# IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

1305 East Walnut – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

Holly Randleman, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O

Rhea Hartley, M.D.
Susan Parker, R.Ph., Pharm.D.
Jason Wilbur, M.D.

Charles Wadle, D.O.
John Ellis, Pharm.D.
Lisa Todd, R.Ph.

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


February 1, 2023

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid
1305 East Walnut
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 1, 2023. At this meeting, the DUR Commission members discussed removal of prior authorization (PA) criteria for Nebivolol (Bystolic) and Potassium Binders, in addition to new or updated PA criteria for Select Topical Psoriasis Agents, Initial Days' Supply Limit Override for Benzodiazepines, and High Dose Opioids. Additionally, the DUR Commission proposed ProDUR quantity limits for select drugs and ProDUR age edits (as detailed below). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a November 9, 2022 letter that was sent to them detailing the proposed removal of prior authorization (PA) criteria for Nebivolol (Bystolic) and Potassium Binders, in addition to new and updated PA criteria for Select Topical Psoriasis Agents, Initial Days' Supply Limit Override for Benzodiazepines, and High Dose Opioids. Also included were ProDUR quantity limits for select drugs and ProDUR age edits (as detailed below).

**Nebivolol (Bystolic)**

*Removal of PA criteria due to the availability of a cost effective generic.*

Current Clinical Prior Authorization Criteria – *Recommendation to Remove PA Criteria*

Prior authorization is required for Bystolic. Payment will be considered in cases where there are documented trials and therapy failures with two preferred cardio-selective beta-blockers of a different chemical entity at a therapeutic dose. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

**Potassium Binders**

*Removal of PA criteria due to the availability of safer, effective products to allow access to the preferred potassium binders without requiring a trial with sodium polystyrene sulfonate (SPS).*

Current Clinical Prior Authorization Criteria – *Recommendation to Remove PA Criteria*
Prior authorization (PA) is required for potassium binders subject to clinical criteria. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of chronic hyperkalemia; and
3. Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.

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

**Select Topical Psoriasis Agents**

Newly Proposed Clinical Prior Authorization Criteria
Prior authorization is required for select topical psoriasis agents. Payment for a non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of plaque psoriasis with involvement estimated to affect ≤ 20% of the body surface area; and
3. Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred medium to high potency topical corticosteroid and a preferred topical vitamin D analog for a minimum of 4 consecutive weeks.

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

**Initial Days' Supply Limit Override – Adding Benzodiazepines**

Current Prior Authorization Criteria
Requests for medications exceeding the initial days' supply limit require prior authorization. Payment will be considered under the following conditions:

1. Diagnosis is provided; and
2. Medical rationale for exceeding the initial days' supply limit is provided; and
3. Requests for opioids exceeding the 7 day initial supply limit will be considered:
    a. For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and
    b. Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do

not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms at www.iowamedicaidpdl.com where appropriate:

i. Quantity Limit Override Form (exceeds established quantity limit)
ii. High Dose Opioid PA Form (exceeds established MME limit)
iii. Short-Acting Opioids PA Form (non-preferred short-acting opioids)
iv. Long-Acting Opioids PA Form (non-preferred long-acting opioids); or

4. Requests for non-opioid drugs subject to the initial days' supply limit will be considered on an individual case-by-case basis, based on medical necessity documentation provided.

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)

Requests for medications exceeding the initial days' supply limit require prior authorization. Payment will be considered under the following conditions:

1. *Patient has an FDA approved or compendia indication for the requested drug* ~~Diagnosis is provided~~; and
2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
3. Medical rationale for exceeding the initial days' supply limit is provided; and
4. Requests for opioids exceeding the 7 day initial supply limit will be considered:
    a. For patients with active cancer, patients experiencing acute sickle cell crises, end-of-life/palliative care, or on an individual case-by-case basis based on medical necessity documentation provided; and
    b. Request must meet all other opioid requirements (quantity limits, morphine milligram equivalents (MME), and the preferred drug list (PDL). If requests do not comply with these requirements, separate, additional, prior authorization is required. Please reference and use the following prior authorization (PA) forms at www.iowamedicaidpdl.com where appropriate:
        i. Quantity Limit Override Form (exceeds established quantity limit)
        ii. High Dose Opioid PA Form (exceeds established MME limit)
        iii. Short-Acting Opioids PA Form (non-preferred short-acting opioids)
        iv. Long-Acting Opioids PA Form (non-preferred long-acting opioids); or
5. *Requests for benzodiazepines exceeding the 7 day initial supply limit will be considered:*
    a. *For patients with active cancer; end-of-life/palliative care, seizure disorder, or on an individual case-by-case basis based on medical necessity documentation provided; and*
    b. *For patients taking concurrent opioids, the prescriber must document the following:*
        i. *The risks of using an opioid and benzodiazepine concurrently have been discussed with the patient; and*
        ii. *Documentation is provided as to why concurrent use is medically necessary; and*
        iii. *A plan to taper the opioid is provided, if appropriate; and*
    c. *Request must meet all other benzodiazepine requirements (quantity limit, PDL, etc.). If requests do not comply with these requirements, separate, additional*

*prior authorization is required. Please use the following PA forms at www.iowamedicaidpdl.com where appropriate:*

i. *Benzodiazepines (non-preferred benzodiazepine)*
ii. *Quantity Limit Override (as posted at www.iowamedicaidpdl.com under Billing/Quantity Limits); and*

6. Requests for ~~non-opioid~~ drugs *or drug classes* subject to the initial days' supply limit *not listed above,* will be considered on an individual case-by-case basis, based on medical necessity documentation provided.

