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 **May 17, 2018** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Product to Market: **Lonhala™ Magnair™**	Non-prefer in the PDL class: *COPD Agents* **Length of Authorization:** 1 year • Lonhala™ Magnair™ (glycopyrrolate) is a long-acting muscarinic antagonist indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease. It is available as a solution for inhalation in a unit-dose, single-use 1 mL vial (each vial contains 25 mcg of glycopyrrolate) in either a Starter Kit, which contains 60 unit-dose vials and 1 Magnair nebulizer system, or a Refill Kit, which contains 60 unit-dose vials and a Magnair handset refill. **Criteria for Approval**: • Diagnosis of chronic obstructive pulmonary disease (COPD); AND • Demonstrate treatment failure with 1 other long-acting muscarinic antagonist (LAMA) agents due to technique/delivery mechanism. • **Age Limit**: ≥ 18 years **Quantity Limit**: 2 vials per day
New Product to Market: **Solosec™**	Non-prefer in the PDL class: *Antibiotics, GI* **Length of Authorization:** Date of Service (1 day) • Solosec™ (secnidazole) is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in adult women. It is available as granules for oral administration in a 2-gram unit-of-use foil packet. **Criteria for Approval**: • Female patient with diagnosis of bacterial vaginosis (BV); AND • No in vitro resistance to nitroimidazole derivatives (metronidazole, tinidazole, secnidazole) or prior failure of metronidazole or tinidazole for the current course of infection; AND • No hypersensitivity to nitroimidazole derivatives; AND • Trail and failure of, or contraindication to, at least 1 preferred non-nitroimidazole (e.g., clindamycin). **Age Limit**: ≥ 18 years **Quantity Limit**: 1 packet per fill

Single Agent Reviews	Options for Consideration
New Products to Market: **Steglatro™ and Segluromet™**	Non-prefer in the PDL class: *Diabetes: SGLT2 Inhibitors (Hypoglycemics, SGLT2s)* **Length of Authorization:** 1 year • Steglatro™ (ertugliflozin), a sodium-glucose co-transporter 2 (SGLT2) inhibitor, is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM). It is available as 5 mg and 15 mg tablets. • Its fixed-dose combination with metformin, Segluromet™ (ertugliflozin/metformin), is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM who are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin. It is available as 2.5/500, 2.5/1000, 7.5/500, and 7.5/1000 mg tablets. **Criteria for Approval**: • Diagnosis of type 2 diabetes; AND • 3-month trial and failure of 1 preferred SGLT2 inhibitor; OR • Contraindication to all preferred SGLT2 inhibitor products. **Age Limit**: ≥ 18 years **Quantity Limit**: – Steglatro™: 1 tablet per day – Segluromet™: 2 tablets per day
New Product to Market: **Steglujan™**	Non-prefer in the PDL class: *Diabetes: DPP-4 Inhibitors (Hypoglycemics, Incretin Mimetics/Enhancers)* **Length of Authorization:** 1 year • Steglujan™ (ertugliflozin/sitagliptin) is a fixed-dose combination of ertugliflozin with DPP-4 inhibitor sitagliptin. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with T2DM when treatment with both ertugliflozin and sitagliptin is appropriate. Steglujan™ is available in 5/100 and 15/100 mg tablets. **Criteria for Approval**: • Diagnosis of type 2 diabetes; AND • 3-month trial and failure of 1 preferred DPP-4 inhibitor AND 1 preferred SGLT2 inhibitor (taken separately or together); OR • 3-month trial and failure of a preferred DPP-4/SGLT2 combination product. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 tablet per day

Note: The following new agent(s) will be reviewed along with their respective classes.

- Erleada™ – Oncology, Oral – Prostate Cancer

Criteria Review	Options for Consideration

Long- And Short-Acting Opioid Prior Authorization Class Criteria	**Note**: Class criteria will be waived for members receiving hospice/palliative/end-of-life care or have a diagnosis of active cancer or sickle cell anemia. Requests for these members will be approved for 1 year.
	
