Kentucky Department for Medicaid Services

Drug Review Options

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

Item	Options for Consideration
New Products to Market: Imbruvica™	Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Imbruvica™ for a diagnosis of mantel cell lymphoma (MCL).
New Products to Market: Farxiga®	Dapagliflozin (Farxiga®) should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
New Products to Market: Brisdelle™	Place this product non preferred in the PDL class titled SSRIs; however, Brisdelle™ (paroxetine capsules) should only be approved for patients meeting ALL of the following criteria: • Diagnosis of moderate to severe vasomotor symptoms in a post-menopausal woman; AND • Trial and failure or contraindication to ONE of the following: o Hormonal therapy (Examples: Premarin, Menest, Estrace, Prempro, Premphase, etc.); or o Other antidepressants-venlafaxine, other formulations of paroxetine, and other SSRIs.
New Products to Market: Brintellix™	Place this product non preferred in the PDL class titled Antidepressants, Other.
New Products to Market: Fetzima™	Place this product non preferred in the PDL class titled Antidepressants: SNRIs
New Products to Market: Fycompa™	Place this product non preferred in the PDL class titled Anticonvulsants: Second Generation.
New Products to Market: Adempas®	Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension; however, approve riociguat (Adempas®) if the following are true: • 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.
New Products to Market: Opsumit®	Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension.
New Products to Market: Aerospan™	Place this product non preferred with similar quantity limits in the PDL class titled Corticosteroids, Inhaled.
New Products to Market: Mirvaso®	Place this product non preferred in the PDL class titled Topical Acne Agents; however, approve for a diagnosis of persistent rosacea.

Item	Options for Consideration
New Products to Market: Olysio™	Place this product preferred with appropriate quantity and duration limits in the PDL class titled Hepatitis C: Oral Protease Inhibitors. Approve simeprevir initially for 8 weeks of therapy if ALL of the following are true: • Diagnosis of hepatitis C virus (HCV) with genotype 1; AND • Patient CANNOT have failed therapy with an oral protease inhibitor indicated for HCV (e.g., Incivek®, Victrelis®, or Olysio™); AND • Must have concurrent (or planning to start) therapy with ribavirin and peginterferon when starting simeprevir; AND • Must be an adult patient age 18 and over; AND • Patient has NOT had liver transplant; AND • Patient is NOT infected with HCV genotype 1a containing the Q80K polymorphism; AND • Patient is NOT co-infected with HCV/HIV; AND • Patient is NOT receiving concomitant therapy with sofosbuvir (Sovaldi™). After 8 weeks of therapy, approve simeprevir, peginterferon alfa and ribavirin for 4 additional weeks of therapy if HCV-RNA is less than 25 IU/mL at treatment week 4. After 8 weeks of therapy, discontinue simeprevir, peginterferon alfa, and ribavirin if HCV-RNA is greater than or equal to 25 IU/mL at treatment week 4.
New Products to Market: Sovaldi™	Place this product preferred with appropriate quantity and duration limits in a new PDL class titled Hepatitis C: NS5B Polymerase Inhibitors; however, only approve sofosbuvir in the following instances: • For diagnosis of HCV with genotype 1 [Triple therapy] Combination with peginterferon and ribavirin – Approval for 12 weeks o Approve; **OR** o Approve for HCV/HIV-1 co-infection; **OR** o Approve for patients with compensated cirrhosis, including those with hepatocellular carcinoma. o Must have concurrent (or planning to start) therapy with ribavirin and peginterferon when starting sofosbuvir for a 12 week duration. • For diagnosis of HCV with genotype 1 [Dual therapy] Combination with ribavirin in patients who are interferon ineligible– Approval for 24 weeks o Approve; **OR** o Approve for HCV/HIV-1 co-infection; **OR** o Approve for patients with compensated cirrhosis, including those with hepatocellular carcinoma. o Must be used in combination with ribavirin therapy. • For diagnosis of HCV with genotype 2 [Dual therapy] Combination with ribavirin – Approval for 12 weeks o Approve; **OR** o Approve for HCV/HIV-1 co-infection; **OR** o Approve for patients with compensated cirrhosis, including those with hepatocellular carcinoma. o Must have concurrent (or planning to start) therapy with ribavirin when starting sofosbuvir for a 12 week duration.

