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 21, 2013 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
New Products to Market: Gilotrif™	Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Gilotrif™ for a diagnosis of metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions or exon 21 (L858R) substitution mutations, which have been detected by an FDA-approved test.
Lipotropics, Statins	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. Continue current quantity limits on agents in the class. 4. For any new chemical entity in the Lipotropics, Statins class, require a PA until reviewed by the P&T Advisory Committee.
Bile Acid Sequestrants	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 Bile Acid Sequestrants class, require a PA until reviewed by the P&T Advisory Committee.
Beta Blockers	1. DMS to select preferred agent (s) based on economic evaluation. At least two non-selective beta blockers, at least one with ISA, should be preferred on the PDL. At least two cardioselective beta blockers, one of which should be metoprolol succinate, should be preferred on the PDL. 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.
Beta Blocker + Diuretic	1. DMS to select preferred agent (s) based on economic evaluation; however, at least three combination products 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 class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Calcium Channel Blockers (DHP)	1. DMS to select preferred agent (s) based on economic evaluation; however, at least three 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 Blocker (DHP) class, require a PA until reviewed by the P&T Advisory Committee.
Ophthalmic Beta Blockers	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 Beta Blockers class, require a PA until reviewed by the P&T Advisory Committee.
Long-Acting Beta$_2$ Adrenergic Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity available in a metered dose inhaler should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Continue quantity limits on agents in this class. 4. For any new chemical entity in the Long-Acting Beta$_2$ Adrenergic Agents class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics, Metformins	1. DMS to select preferred agent (s) based on economic evaluation; however, at least metformin 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 Hypoglycemics, Metformins class, require a PA until reviewed by the P&T Advisory Committee.
Bone Resorption Suppression and Related Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least alendronate, calcitonin-salmon and raloxifene should be preferred on the PDL. Additionally, at least one bisphosphonate with a once-weekly dosing formulation should be preferred on the PDL 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Bone Resorption Suppression and Related Agents class, require a PA until reviewed by the P&T Advisory Committee.
***H. pylori* Treatment**	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent containing a Proton Pump Inhibitor (PPI), clarithromycin and either amoxicillin or metronidazole should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Agents in this class should have quantity limits based on the FDA-approved maximum dose. 4. For any new chemical entity in the *H. pylori* Treatment class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Oral Antifungals	1. DMS to select preferred agent(s) based on economic evaluation; however, at least fluconazole, griseofulvin, nystatin and terbinafine 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 Oral Antifungal class, require a PA until reviewed by the P&T Advisory Committee.
Itraconazole Clinical Criteria	Diagnoses to approve itraconazole: • Tinea corporis (body ringworm), Tinea cruris (jock itch), or Tinea pedis (athlete's foot): o If the patient has NOT had a therapeutic failure on at least one topical antifungal medication, approve after trial and failure of a topical antifungal medication. o If the patient has had a failure on at least one topical antifungal medication, approve: itraconazole capsules for once daily dosing for a 4-week continuous course of therapy. • Patient can receive itraconazole automatically if diagnosis is Tinea Capitis for up to 4 weeks • Onychomycosis (fungal infection of the fingernails or toenails): For the initial treatment of a fingernail or toenail infection (rather than continuation of therapy or retreatment) AND ALSO for retreatment if there has been an interval of 3 months between the initial treatment of fingernail infection and a second treatment or an interval of 6 months between the initial treatment of toenail infection and a second treatment: o Fingernail Infection: Approve: itraconazole capsules for twice daily dosing for an 8-week continuous course of therapy. o Toenail Infection: Approve: itraconazole capsules for once daily dosing for a 12-week continuous course of therapy. • For the treatment of a systemic or other serious fungal infection (e.g., esophageal candidiasis, blastomycosis, aspergillosis, cutaneous sporotrichosis), approve the requested quantity for 6 months.
Antivirals, Herpes	1. DMS to select preferred agent (s) based on economic evaluation; however, at least acyclovir and either valacyclovir or famciclovir 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 Antivirals, Herpes class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Antivirals, Flu	1. DMS to select preferred agent (s) based on economic evaluation; however, at least amantadine, oseltamivir, and zanamivir should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. DMS to consider CDC recommendation updates regarding antiviral therapy for the treatment of influenza. The Medical Director, with Commissioner approval, may make changes to the PDL listing based on the CDC recommendations until this class can be considered at the next scheduled review. 4. For any new chemical entity in the Antivirals, Flu class, require a PA until reviewed by the P&T Advisory Committee.