	Class Criteria for Initial Approval (exceptions apply to short-acting opioids for acute pain; additional criteria may also apply to specific formulation)
	• Prescriber has evaluated the member for risk of diversion, harm or misuse:
	  ○ Prescriber attests that KASPER report for the past 12 months has been reviewed; AND
	  ○ Prescriber submits urine drug screen (UDS) results dated within the past 30 days; AND
	  ○ If UDS is positive for illicit or unexpected substances, prescriber attests that naloxone was or will be prescribed; AND
	• Prescriber submits an assessment of baseline pain and function (e.g., PEG scale); AND
	• Prescriber attestation or documentation that non-opioid therapies (e.g., exercise therapy, cognitive behavioral therapy, NSAIDs, etc.) have been tried and/or are being used and optimized as appropriate; AND
	• For females of child-bearing age, prescriber attests that the member has been counseled regarding the risks of becoming pregnant while on this medication, including the risk of neonatal abstinence syndrome (NAS); AND
	• Patient does NOT have respiratory depression, acute or severe bronchial asthma, or hypercarbia; AND
	• Patient does NOT have known or suspected GI obstruction (e.g., paralytic ileus); AND
	• Up to 1 long-acting opioid and 1 short-acting opioid may be used at a time.
	
	Class Criteria for High Morphine Milligram Equivalent (MME) Requests – Over 90 MME per Day
	• Additional criteria shall apply for NEW requests where the cumulative opioid dose across all prescriptions is > 90 morphine milligram equivalents (MME):
	  ○ Note: Buprenorphine products (for opioid addiction treatment or pain) are not assigned an MME value and will not be included in the calculation.
	  ○ Prescriber is, or has proof of consultation with, a Pain Management Specialist OR specialist in an appropriate discipline (e.g., orthopedist, neurologist, spine specialist, etc.) for evaluation of the source of pain and/or treatment of any underlying conditions; AND
	  ○ Prescriber must submit clinical justification for exceeding 90 MME/day; AND
	  ○ Prescriber attests that a naloxone prescription and associated counseling on its use was, or will be, *offered* to the member.
	
	Class Criteria for Approval of Very High MME Requests – Over 200 MME per Day
	• Additional criteria shall apply to ANY request where the cumulative opioid dose across all prescriptions is > 200 MME/day:
	  ○ Note: Buprenorphine products (for opioid addiction treatment or pain) are not assigned an MME value and will not be included in the calculation.
	  ○ Prescriber is, or has proof of consultation with, a Pain Management Specialist; AND
	  ○ Prescriber submits clinical justification for exceeding 200 MME/day; AND
	  ○ Prescriber submits documentation (e.g., progress notes) showing attempts and/or plans to taper below 200 MME/day as well as other non-opioid components (e.g., NSAIDs, physical therapy, etc.) of the treatment plan; AND
	  ○ Prescriber attests that a naloxone prescription and associated counseling on its use, was or will be *given* to the member.

Criteria Review	Options for Consideration

	Class Criteria for Opioids and Benzodiazepines
	• Additional criteria shall apply when opioids are prescribed concurrently with benzodiazepines and/or KASPER report shows a benzodiazepine prescription in the past 12 months:
	  ○ Prescriber must submit clinical justification for the concurrent use of benzodiazepines and opioids; AND
	  ○ Prescriber attests that the member and/or caregiver(s) have been, or will be, counseled about the increased risks of slowed or difficult breathing and/or excessive sedation, and the associated signs and symptoms; AND
	  ○ Prescriber attests that a naloxone prescription and associated counseling on its use, was or will be *given* to the member.
	
	Class Criteria for Naloxone Prescribing
	• Prescriber attests that a naloxone prescription and associated counseling on its use was, or will be, *offered* to the member when any of the following are true (e.g., found on KASPER report, medication list, or diagnosis list):
	  ○ Opioid(s) is/are concurrently prescribed with a skeletal muscle relaxant (e.g., cyclobenzaprine); OR
	  ○ Opioid(s) is/are concurrently prescribed with a sedative hypnotic (e.g., zolpidem); OR
	  ○ Opioid(s) is/are concurrently prescribed with gabapentin; OR
	  ○ Member has a history of opioid or other controlled substance overdose; OR
	  ○ Member has a history of substance use disorder (SUD).
	
