Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following table lists the agenda items scheduled for review, as well as options for consideration, at the March 17, 2016 meeting of the Pharmacy and Therapeutics Advisory Committee.

Item	Options for Consideration
New Products to Market: **Belbuca™**	Non-prefer in PDL class: *Analgesics Narcotics, Long-Acting* **Length of Authorization:** 6 months, or expected duration of treatment if less than 6 months. • Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. • Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; and – Contraindication to preferred drugs. • Patient has inability to take oral medication **OR** patient has a documented clinical trial with a combination of **three preferred LONG acting opiate analgesics** agents. • Patient is 18 years or older. • Refer all requests for concomitant use of long-acting narcotics to pharmacist for review. **Quantity Limit** = 2 buccal films per day.
New Products to Market: **Vivlodex™**	Non-prefer in the PDL class: *NSAIDs* **Length of Authorization:** 1 year • Indicated for management of osteoarthritis (OA) pain. • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; and – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure of no less than 30 days with **TWO** preferred drugs in the class? Document the details. • Meloxicam tablet is covered without PA; clinical reason as to why

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	meloxicam tablet cannot be used. • The safety and effectiveness of Vivlodex in pediatric patients have not been established. **Quantity Limit** = 1 capsule per day.
New Products to Market: **Ninlaro™**	Non-prefer in PDL class: *Oncology Oral, Hematologic* **Length of Authorization:** 1 year • Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. • Safety and effectiveness have not been established in pediatric patients.
New Products to Market: **Alecensa®**	Non-prefer in the PDL class: *Oncology Oral, Lung* • Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer who have progressed on or are intolerant to crizotinib • Monitor ALT, AST, and total bilirubin every 2 weeks during the first 2 months of treatment, then periodically during treatment (discontinue based on severity of drug reaction). • Ensure patient is not pregnant **Quantity Limit** = 2 capsules per day
New Products to Market: **Tagrisso™**	Non-prefer in PDL class: *Oncology Oral, Lung* **Length of Authorization:** 1 year • Indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, who have progressed on or after EGFR TKI therapy. • Prescriber needs to submit lab work documenting this mutation as detected by an FDA-approved test. • The safety and effectiveness of Tagrisso have not been established in pediatric patients. **Quantity Limit** = 1 tablet per day.
New Products to Market: **Cotellic®**	Non-prefer in PDL class: *Oncology Oral, Skin* **Length of Authorization:** 1 year • Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib. • Prescriber needs to submit lab work documenting this mutation as detected by an FDA-approved test. • The safety and effectiveness of Cotellic have not been established in pediatric patients. **Limitation of Use:** Cotellic is not indicated for treatment of patients with wild-type BRAF melanoma.

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New Products to Market: **Uptravi®**	Non-prefer in the PDL class: *PAH Agents, Oral & Inhaled* **Length of Authorization:** 1 year • Indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; and – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with **ONE** preferred drug in the class in the last 6 months? Document the details. • The safety and effectiveness of Uptravi in pediatric patients have not been established. **Quantity Limit** = 2 tablets per day for Uptravi 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,000 mcg, 1,200 mcg, 1,400 mcg, and 1,600 mcg tablets. No quantity limit on the Uptravi Titration Pack.
New Products to Market: **Enstilar®**	Non-prefer in PDL class: *Antipsoriatics, Topical* **Length of Authorization:** 4 weeks • Indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older. • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; and – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with **ONE** preferred drug in the class? Document the details. • Minimum age restriction of 18 years of age. • Apply Enstilar® Foam to affected area(s) once daily for up to 4 weeks.

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New Products to Market: **Seebri™ Neohaler®**	Non-prefer in PDL class: *COPD Agents* **Length of Authorization:** 1 year • Indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; and – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with **ONE** preferred drug in the same class? If so, document the details and approve. • Seebri Neohaler is not indicated for use in children. The safety and efficacy of Seebri Neohaler in pediatric patients have not been established. **Quantity Limit** = 2 inhalations per day (1 inhaler per month)
New Products to Market: **Utibron™ Neohaler®**	Non-prefer in the PDL class: *COPD Agents* **Length of Authorization:** 1 year • Indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). • Is there any reason that the patient cannot be switched to a preferred medication? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; and – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with **ONE** preferred drug in the same class? If so, document the details and approve. • Utibron Neohaler is not indicated for use in children. The safety and efficacy of Utibron Neohaler in pediatric patients have not been established. **Limitations of Use**: Not indicated for the relief of acute bronchospasm or for the treatment of asthma. **Quantity Limit** = 2 inhalations per day (1 inhaler per month)
New Products to Market: **Viberzi®**	Non-prefer in the PDL class: *GI Motility, Chronic* **Length of Authorization:** 1 year • Indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D). • The safety and effectiveness of Viberzi have not been established in pediatric patients. **Quantity Limit** = 2 tablets per day.

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New Products to Market: **Tresiba®**	Non-prefer in the PDL class: *Hypoglycemics, Insulins & Related* **Length of Authorization:** 1 year • Indicated to improve glycemic control in adults with diabetes mellitus. • Is there any reason that the patient cannot be switched to a preferred medication in the class? Document the details. Acceptable reasons include – Adverse reaction to preferred drugs; – Allergy to preferred drugs; and – Contraindication to preferred drugs. • Has the patient had a therapeutic trial and treatment failure with **ONE** preferred drug in the same class? Document the details. • Insulin Pens – Physical reasons such as dexterity problems/vision impairment; – Must be self-administered; and – NOT just for convenience. **Limitations of Use:** Not recommended for treating diabetic ketoacidosis.
Antipsoriatics, Topical	• DMS to select preferred agent (s) based upon economic evaluation; however, at least one unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and will require Prior Authorization (PA). • For any new chemical entity in the Topical Psoriasis Agents, require a PA until reviewed by the P&T Committee.
COPD Agents	• DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. At least one combination product and tiotropium should be among the preferred products. • Agents not selected as preferred will be considered non-preferred and will require PA. • Continue quantity limits on agents in this class. • For any new chemical entity in the COPD Agents class, require a PA until reviewed by the P&T Advisory Committee.