	• For diagnosis of HCV with genotype 3 [Dual therapy] Combination with ribavirin – Approval for 24 weeks o Approve; **OR** o Approve for HCV/HIV-1 co-infection; **OR** o Approve for patients with compensated cirrhosis, including those with hepatocellular carcinoma. o Must have concurrent (or planning to start) therapy with ribavirin when starting sofosbuvir for a 24 week duration • For diagnosis of HCV with genotype 4 [Triple therapy] Combination with peginterferon and ribavirin – Approval for 12 weeks o Approve; **OR** o Approve for HCV/HIV-1 co-infection; **OR** o Approve for patients with compensated cirrhosis, including those with hepatocellular carcinoma. o Must have concurrent (or planning to start) therapy with ribavirin and peginterferon when starting sofosbuvir for a 12 week duration • For diagnosis of hepatocellular carcinoma awaiting liver transplantation [Dual therapy] Combination with ribavirin – Approval for 48 weeks or until the time of liver transplantation, whichever occurs first o Approve in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria, and awaiting liver transplantation ▪ Milan criteria defined as: o The presence of a tumor 5 cm or less in diameter in subjects with single hepatocellular carcinoma; **AND** o No more than three tumor nodules, each 3 cm or less in diameter, in subjects with multiple tumors; **AND** o No extrahepatic manifestations of the cancer and no evidence of vascular invasion of the tumor. o Must have concurrent (or planning to start) therapy with ribavirin when starting sofosbuvir for a 48 week duration or until the time of liver transplantation, whichever occurs first.
<u>Injectable Insulins</u>	1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one insulin per class (bolus, basal, premixed, rapid-acting, biphasic, and long-acting) 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 Injectable Insulins class, require a PA until reviewed by the P & T Advisory Committee.

Item	Options for Consideration
Insulin Pen/Cartridge Clinical Criteria	Non-Preferred Insulin Pens/Cartridges will be approved after trial and failure of one preferred insulin pen/cartridge belonging to the same insulin class (bolus, basal, premixed, rapid-acting, biphasic, and long-acting) if any one of the following is true: • Patient is 15 years of age and under; OR • Patient or active care-giver is unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension.
Amylin Analogue	1. DMS to select preferred agent (s) based on economic evaluation. 2. Allow for use of pramlintide with active insulin therapy only. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Amylin Analogue class, require a PA until reviewed by the P&T Advisory Committee.
Amylin Analogue Clinical Criteria	Pramlintide (Symlin®) will be approved if insulin is seen in history within the past 90 days.
GLP-1 Receptor Agonists	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Continue to require PA for all agents in this class to ensure appropriate utilization. 3. For any new chemical entity in the GLP-1 Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee.
GLP-1 Receptor Agonists Clinical Criteria	GLP-1 Receptor Agonists will be approved if metformin, a sulfonylurea, insulin, a DPP-4 Inhibitor, or a TZD is seen in history within the past 90 days.
Alpha-Glucosidase Inhibitors	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 Alpha-Glucosidase Inhibitor class, require a PA until reviewed by the P&T Advisory Committee.
Meglitinides	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one single entity agent 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 Meglitinides class, require a PA until reviewed by the P&T Advisory Committee.
Sulfonylureas	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique second generation sulfonylureas 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 Sulfonylureas class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Androgenic Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one topical formulation of testosterone 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 Androgenic Agents class, require a PA until reviewed by the P&T Advisory Committee.
Erythropoiesis Stimulating Proteins	1. DMS to select preferred agent (s) based upon economic evaluation. 2. All erythropoiesis stimulating agents should require Prior Authorization. 3. For any agent not selected as preferred, DMS should allow continuation of therapy if there is a paid claim in the past 90 days. 4. For any new chemical entity in the Erythropoiesis Stimulating Proteins class, require a PA until reviewed by the PTAC.
Erythropoiesis Stimulating Proteins Clinical Criteria	Erythropoiesis stimulating agents should be approved for recipients meeting one of the following criteria: • The patient has a hemoglobin of less than 12 g/dL **AND one** of the following diagnoses: o Anemia associated with chronic renal failure **OR** anemia associated with kidney transplantation; **OR** o Treatment of chemotherapy induced anemia for non-myeloid malignancies; **OR** o Drug-induced anemia (examples, not all inclusive: Retrovir® **or** Combivir® **or** ribavirin); **OR** o Autologous blood donations by patients scheduled to undergo nonvascular surgery.
Thrombopoiesis Stimulating Proteins	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one product indicated for the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) and one product indicated for the prevention of severe thrombocytopenia and the reduction of platelet transfusions following myelosuppressive chemotherapy should be preferred. 2. All agents in this class should require PA to ensure appropriate utilization. 3. For any new chemical entity in the Thrombopoiesis Stimulating Proteins class, require a PA until reviewed by the P&T Advisory Committee.
Thrombopoiesis Stimulating Proteins Clinical Criteria	• Promacta® will be approved for a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) OR for the treatment of thrombocytopenia in patients with chronic hepatitis C. • Nplate™ will be approved for a diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP). • Neumega® will be approved for a diagnosis of severe thrombocytopenia following myelosuppressive chemotherapy.

Item	Options for Consideration
Antihyperuricemics	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 Antihyperuricemics class, require a PA until reviewed by the P&T Advisory Committee.
Febuxostat Clinical Criteria	Febuxostat (Uloric®) will be approved after and adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6mg/dL OR intolerance OR contraindication to allopurinol.
Colchicine Clinical Criteria	Colchicine (Colcrys™) will be approved if any one of the following is true: • Diagnosis of Familial Mediterranean Fever; OR • Trial and failure of one of the following: o NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen) or o Corticosteroid.
Phosphate Binders	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be a calcium based phosphate binder, 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 Phosphate Binders class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Antivirals	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity in a self administrable dosage form 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 Ophthalmic Antivirals class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Antifungals	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 Ophthalmic Antifungals class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Quinolones	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which is a fourth generation agent, 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 Ophthalmic Antibiotics, Quinolones class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Ophthalmic Macrolides	1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one ophthalmic macrolide should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Ophthalmic Macrolide class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Antibiotics, Non-Quinolones	1. DMS to select preferred agent (s) based on economic evaluation; however, at least four 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 Ophthalmic Antibiotics, Non-Quinolones class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Antibiotic-Steroid Combinations	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 Ophthalmic Antibiotics-Steroid Combinations class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Vasoconstrictors	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 Ophthalmic Vasoconstrictors class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Antihistamines	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 Ophthalmic Antihistamines class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Mast Cell Stabilizers	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 Ophthalmic Mast Cell Stabilizers class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Ophthalmic Anti-Inflammatory Steroids	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 Ophthalmic Anti-inflammatory Steroids class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic NSAIDs	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 Ophthalmic NSAIDs class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Carbonic Anhydrase Inhibitors	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 Ophthalmic Carbonic Anhydrase Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Prostaglandin Analogs	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. Continue current quantity limits on agents in this class. 4. For any new chemical entity in the Ophthalmic Prostaglandin Analogs class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Glaucoma Direct Acting Miotics	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 Ophthalmic Glaucoma Direct Acting Miotics class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Sympathomimetics	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 Ophthalmic Sympathomimetics class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Ophthalmic Combinations for Glaucoma	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one combination product containing an ophthalmic beta-agonist 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 Ophthalmic Combinations for Glaucoma class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Immunomodulator	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 Ophthalmic Immunomodulator class, require a PA until reviewed by the P&T Advisory Committee.
Cyclosporine Ophthalmic Clinical Criteria	Cyclosporine ophthalmic 0.05% emulsion (Restasis®) will be approved if one of the following is true: • Patient is status-post corneal transplant; **OR** • Patient has tried/failed polyvinyl alcohol (Artificial Tears) in the past 90 days.
Ophthalmic Mydriatics & Mydriatic Combinations	1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be atropine, 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 Ophthalmic Mydriatics & Mydriatic Combos class, require a PA until reviewed by the P&T Advisory Committee.