	Class Criteria for Renewal
	• Prescriber must submit proof of monitoring for evidence of diversion, harm, and misuse:
	  ○ Attest that KASPER report has been checked within the past 3 months; AND
	  ○ Submit most recent urine drug screen (UDS) results dated within the past 30 days; AND
	  ○ Prescriber explanation is required if UDS is positive for illicit or unexpected substances; AND
	  ○ If UDS is positive for illicit or unexpected substances, prescriber attests that naloxone was or will be prescribed.
	• Prescriber must submit an assessment of current pain and function (e.g., PEG scale).; AND
	  ○ Recipient must demonstrate a 30% improvement from baseline to continue current dose.
	• Prescriber must report whether patient has required use of opioid rescue medication (e.g., naloxone) or has been hospitalized or otherwise treated for opioid or other controlled substance overdose in the past 6 months.
	• If member has opioid overdose or use of naloxone within the past 6 months, the prescriber must submit a plan for preventing future overdoses (e.g., dose reduction).

Long-Acting Opioid Criteria Review	**Current Criteria**:
	• All medications are subject to a quantity limit in line with package insert.
	• Fentanyl (preferred strengths) clinical criteria:
	  ○ Diagnosis of chronic pain; AND
	  ○ Trial and failure of extended-release morphine.
	• Generic morphine sulfate ER is available without PA.
	
	Recommended Changes:
	1. Require PA for all long-acting opioids.

Criteria Review	Options for Consideration

	Length of Authorization: 6 months (1 year for active cancer, sickle cell anemia or hospice/palliative care)
	Criteria for Approval:
	• All opioid class criteria must be met; AND
	• Patient has severe pain requiring daily, around-the-clock, long-term pain management as evidenced by:
	  ○ Pain lasting > 3 consecutive months; AND
	  ○ Trial and failure within the past 90 days of 1 non-opioid analgesic (i.e., NSAIDs, APAP) at maximum tolerated doses without pain relief and/or functional improvement; AND
	  ○ Trial and failure within the past 90 days of at least 1 short-acting opioid analgesic at maximum tolerated doses without adequate relief of pain.
	Renewal Criteria:
	• All opioid PA class criteria for renewal must be met.

Short-Acting Opioid Criteria Review	**Current Criteria**:
	Prior authorization (PA) for products that contain a combination of a narcotic analgesic plus APAP, ASA or another NSAID after the initial 30 days of therapy per 366 days. A prior authorization, which can only be obtained by the prescriber, will be granted for the following instances:
	• Patient has a diagnosis for which short-term pain management is expected; approve for 3 months; OR
	• Patient has a diagnosis for which long-term pain management is expected OR patient is currently taking a long-acting narcotic concomitantly; approve for 6 months.
	
	Recommended Changes:
	1. Apply a minimum age of 18 years on codeine- and tramadol-containing products.
	2. Apply a minimum age of 18 years for any narcotic-containing cough and cold products.
	3. For opioid-naïve recipients (defined as ≤ 14 days of opioid use in the past 90 days of pharmacy claims), require PA for any short-acting narcotic where:
	  a. The claim is for > 7 day supply for members ≥ 18 years old; OR
	  b. The claim is for > 3 day supply for members < 18 years old; OR
	  c. The claim brings the cumulative supply of short-acting opioids in the past 90 days to > 14 days; OR
	  d. Product is ≥ 30 MME in a single dosing unit (e.g., hydromorphone 8 mg tablet) or a concentrated liquid (e.g., morphine sulfate 20 mg/mL).
	
	Length of Authorization: 30 days
	Criteria for Approval:
	• **Note**: Approve 1 year for active cancer, sickle cell anemia, and/or hospice/palliative care.
	• **Note**: Prescriber must submit PA request.
	• Only 1 short-acting opioid will be used at a time; AND
	• Trial and failure of, or contraindication to, at least 1 non-opioid pain medication (e.g., APAP, NSAIDs); OR
	• Medication is prescribed by a treating physician within 14 days of:
	  ○ A major surgery, any operative or invasive procedure or a delivery; OR

- A significant trauma, being any acute blunt, blast, or penetrating bodily injury that has a risk of death, physical disability, or impairment; OR
- Other clinical justification as to why treatment with opioids should extend beyond 14 days.

