IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
100 Army Post Road – Des Moines, IA 50315 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O
Mark Graber, M.D., FACEP, MSHCE
Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Laurie Anderson, R.Ph., Pharm.D.
Jason Wilbur, M. D.
Charles Wadle, D.O.
Sandy Pranger, R.Ph.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

August 2, 2018

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 1, 2018. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Chronic Pain Syndromes; CNS Stimulants and Atomoxetine; Tezacaftor/Ivacaftor (Symdeko); and Letermovir (Prevymis). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a June 12, 2018 letter that was sent to them detailing the proposed criteria for Chronic Pain Syndromes; CNS Stimulants and Atomoxetine; Tezacaftor/Ivacaftor (Symdeko); and Letermovir (Prevymis).

Chronic Pain Syndromes

Proposed Clinical Prior Authorization Criteria *(changes highlighted/stricken/italicized)*
A prior authorization is required for pregabalin (Lyrica®) and milnacipran (Savella™). These drugs will be considered for their FDA indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. ~~There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization.~~ *Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life.* Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. Payment will be considered under the following conditions:

1. A diagnosis of fibromyalgia (Lyrica® and Savella™)
   a. a trial and therapy failure at a therapeutic dose with gabapentin plus one of the following preferred generic agents: tricyclic antidepressant or SNRI **WITH**
   b. documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.)
2. A diagnosis of post-herpetic neuralgia (Lyrica®)
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate.
3. A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica®)
   A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant *or* duloxetine ~~or topical lidocaine~~.
4. A diagnosis of partial onset seizures, as adjunct therapy (Lyrica®)
5. *A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica®)*

CNS Stimulants and Atomoxetine

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial with the preferred ~~immediate release and~~ extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required. *Requests will be considered for an FDA approved age for the submitted diagnosis*. Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website ~~at~~ https://pmp.iowa.gov/IAPMPWebCenter/. Payment for CNS stimulants and atomoxetine will be considered under the following conditions:

1. ~~Attention Deficit Disorder (ADD) or~~ Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more **current** environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms *improvement in symptoms from baseline* ~~the patient continues to require medication to treat the symptoms of ADD/ADHD~~ will be required for renewals or patients newly eligible that are established on medication to treat ~~ADD/~~ADHD. *Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening), and will be limited to one unit dose per day.*
2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).
3. Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.

The required trials may be overridden when documented evidence is provided that the use of

these agents would be medically contraindicated.

Tezacaftor/Ivacaftor (Symdeko)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Symdeko (tezacaftor/ivacaftor). Payment will be considered for patients when the following criteria are met:

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of cystic fibrosis (CF)*;* and
3. Patient is homozygous for the F508del mutation or patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor (listed in the FDA approved labeling) based on *in vitro* data and/or clinical evidence.
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST/ALT) are provided.

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. Adherence to tezacaftor/ivacaftor therapy is confirmed; and
2. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.

Letermovir (Prevymis)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for oral letermovir. Requests for intravenous letermovir should be directed to the members medical benefit. Payment will be considered under the following conditions:

1. Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and
2. Patient or donor is CMV-seropositive R+ (attach documentation); and
3. Patient has received an allogeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provide date patient received HSCT); and
4. Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and
5. Patient is 18 years of age or older; and
6. Dose does not exceed:
    a. 240mg once daily when co-administered with cyclosporine;
    b. 480mg once daily; and
7. Patient must not be taking the following medications:
    a. Pimozide; or
    b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
    c. Rifampin; or
    d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
8. Patient does not have severe (Child-Pugh Class C) hepatic impairment (provide score); and
9. Therapy duration will not exceed 100 days post-transplantation.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Chronic Pain Syndromes; CNS Stimulants and Atomoxetine; Tezacaftor/Ivacaftor (Symdeko); and Letermovir (Prevymis).

Sincerely,

Pamela Smith R.Ph.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME