IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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May 2, 2019

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, May 1, 2019. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Sodium Oxybate (Xyrem); Buprenorphine/Naloxone; Short-Acting Opioids; and Long-acting Opioids. The DUR Commission members also discussed proposed ProDUR edits for concurrent use of opioids and benzodiazepines and concurrent use of opioids and antipsychotics. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a February 12, 2019 letter that was sent to them detailing the proposed criteria for Sodium Oxybate (Xyrem); Buprenorphine/Naloxone; Short-Acting Opioids; and Long-acting Opioids in addition to the proposed ProDUR edits for concurrent use of opioids and benzodiazepines and concurrent use of opioids and antipsychotics.

Sodium Oxybate (Xyrem)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered ~~for patients 18 years of age or older~~ under the following conditions:

1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline*; or*~~.~~
2. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant*; and*~~.~~
3. *Patient meets the FDA approved age; and*
4. *Is prescribed within the FDA approved dosing; and*

5. Patient *and provider are* ~~is~~ enrolled in the Xyrem® REMS Program*; and*~~.~~
6. Patient has been instructed to not drink alcohol when using Xyrem®*; and*~~.~~
7. Patient~~s with and without a history of substance abuse have~~ *has* been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence*; and*~~.~~
8. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered*; and*~~.~~
9. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website ~~at https://pmp.iowa.gov/IAPMPWebCenter/~~ prior to requesting prior authorization.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Buprenorphine/Naloxone

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for *transmucosal* buprenorphine or buprenorphine/naloxone. *Requests will be considered for FDA approved dosing, including induction and maintenance dose.* Requests for doses above 24mg per day ~~or greater than once daily dosing~~ will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. *After the initial 3 month prior authorization, renewal requests for doses ≤ 16mg per day may be considered for 12 month renewals as long as the member meets all other prior authorization criteria.* ~~Concomitant use with opioids or tramadol will be prohibited.~~ Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. Requests for surgically implanted buprenorphine *or buprenorphine depot injection* products will not be considered through the pharmacy benefit and should be directed to the member's medical benefit. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of opioid dependence and meets the FDA approved age: AND
2. Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number *(provide X DEA number)*; AND
3. ~~Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND~~
4. Documentation the Iowa Prescription Monitoring Program *(PMP)* website has been reviewed for the patient's use of controlled substances; AND
5. ~~A projected treatment plan is provided, including:~~
    a. ~~Anticipated induction/stabilization dose,~~
    b. ~~Anticipated maintenance dose,~~
    c. ~~Expected frequency of office visits, and~~
    d. ~~Expected frequency of counseling/psychosocial therapy visits.~~
6. ~~A treatment plan is provided for patients taking buprenorphine in combination with a benzodiazepine or central nervous system (CNS) depressant, including:~~
    a. ~~Documentation patient has been educated on the serious risks of combined use;~~
    b. ~~A plan to taper the benzodiazepine or CNS depressant to discontinuation, if possible;~~
    c. ~~Consideration of alternate anxiety or insomnia treatment options when the benzodiazepine or CNS depressant is used for anxiety or insomnia; and~~
    d. ~~Other prescribers involved in the care of the patient are aware of the patient's~~

~~use of buprenorphine; AND~~

7. Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant *or depot injection*.
8. Requests for single ingredient buprenorphine will only be considered for pregnant patients.

Requests for renewal must include:

~~1. An updated treatment plan, documenting the following:~~
   ~~a. Consideration of a medical taper to the lowest effective dose based on a self-assessment scale and~~
   ~~b. Assessment of concomitant benzodiazepine or CNS depressant use (if applicable) as outlined above, AND~~
2. Documentation the Iowa ~~Prescription Monitoring Program~~ *PMP* website has been reviewed for the patient's use of controlled substances since the last prior authorization request, AND
3. *Patient does not have documentation of concomitant use of an opioid or tramadol with the requested buprenorphine product, as seen in paid pharmacy claims, AND*

~~4. Documentation of a current, negative drug screen,~~

~~5. Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.~~

6. ~~Documentation the p~~ Patient is not using transmucosal buprenorphine with ~~the~~ buprenorphine implant *or depot injection*.

Short-Acting Opioids

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for all non-preferred short acting opioids. *Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request).* Payment will be considered under the following conditions:

1. Patient has pain severe enough to require opioid treatment; and
2. Patient has tried and failed at least two non-pharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
3. Patient has tried and failed at least two non-opioid pharmacologic therapies (*e.g.* acetaminophen or NSAIDs); and
4. Patient has documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting opioids (based on opioid ingredient only) at therapeutic doses; and
5. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and
6. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids~~.~~*; and*
7. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*

a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
b. *Documentation as to why concurrent use is medically necessary is provided; and*
c. *A plan to taper the benzodiazepine is provided, if appropriate.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. Patient has experienced improvement in pain control and level of functioning; and
2. Prescriber has reviewed the patient's use of controlled substances on the Iowa PMP website ~~at~~ ~~https://pmp.iowa.gov/IAPMPWebCenter/~~ and has determined continued use of a short-acting opioid is appropriate for this member~~.~~*; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
   a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
   b. *Documentation as to why concurrent use is medically necessary is provided; and*
   c. *A plan to taper the benzodiazepine is provided, if appropriate.*

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.

Long-Acting Opioids

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization is required for all non-preferred long-acting opioids. *Prior authorization (PA) is also required for members when the total daily opioid dose (combined across all opioids) exceeds the set morphine milligram equivalent (MME) threshold (include High Dose Opioids PA form with request).* Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and
2. Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and
3. Patient has tried and failed at least two nonopioid pharmacologic therapies (*e.g.* acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
4. There is documentation of previous trial and therapy failure with one preferred long-acting opioid at maximally tolerated dose; and
5. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization; and
6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website ~~at~~ ~~https://pmp.iowa.gov/IAPMPWebCenter/~~ and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and
7. Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.
8. Requests for long-acting opioids will only be considered for FDA approved dosing intervals. As-needed (PRN) dosing will not be considered~~.~~*; and*

9. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the benzodiazepine is provided, if appropriate.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. Patient has experienced improvement in pain control and level of functioning; and
2. Prescriber has reviewed the patient's use of controlled substances on the Iowa ~~Prescription Monitoring Program~~ *PMP* website ~~at~~ ~~https://pmp.iowa.gov/IAPMPWebCenter/~~ and has determined continued use of a long-acting opioid is appropriate for this member~~.~~*; and*
3. *For patients taking concurrent benzodiazepines, the prescriber must document the following:*
    a. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
    b. *Documentation as to why concurrent use is medically necessary is provided; and*
    c. *A plan to taper the benzodiazepine is provided, if appropriate.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

ProDUR Edit Recommendations

Due to requirements specific to Drug Utilization Review in H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, the DUR Commission made the following recommendations:

- Concurrent use of Opioids and Benzodiazepines
    - A soft edit that would identify members with concurrent use of an opioid and benzodiazepine in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the point of sale (POS). Claims would not be blocked.
- Concurrent use of Opioids and Antipsychotics
    - A soft edit that would identify members with concurrent use of an opioid and antipsychotic in their recently paid pharmacy claims. A message regarding the concurrent therapy would be sent to pharmacies via the POS. Claims would not be blocked.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Sodium Oxybate (Xyrem); Buprenorphine/Naloxone; Short-Acting Opioids; and Long-acting Opioids in addition to the proposed ProDUR edits for concurrent use of opioids and benzodiazepines and concurrent use of opioids and antipsychotics.

Sincerely,

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Cc: Erin Halverson, R.Ph, IME
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