- If the request is for a high strength or concentrated dosage form, the prescriber must submit rationale why lower strength or less-concentrated products cannot be used.
- Additional clinical justification will be required for doses that exceed quantity limits.

4. For recipients with a history of opioid use (> 14 days of opioid use in the past 90 days of pharmacy claims), require PA for any claims where the incoming claim will exceed 30 days of opioid use in the past 90 days.

Length of Authorization: 3 or 6 months
Criteria for Approval:

- All opioid PA class criteria must be met; AND
- Trial and failure of, or contraindication to, at least 1 non-opioid pain medication (e.g., APAP, NSAIDs) within the past 6 months; AND
- Prescriber must submit a diagnosis more specific than pain:
  - If short-term pain management is expected/indicated; approve for 3 months; OR
  - If long-term (e.g., > 3 months) pain management is expected/indicated OR patient is currently taking a long-acting narcotic; approve for 6 months.

Criteria for Renewal:

- All opioid class criteria for renewal must be met.

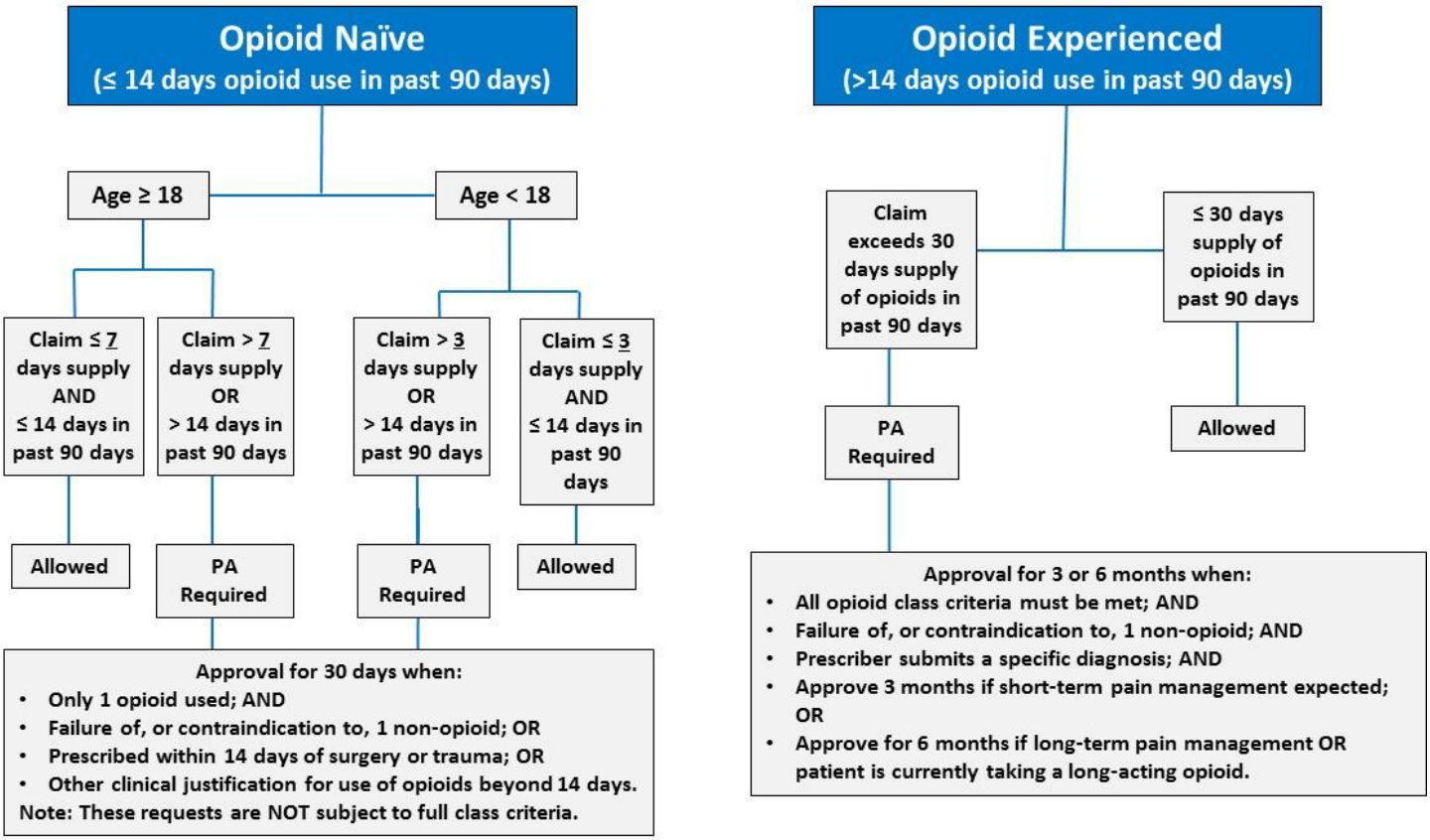
5. All short-acting opioid users will be subject to a quantity per day limit consistent with ≤ 90 morphine milligram equivalents (MME) per day and/or 4,000 mg per day of acetaminophen (APAP).
   - The quantity limit cannot be overridden at point-of-sale (POS); prescriber must submit a PA.