Sulfonamides, Folate Antagonists	1. DMS to select preferred agent (s) based on economic evaluation; however, at least trimethoprim/sulfamethoxazole 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 Sulfonamides, Folate Antagonist class, require a PA until reviewed by the P&T Advisory Committee.
Hepatitis B Agents	1. DMS to select preferred agent (s) based on economic evaluation; however, at least entecavir and lamivudine 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 Hepatitis B Agents class, require a PA until reviewed by the P&T Advisory Committee.
Hepatitis C: Interferons	1. DMS to select preferred agent (s) based on economic evaluation; however, at least peginterferon alfa should be preferred. 2. Agents not selected as preferred will be considered non preferred. 3. PDL selected agents will apply for any new courses of therapy only. 4. Place clinical prior authorization around the entire class to ensure appropriate utilization. 5. Continue current quantity limits based on maximum approved dose. 6. For any new chemical entity in the Hepatitis C: Interferons class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration

Hepatitis C: Interferon Clinical Criteria	**Treatment Naive Patients:**
	After the initial 18 weeks of therapy, interferons will be approved for a diagnosis of Hepatitis C if there is an Early Virologic Response. Early Virologic Response will be defied as either undetectable HCV RNA (<50 IU/mL) or at least a 2 logarithmic drop in HCV RNA levels from baseline at treatment week 12. Limitations on length of therapy is based on product and specific diagnosis:
	• Interferon alfacon-1
	  ○ INF naïve – 24 weeks total therapy
	  ○ INF relapse – 48 weeks total therapy
	• Peginterferon alfa-2a OR 2b
	  ○ Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy
	  ○ Genotype 2, 3 – 24 weeks total therapy
	Previously Treated or Relapsed Patients:
	Interferon therapy will only be approved in patients who have previously been treated if:
	• An Early Virologic Response was determined during the previous treatment course; OR
	• Patient was a partial or null responder to treatment with dual therapy consisting of interferon and ribavirin and
	  ○ Patient has diagnosis of genotype 1 Hepatitis C; and
	  ○ The prescriber feels that triple therapy may solicit a response.
	Limitations on length of therapy are based on product and specific diagnosis:
	• Interferon alfacon-1
	  ○ INF naïve – 24 weeks total therapy
	  ○ INF relapse – 48 weeks total therapy
	• Peginterferon alfa-2a OR 2b
	  ○ Genotype 1, 4, age 2-17 years, OR HIV positive – 48 weeks total therapy
	  ○ Genotype 2, 3 – 24 weeks total therapy

Hepatitis C: Oral Protease 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. 3. PDL selected agents will apply for any new courses of therapy only. 4. Place clinical prior authorization around the entire class to ensure appropriate utilization. 5. Continue quantity and duration limitations based on approved maximum dose and duration. 6. For any new chemical entity in the Hepatitis C: Oral Protease Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Hepatitis C: Oral Protease Inhibitors Clinical Criteria	Boceprevir (Victrelis™) will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection after the patient has received 4 weeks of ribavirin and peginterferon therapy if the patient is receiving concurrent therapy with ribavirin and peginterferon. Telaprevir (Incivek™) will be approved for a diagnosis of hepatitis C (CHC) genotype 1 infection if the patient is receiving concurrent therapy with ribavirin and peginterferon. Quantity and Duration Limits: • Incivek™: 6 per day; 1 course of oral protease inhibitor therapy per lifetime • Victrelis™: 12 per day; 1 course of oral protease inhibitor therapy per lifetime
Hepatitis C: Ribavirins	1. DMS to select preferred agent (s) based on economic evaluation; however, at least ribavirin should be preferred. 2. Agents not selected as preferred will be considered non preferred. 3. Place clinical prior authorization around the entire class of ribavirins to ensure appropriate utilization. 4. For any new chemical entity in the Hepatitis C: Ribavirins class, require a PA until reviewed by the P&T Advisory Committee.
Hepatitis C: Ribavirins Clinical Criteria	Ribavirins will pay at point-of-sale if there is concurrent interferon therapy in history.
Progestins for Cachexia	1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one unique chemical entity must 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 Progestins for Cachexia class, require a PA until reviewed by the P&T Advisory Committee.
Pancreatic Enzymes	1. DMS to select preferred agent (s) based on economic evaluation; however, at least one pancreatic enzyme 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 Pancreatic Enzyme class, require a PA until reviewed by the P&T Advisory Committee.
Topical Immunomodulators	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 Topical Immunomodulators, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Immunosuppressants	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 will require Prior Authorization. 3. DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 4. For any new chemical entity in the Immunosuppressants class, require a PA until reviewed by the P&T Advisory Committee.