## High Dose Opioids

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day (See CDC Guideline for Prescribing Opioids for Chronic Pain at https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and
2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and
3. 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
4. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
5. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and
6. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
7. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and
8. Chart notes from a recent office visit for pain management is included documenting the following:
    a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
    b. Treatment goals; and
9. Patient has been informed of the risks of high-dose opioid therapy; and
10. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and
11. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and
12. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and
13. The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and
14. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and

15. Patient has been educated on opioid overdose prevention; and
16. Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and
17. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and
18. A documented dose reduction is attempted at least annually.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and
2. Patient has not experienced an overdose or other serious adverse event; and
3. Patient is not exhibiting warning signs of opioid use disorder; and
4. The benefits of opioids continue to outweigh the risks; and
5. A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and
6. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and
7. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.
8. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
9. Patient has been reeducated on opioid overdose prevention; and
10. Patient's household members have been reeducated on the signs of opioid overdose and how to administer naloxone.

Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for use of high-dose opioids ≥ 90 morphine milligram equivalents (MME) per day (See CDC *Clinical Practice* Guideline for Prescribing Opioids for ~~Chronic~~ Pain ~~–~~ *United States, 2022* at https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1.htm_w ~~https://www.cdc.gov/drugoverdose/prescribing/guideline.html~~). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and
2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and
3. 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
4. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants); and
5. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and

6. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
7. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and
8. Chart notes from a recent office visit *or telehealth visit* for pain management *are* ~~is~~ included documenting the following:
    a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
    b. Treatment goals; and
9. Patient has been informed of the risks of high-dose opioid therapy; and
10. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and
11. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and
12. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and
13. The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and
14. Patient has *documentation of receipt of an* ~~been provided a prescription for a preferred~~ *opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within the prior 24 months of high dose opioid request* ~~naloxone product~~ for the emergency treatment of an opioid overdose; and
15. Patient has been educated on opioid overdose prevention; and
16. Patient's household members have been educated on the signs of opioid overdose and how to administer *an opioid reversal agent* ~~naloxone~~; and
17. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and
18. A documented dose reduction is attempted at least annually.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and
2. Patient has not experienced an overdose or other serious adverse event; and
3. Patient is not exhibiting warning signs of opioid use disorder; and
4. The benefits of opioids continue to outweigh the risks; and
5. A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and
6. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and
7. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.
8. Patient has *documentation of receipt of an* ~~been provided a prescription for a preferred~~ *opioid reversal agent (e.g. as seen in pharmacy claims or documentation from the Iowa PMP of dispensation [attach documentation]) within 24 months of high*

*dose opioid request* ~~naloxone product~~ for the emergency treatment of an opioid overdose; and

9. Patient has been reeducated on opioid overdose prevention; and
10. Patient's household members have been reeducated on the signs of opioid overdose and how to administer *an opioid reversal agent* ~~naloxone~~.

**Proposed ProDUR Quantity Limits**

| **Drug** | **Quantity Limit per 30 Days** (unless otherwise stated) |
|---|---|
| Bystolic 2.5 mg, 5 mg, 10 mg (nebivolol) | 30 |
| Bystolic 20 mg (nebivolol) | 60 |
| Lokelma 5 g, 10 g (sodium zirconium cyclosilicate) | 34 packets |
| Veltassa 8.4 g, 16.8 g, 25.2 g (patiromer) | 30 packets |
| Vtama 1% (tapinarof) | 60 g (1 tube) |

**Proposed ProDUR Age Edit**

| **Drug** | **Age Edit** |
|---|---|
| Lokelma (sodium zirconium cyclosilicate) | 18 years of age and older |
| Veltassa (patiromer) | 18 years of age and older |

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for removal of prior authorization (PA) criteria for Nebivolol (Bystolic) and Potassium Binders, in addition to new or updated PA criteria for Select Topical Psoriasis Agents, Initial Days' Supply Limit Override for Benzodiazepines, and High Dose Opioids, as well as the ProDUR quantity limits and ProDUR age edits.

Sincerely,

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

Cc: Erin Halverson, R.Ph, Iowa Medicaid
Gina Kuebler, R.Ph, Iowa Medicaid