# Kentucky Department for Medicaid Services

## Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the September 17, 2015 meeting of the Pharmacy and Therapeutics Advisory Committee.

| Item | Options for Consideration |
|---|---|
| **New Products to Market: Orkambi®** | Lumacaftor-ivacaftor (Orkambi®) will be approved:<br>• Initially (6 months) if ALL of the following criteria are met:<br>o Age ≥ 12 years; AND<br>o Diagnosis of cystic fibrosis homozygous for the F508del mutation in the CFTR gene confirmed by an FDA-cleared CF mutation test; AND<br>o Baseline $FEV_1$ between 40-90%; serum transaminases < 3x ULN and bilirubin < 2x ULN; AND<br>o Baseline ophthalmic examinations if patient is 12 to 18 years of age.<br>• For continuation of therapy if ALL of the following criteria are met:<br>o Stable or improved $FEV_1$ ; AND<br>o Serum ALT or AST ≤5 x upper limit of normal (ULN), or ALT or AST ≤3 x ULN with bilirubin ≤2 x ULN. |
| **New Products to Market: Stiolto™ Respimat®** | Place this product non preferred with similar quantity limits in the PDL class titled COPD Agents. |
| **New Products to Market: Entresto™** | Place this product non preferred in the PDL class titled Angiotensin Receptor Blockers; however, approve Entresto™ if ALL of the following criteria are met:<br>• Age ≥ 18 years ; AND<br>• Diagnosis of chronic heart failure (NYHA Class II-IV); AND<br>• Left ventricular ejection fraction ≤ 40%; AND<br>• No history of angioedema related to previous ACE inhibitor or ARB therapy; AND<br>• No use of an ACE inhibitor within 36 hours of starting sacubitril/valsartan or during therapy; AND<br>• Patient does NOT have diabetes and taking aliskiren; AND<br>• Patient is NOT pregnant. |

| Item | Options for Consideration |
|---|---|
| **Oral Oncology, Renal Cell Carcinoma** | 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.<br>2. Continue quantity limits based on FDA-approved maximum dose.<br>3. Agents not selected as preferred will be considered non preferred and require PA.<br>4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back.<br>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. |
| **Oral Oncology, Prostate Cancer** | 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.<br>2. Continue quantity limits based on FDA-approved maximum dose.<br>3. Agents not selected as preferred will be considered non preferred and require PA.<br>4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back.<br>5. For any new chemical entity in the Oral Oncology, Prostate Cancer class, require a PA until reviewed by the P&T Advisory Committee. |
| **Alzheimer's Agents** | 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one single-entity acetylcholinesterase inhibitor and one single-entity NMDA receptor antagonist should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. For any new chemical entity in the Alzheimer's Agents class, require a PA until reviewed by the P&T Advisory Committee. |
| **Antialcoholic Preparations** | 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least two unique chemical entities, one of which should be intramuscular naltrexone, should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. Any new chemical entity in the Antialcoholic Preparations class should require a PA until reviewed by the P&T Advisory Committee. |
| **Anxiolytics** | 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least five unique chemical entities, one of which is not a controlled substance, should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. Any new chemical entity in the Anxiolytics class should require a PA until reviewed by the P&T Advisory Committee. |

| Item | Options for Consideration |
|---|---|
| **Anxiolytic Duration Edit** | Benzodiazepines, with the exception of clonazepam, will be available without requiring a prior authorization for the initial 60 days per year. For therapy beyond 60 days, prior authorization will be required and approved as follows:<br>• Request must come from the physician; AND<br>• Approve for 6 months for the following diagnoses:<br>o Anxiety; or<br>o Anxiety disorder; or<br>o Panic attacks/disorder; or<br>o Agoraphobia; or<br>o Social phobia; or<br>o Depression; or<br>o Chemotherapy-induced nausea & vomiting; or<br>o Status epilepticus; OR<br>• Approve for 1 month for a diagnosis of acute alcohol withdrawal; OR<br>• Approve for 1 year for a diagnosis of seizures. |
| **Monoamine Oxidase Inhibitors (MAOIs)** | 1. DMS to select preferred agent(s) based upon economic evaluation.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. Any new chemical entity in the Monoamine Oxidase Inhibitors class should require a PA until reviewed by the P&T Advisory Committee. |
| **Antidepressants, Other** | 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least bupropion and trazodone should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. Any new chemical entity in the Antidepressants, Other class should require a PA until reviewed by the P&T Advisory Committee. |
| **Selective Norepinephrine Reuptake Inhibitors (SNRIs)** | 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least one long acting SNRI should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. For any new chemical entity in the Selective Norepinephrine Reuptake Inhibitors (SNRIs) class, require a PA until reviewed by the P&T Advisory Committee. |
| **Milnacipran (Savella™) Clinical Criteria** | Milnacipran (Savella™) will be approved for a diagnosis of fibromyalgia only. |
| **Duloxetine Clinical Criteria** | Duloxetine will be approved for the following diagnoses:<br>• Depression/Major Depressive Disorder/Generalized Anxiety Disorder/Social Anxiety Disorder/Panic Disorder: Approval after trial and failure of or intolerance or contraindication to one preferred SNRI; OR<br>• Diabetic peripheral neuropathic pain; OR<br>• Fibromyalgia; OR<br>• Chronic musculoskeletal pain: Approval after trial and failure of or intolerance or contraindication to one NSAID. |