Proposed Quantity Limits for Oral Dosage Forms

Drug and Strength	Maximum Quantity per Day
Codeine-containing products: 12 mg per 5 mL liquids 15 mg 30 mg 60 mg	 240 mL (160 mL if w/ APAP) 20 tablets (12 if w/ APAP) 20 tablets (12 if w/ APAP) 10 tablets
Dihydrocodeine-containing tablets (16 mg)	12 tablets
Hydrocodone-containing tablets: 7.5 mg per 15 mL solution 10 mg per 15 mL solution 2.5 mg tablets 5 mg tablets 7.5 mg tablets 10 mg tablets	 180 mL 120 mL 12 tablets 12 tablets 12 tablets 8 tablets
Hydromorphone: 1 mg per mL solution 3 mg suppository 2 mg tablet 4 mg tablet 8 mg tablet	 20 mL 6 suppositories 10 tablets 5 tablets PA required

Criteria Review	Options for Consideration	
	Levorphanol 2mg tablets	4 tablets
	Meperidine: 50 mg per 5 mL solution 50 mg tablet 100 mg tablet	 90 mL 18 tablets 9 tablets
	Morphine sulfate: 10 mg per 5 mL solution 20 mg per 5 mL solution 20 mg per mL solution 10 mg suppositories 20 mg suppositories 15 mg IR tablets 30 mg IR tablets	 45 mL 22.5 mL Require PA 8 suppositories 4 suppositories 6 tablets Require PA
	Oxycodone-containing products: 5 mg per 5 mL solution 2.5 mg 5 mg 7.5 mg 10 mg 15 mg 20 mg & 30 mg	 60 mL 12 tablets 12 tablets 8 tablets 6 tablets 4 tablets Require PA
	Oxymorphone tablets: 5 mg 7.5 mg	 6 tablets 4 tablets
	Pentazocine-containing tablets (50 mg)	4 tablets
	Tapentadol (Nucynta) tablets: 50 mg 75 mg & 100 mg	 4 tablets Require PA
	Tramadol-containing products: 37.5 mg 50 mg	 8 tablets 8 tablets

Kentucky Medicaid Pharmacy Program Pathway for Short-Acting Opioid Prescriptions



Note: Quantity limits will apply to all prescriptions. Additional PA required for requests to exceed established quantity limits.

Note: Members receiving hospice/palliative care or have a diagnosis of active cancer or sickle cell anemia will be approved for 1 year.

Full Class Reviews	Options for Consideration
Analgesics, Narcotics Long **(Narcotics: Long-Acting)**	**Narcotics: Long-Acting** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 long-acting form of morphine and transdermal fentanyl should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Narcotics: Long-Acting* class, require PA until reviewed by the P&T Advisory Committee.
Analgesics, Narcotics Short **(Narcotic Agonist/ Antagonists; Narcotics: Fentanyl Buccal Products; Narcotics: Short-Acting)**	**Narcotic Agonist/Antagonists** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Narcotic Agonist/Antagonists* class, require PA until reviewed by the P&T Committee. **Narcotics: Fentanyl Buccal Products** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Narcotic Agonist/Antagonists* class, require PA until reviewed by the P&T Committee.