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COPD Clinical Criteria	**Length of Authorization:** 1 Year Daliresp® is approvable if • The diagnosis is COPD **AND** the patient has tried/failed **ONE** of the following: – Ipratropium; OR – Ipratropium/Albuterol; OR – Spiriva; OR – A beta agonist (short or long acting) used on a scheduled basis **Criteria to approve a non-preferred agent in this class:** • Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include – Allergy to medications not requiring prior approval; – Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and – 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: – If there has been a therapeutic failure to no less than a **two-week** trial of at least **two** preferred medications; **AND** – The requested medication's corresponding generic (if covered by the Commonwealth) has been attempted with **multiple** manufacturers (if available) and failed or is contraindicated.
GI Motility, Chronic	• DMS to select preferred agent (s) based on economic evaluation; however, at least one 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 GI Motility, Chronic class, require a PA until reviewed by the P&T Committee.
Hypoglycemics **alpha-glucosidase inhibitors**	• DMS to select preferred agent (s) based on economic evaluation; however, at least one 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 Alpha-Glucosidase Inhibitor class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics **Amylin Analogues**	• DMS to select preferred agent (s) based on economic evaluation. • Allow for use of pramlintide with active insulin therapy only. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Amylin Analogue class, require a PA until reviewed by the P&T Advisory Committee.

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Hypoglycemics **DPP4 Inhibitors**	• DMS to select preferred agent (s) based on economic evaluation; however, at least one single entity agent should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the DPP4-Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics **GLP-1s**	• DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. • Continue to require PA for all agents in this class to ensure appropriate utilization. • For any new chemical entity in the GLP-1 Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics **Insulins and Related**	• 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. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Injectable Insulins class, require a PA until reviewed by the P & T Advisory Committee.
Hypoglycemics **Meglitinides**	• DMS to select preferred agent (s) based on economic evaluation; however, at least one single entity agent should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Meglitinides class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics **Metformins**	• DMS to select preferred agent (s) based on economic evaluation; however, at least metformin should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Hypoglycemics, Metformins class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics **SGLT2s**	• DMS to select preferred agent (s) based on economic evaluation; however, at least one 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 Diabetes: SGLT2 Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics **Sulfonylureas**	• DMS to select preferred agent (s) based on economic evaluation; however, at least two unique second generation sulfonylureas should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Sulfonylureas and Combination class, require a PA until reviewed by the P&T Advisory Committee.

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Hypoglycemics, TZDs	• DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. • Continue quantity limits based on maximum recommended dose. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Diabetes: Thiazolidinediones class, require a PA until reviewed by the P&T Advisory Committee.
Hypoglycemics Clinical Criteria Review INSULINS	**Length of Authorization:** 1 Year • Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: – Allergy to medications not requiring prior approval; – Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and – 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: – If there has been a therapeutic failure of at least **one preferred medication within the last 90 days, within the same class; AND** – The requested medication's corresponding generic (if covered by the Commonwealth) has been attempted with **multiple manufacturers** (if available) and failed or is contraindicated. **For Pens and Cartridges:** • Patient is 15 years of age and under; OR • Patients or active care-givers that are unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension can be approved for pens/cartridges.
Hypoglycemics Clinical Criteria Review BYETTA	• Preferred GLP-1 Agonists (Byetta) will be approved if metformin, a sulfonylurea, insulin, a DDP-4 inhibitor, OR a thiazolidinedione (TZD) is seen in history within the past 90 days.
Hypoglycemics Clinical Criteria Review SYMLIN	• A trial of ANY insulin in the last 90 days will suffice for approval on this medication.

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Hypoglycemics Clinical Criteria Review ORAL AGENTS	**Length of Authorization:** 1 Year • Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include – Allergy to medications not requiring prior approval; – Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and – 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: – If there has been a therapeutic failure to no less than a **one-month** of at least **two** preferred medications (unless only 1 available); **AND** – The requested medication's corresponding generic (if covered by the state) has been attempted with **multiple manufacturers** (if available) and failed or is contraindicated.
Hypoglycemics Clinical Criteria Review SGLT2s	• SGLT2 Inhibitors should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
Hypoglycemics Clinical Criteria Review PRANDIMET	• Diagnosis is Diabetes Mellitus Type 2 AND patient is currently treated with a meglitinide and metformin; **OR** • Patient is inadequately controlled on a meglitinide alone or metformin alone.
Hypoglycemics Clinical Criteria Review DPP4 INHIBITORS	**Length of Authorization:** 1 Year A preferred DPP-4 Inhibitor will be approved for one of the following reasons: • Metformin, insulin, sulfonylurea, or a thiazolidinedione is seen in history within the past 90 days; **OR** • The patient has a diagnosis of Chronic Renal Insufficiency or Chronic Renal Failure (ICD-10 = 585.9). **Approval criteria for a non-preferred DPP4 Inhibitor:** • Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: – Allergy to medications not requiring prior approval; – Contraindication to or drug-to-drug interaction with medications not requiring prior approval; and – 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: – If there has been a therapeutic failure of at least **two** preferred medications; **AND** – The requested medication's corresponding generic (if covered by the Commonwealth) has been attempted with **multiple manufacturers** (if available) and failed or is contraindicated.