| Item | Options for Consideration |
|---|---|
| **Selective Serotonin Reuptake Inhibitors (SSRIs)** | 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least four unique chemical entities should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. Any new chemical entity in the Selective Serotonin Reuptake Inhibitors (SSRI) class should require a PA until reviewed by the P&T Advisory Committee. |
| **Tricyclic Antidepressants** | 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least four unique chemical entities should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. For any new chemical entity in the Tricyclic Antidepressants class, require a PA until reviewed by the P&T Advisory Committee. |
| **First-Generation Anticonvulsants** | 1. DMS to select preferred agent (s) based on economic evaluation; however, at least six unique chemical entities should be preferred.<br>2. Agents not selected as preferred will be considered non preferred and require prior authorization.<br>3. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days.<br>4. For any new chemical entity in the First-Generation Anticonvulsants class, require a PA until reviewed by the P&T Advisory Committee. |
| **Clobazam (Onfi™) Clinical Criteria** | Clobazam (Onfi™) will be approved for the following diagnoses:<br>• Lennox-Gastaut Syndrome; OR<br>• Seizure disorder after trial and failure of one anticonvulsant. |
| **Second-Generation Anticonvulsants** | 1. DMS to select preferred agent (s) based on economic evaluation; however, at least seven unique chemical entities should be preferred.<br>2. Agents not selected as preferred will be considered non preferred and require prior authorization.<br>3. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days.<br>4. For any new chemical entity in the Second-Generation Anticonvulsants class, require a PA until reviewed by the P&T Advisory Committee. |
| **Rufinamide (Banzel™) Clinical Criteria** | Rufinamide (Banzel™) will be approved for the following diagnoses:<br>• Lennox-Gastaut Syndrome; OR<br>• Seizure disorder after trial and failure of one anticonvulsant. |
| **Pregabalin (Lyrica®) Clinical Criteria** | Pregabalin (Lyrica®) will be approved for the following diagnoses:<br>• Diabetic Peripheral Neuropathy (DPN); OR<br>• Neuropathic pain associated with spinal cord injury; OR<br>• Postherpetic Neuralgia (PHN) AFTER adequate trial and failure of at least one of these first-line agents:<br>o Tricyclic antidepressant (TCAs); or<br>o Anticonvulsant: gabapentin; or<br>o Topical: Lidocaine 5% patch; OR<br>• Adjunct for partial onset seizure disorder; OR<br>• Fibromyalgia |

| Item | Options for Consideration |
|---|---|
| **Vigabatrin (Sabril®) Clinical Criteria** | Vigabatrin (Sabril®) will be approved for the following diagnoses:<br>• Infantile spasms; OR<br>• Seizure disorder after trial and failure of one anticonvulsant. |
| **Carbamazepine Derivatives** | 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.<br>2. Agents not selected as preferred will be considered non preferred and require prior authorization.<br>3. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days.<br>4. For any new chemical entity in the Anticonvulsants, Carbamazepine Derivatives class, require a PA until reviewed by the P&T Advisory Committee. |
| **Gabapentin Enacarbil (Horizant™) Clinical Criteria** | Gabapentin enacarbil (Horizant™) will be approved for the following diagnoses:<br>• Restless leg syndrome after trial and failure of **ONE** of the following:<br>o Levodopa/Carbidopa; **or**<br>o Pramipexole; **or**<br>o Ropinirole; **OR**<br>• Postherpetic neuralgia |
| **Lidocaine Patch Clinical Criteria** | Lidocaine patches will be approved for the following diagnoses:<br>• Diagnosis of Post Herpetic Neuralgia; OR<br>• Diagnosis of neuropathic pain after trial and failure of one agent in **ANY** of the following medication classes:<br>o Tricyclic antidepressant; or<br>o Anticonvulsant; or<br>o SNRI |
| **Capsaicin Patches (Qutenza®) Clinical Criteria** | Capsaicin Patches (Qutenza®) will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents:<br>• Gabapentin; OR<br>• Pregabalin; OR<br>• Lidocaine transdermal patches; OR<br>• A tricyclic antidepressant. |
| **Paroxetine Mesylate (Brisdelle™) Clinical Criteria** | Paroxetine mesylate (Brisdelle™) will be approved for patients meeting ALL of the following criteria:<br>• Diagnosis of moderate to severe vasomotor symptoms associated with menopause; AND<br>• Patient is post-menopausal; AND<br>• Trial and failure of or contraindication to ONE of the following:<br>o Hormonal therapy (Examples: Premarin, Menest, Estrace, Prempro, Premphase, etc.); or<br>o Other antidepressants (Examples: venlafaxine, other formulations of paroxetine, other SSRIs, etc.). |