Full Class Reviews	Options for Consideration
	Narcotics: Short-Acting • DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of hydrocodone, hydromorphone, morphine, and oxycodone should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Analgesics Narcotics: Short-Acting* class, require PA until reviewed by the P&T Advisory Committee.
Antineoplastic Agents, Topical	**Antineoplastic Agents, Topical** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 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 *Antineoplastic Agents, Topical* class, require PA until reviewed by the P&T Committee.
Colony Stimulating Factors	**Colony Stimulating Factors** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 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 *Colony Stimulating Factors* class, require PA until reviewed by the P&T Committee.
NSAIDs **(Non-Steroidal Anti-Inflammatory Drugs)**	**NSAIDs** • DMS to select preferred agent(s) based upon economic evaluation; however, at least 6 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)* class, should require PA until reviewed by the P&T Advisory Committee.

Oncology, Oral – Breast Cancer
 	
(Oral Oncology Agents, Breast Cancer)
	Oral Oncology Agents, Breast Cancer
	• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 aromatase inhibitor, 1 kinase inhibitor, and generic tamoxifen should be preferred.
	• Agents not selected as preferred will be considered non-preferred and will require PA.
	• For any new chemical entity in the *Oral Oncology Agents, Breast Cancer* class, require PA until reviewed by the P&T Committee.
	
	Ibrance Criteria Review
	Current Criteria:
	Available without prior authorization.
	Quantity Limit: 1 per day
	
	Recommended Criteria:
	Change to preferred with clinical criteria in line with other agents in the class.
	Length of Authorization: 6 months
	• Female patient with a diagnosis of advanced or metastatic breast cancer that is:
	  ○ Hormone receptor (HR)-positive; AND
	  ○ Human epidermal growth factor receptor 2 (HER2)-negative.
	• Ibrance is being used according to an FDA-approved indication, such as:
	  ○ With an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women; OR
	  ○ With fulvestrant in women with disease progression following endocrine therapy.
	Age Limit = > 18 years
	Quantity Limit: 1 per day

Full Class Reviews	Options for Consideration
Oncology, Oral – Prostate Cancer **(Oral Oncology Agents, Prostate Cancer)**	**Oral Oncology Agents, Prostate Cancer** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Oral Oncology Agents, Prostate Cancer* class, require PA until reviewed by the P&T Committee **New agent in the class: Erleada™** Prefer with clinical criteria in this class. **Length of Authorization**: 6 months • Erleada™ (apalutamide) is an androgen receptor inhibitor indicated for use in the treatment of non-metastatic castration-resistant prostate cancer. It is available as 60 mg tablets. **Criteria for Approval:** • Diagnosis of NON-metastatic castration-resistant disease (nmCRPC); AND • Patient will receive a gonadotropin-releasing hormone (GnRH)-analog or has had a bilateral orchiectomy. **Renewal Criteria** • Patient continues to meet the above criteria; **AND** • Stabilization of disease or decrease in size of tumor or tumor spread. **Age Limit**: ≥18 years **Quantity Limits**: 4 tablets per day
Oncology, Oral – Skin Cancer **(Oral Oncology Agents, Skin Cancer)**	**Oral Oncology Agents, Skin Cancer** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Oral Oncology Agents, Skin Cancer* class, require PA until reviewed by the P&T Committee.
Opiate Dependence Treatments	**Opiate Dependence Treatments** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 buprenorphine/naloxone product should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Opiate Dependence Treatments* class, require PA until reviewed by the P&T Committee.

Consent Agenda	Options for Consideration
For the following therapeutic classes, there are **no recommended changes to the currently posted Preferred Drug List (PDL) status**; these may be voted on as a group:	
Androgenic Agents	Oncology, Oral – Lung Cancer
Antihyperuricemics	Oncology, Oral – Other
Bone Resorption Suppression and Related	Oncology, Oral – Renal Cell Carcinoma
Erythropoiesis Stimulating Proteins	Pancreatic Enzymes
Glucocorticoids, Oral	Progestins for Cachexia
Growth Hormone	Phosphate Binders
Oncology, Oral – Hematologic Cancers	Thrombopoiesis Stimulating Proteins