&T Advisory Committee.
<p align="center"><u>Oral Oncology, Hematologic Cancer</u></p>	<ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. Due to new data on the treatment of CML, both imatinib and EITHER dasatinib OR nilotinib should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology, Hematologic Cancer class, require a PA until reviewed by the P&T Advisory Committee.

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<u>Oral Oncology, Other</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology, Other class, require a PA until reviewed by the P&T Advisory Committee.
<u>ACE Inhibitors</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the ACE Inhibitor class, require a PA until reviewed by the P&T Advisory Committee.
<u>ACEI + Diuretic Combinations</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the ACEI + Diuretic Combination class, require a PA until reviewed by the P&T Advisory Committee.
<u>Angiotensin Receptor Blockers</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Angiotensin Receptor Blockers class, require a PA until reviewed by the P&T Advisory Committee.
<u>ARB + Diuretic Combinations</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the ARB + Diuretic Combinations class, require a PA until reviewed by the P&T Advisory Committee.
<u>Direct Renin Inhibitors</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and require prior authorization. 3. For any new chemical entity in the Direct Renin Inhibitors Class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
<u>Direct Renin Inhibitors Clinical Criteria</u>	Direct Renin Inhibitors will be approved after trial and failure of either of the following: <ul style="list-style-type: none"> • Angiotensin converting enzyme (ACE) inhibitor; OR • Angiotensin II receptor blocker (ARB).
<u>Calcium Channel Blockers (DHP)</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be amlodipine, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Calcium Channel Blockers (DHP) class, require a PA until reviewed by the P&T Advisory Committee.
<u>Calcium Channel Blockers (Non-DHP)</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Calcium Channel Blockers (Non-DHP) class, require a PA until reviewed by the P&T Advisory Committee.
<u>Angiotensin Modulator + CCB Combinations</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Angiotensin Modulator + CCB Combinations class, require a PA until reviewed by the P&T Advisory Committee.
<u>Angiotensin Modulator + CCB Combinations Clinical Criteria</u>	Angiotensin Modulator + CCB Combinations will be approved after trial and failure of either of the following: <ul style="list-style-type: none"> • Angiotensin converting enzyme (ACE) inhibitor; OR • Angiotensin II receptor blocker (ARB).
<u>Beta Blockers</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. At least one non-selective and at least two cardioselective beta blockers should be preferred on the PDL. Included among the preferred products should be metoprolol succinate, metoprolol tartrate, and a short-acting and a long-acting propranolol product. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Beta Blockers class, require a PA until reviewed by the P&T Advisory Committee.
<u>Beta Blocker + Diuretic Combinations</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three combination products, one of which is atenolol/chlorthalidone, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Beta Blocker + Diuretic Combinations class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
<u>Alpha/Beta Blockers</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least carvedilol should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Alpha/Beta Blockers class, require a PA until reviewed by the P&T Advisory Committee.
<u>Statins</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one agent representing each of the treatment intensity levels (high-intensity, moderate-intensity and lower-intensity) should be preferred. 2. Continue quantity limits on agents in this class based on maximum recommended dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Statins class, require a PA until reviewed by the P&T Advisory Committee.
<u>Fibric Acid Derivatives</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one fenofibrate product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Fibric Acid Derivatives class, require a PA until reviewed by the P&T Advisory Committee.
<u>Niacin Derivatives</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Niacin Derivatives class, require PA until reviewed by the P&T Advisory Committee.
<u>Bile Acid Sequestrants</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least cholestyramine should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Bile Acid Sequestrants class, require a PA until reviewed by the P&T Advisory Committee.
<u>Cholesterol Absorption Inhibitor</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Cholesterol Absorption Inhibitor class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
<u>Omega-3 Fatty Acids</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Omega-3 Fatty Acids class, require a PA until reviewed by the P&T Advisory Committee.
<u>Omega-3 Fatty Acids Clinical Criteria</u>	<p>Omega-3 Fatty Acids will be approved after trial and failure of either of the following:</p> <ul style="list-style-type: none"> • Fibric acid derivative; OR • Statin.
<u>Apolipoprotein B Synthesis Inhibitors</u>	<ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Apolipoprotein B Synthesis Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.
<u>Apolipoprotein B Synthesis Inhibitors Clinical Criteria</u>	<p>Approval of Apolipoprotein B Synthesis Inhibitors will be granted as described below.</p> <ul style="list-style-type: none"> • For initial treatment, approve for 6 months if ALL of the following are true: <ul style="list-style-type: none"> ○ Diagnosis of homozygous familial hypercholesterolemia (HoFH) with untreated total cholesterol (TC) >500 mg/dL; AND ○ Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; AND ○ Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; AND ○ Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; AND ○ Patient tried and failed at least a 3 month trial of the maximally tolerated dose with two (2) of the following statins: simvastatin 40mg (Zocor[®]), atorvastatin 80mg (Lipitor[®]) OR rosuvastatin 40mg (Crestor[®]), unless contraindicated; AND ○ Patient tried and failed at least a 3 month trial combination with both ezetimibe 10mg (Zetia[®]) AND atorvastatin 80mg (Lipitor[®]) OR simvastatin 40mg (Zocor[®]), unless contraindicated; AND ○ Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol \geq 300 mg/dL (or non-HDL cholesterol \geq 330 mg/dL). • For continuation of treatment, approve for one year if ALL of the following are true: <ul style="list-style-type: none"> ○ Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) from baseline; AND

	<ul style="list-style-type: none">○ Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); AND○ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, serious injection site reactions, and flu-like symptoms.
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