IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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May 7, 2025

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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, May 7, 2025. At this meeting, the DUR Commission members discussed prior authorization (PA) criteria for Aprocitentan (Tryvio); CNS Stimulants; Letermovir (Prevymis); Peanut (*Arachis hypogaea*) Allergen Powder-DNFP (Palforzia); Oxybate Products; Tirzepatide (Zepbound) for OSA; and removal of PA criteria for Direct Oral Anticoagulants. Additionally, the DUR Commission discussed a ProDUR quantity limit for Eliquis. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a February 10, 2025 letter that was sent to them detailing PA criteria for Aprocitentan (Tryvio); CNS Stimulants and Atomoxetine; Letermovir (Prevymis); Peanut (*Arachis hypogaea*) Allergen Powder-DNFP (Palforzia); Oxybate Products; Tirzepatide (Zepbound) for OSA; removal of PA criteria for Direct Oral Anticoagulants; and a ProDUR quantity limit for Eliquis.

Aprocitentan (Tryvio)

Newly Proposed Prior Authorization Criteria

Prior authorization (PA) is required for aprocitentan (Tryvio). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions 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 resistant hypertension; and
3. Secondary causes of hypertension have been ruled out; and

4. Patient has been adherent with standard background antihypertensive therapy, which includes at least one agent from each of the following classes, taken concurrently at maximally tolerated doses:
    a. Angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARB);
    b. Calcium channel-blockers (CCB);
    c. Diuretics;
    d. Mineralocorticoid receptor antagonist (MRA); and
5. Patient's blood pressure remains above target goal despite adherence with the above agents; and
6. Will be used in combination with at least three other antihypertensive agents at maximally tolerated doses.

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

CNS Stimulants (formerly CNS Stimulants and Atomoxetine)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Prior to requesting PA for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations. Payment for CNS stimulants and atomoxetine will be considered when patient has an FDA approved or compendia indication for requested drug under the following conditions:

1. 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 will be required for renewals or patients newly eligible that are established on medication to treat 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. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day. Use of an amphetamine agent plus a methylphenidate agent will not be considered for a diagnosis of ADHD.
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.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for CNS stimulants ~~and atomoxetine~~ for patients 21 years of age or older. Prior to requesting PA for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations. Payment for CNS stimulants ~~and atomoxetine~~ will be considered when patient has an FDA approved or compendia indication for requested drug under the following conditions:

1. 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 will be required for renewals or patients newly eligible that are established on medication to treat 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. Children (< 21 years of age) are limited to the use of long-acting agents with one unit of a short acting agent per day. Use of an amphetamine agent plus a methylphenidate agent will not be considered for a diagnosis of ADHD.
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 DUR Commission has reviewed the existing quantity limits for atomoxetine and determined that no adjustments are necessary. Furthermore, the Commission advises implementing the same age restriction for atomoxetine as is applied to other preferred CNS stimulants, requiring prior authorization for members under six years old.

Direct Oral Anticoagulants – Removal of Prior Authorization Criteria

Current Clinical Prior Authorization Criteria (*Recommendation: remove PA criteria*)
Prior authorization (PA) is not required for preferred direct oral anticoagulants (DOACs). PA is required for non-preferred DOACs. Requests will be considered for FDA approved

dosing and length of therapy for submitted diagnosis. Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications for the requested drug
under the following conditions:

1. Patient is within the FDA labeled age for indication; and
2. Patient does not have a mechanical heart valve; and
3. Patient does not have active bleeding; and
4. For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥1; and
5. A recent creatinine clearance (CrCl) is provided; and
6. A recent Child-Pugh score is provided; and
7. Patient's current body weight is provided; and
8. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred DOACs; and.
9. For requests for edoxaban, when prescribed for the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE), documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin) is provided.

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

Additionally, the DUR Commission recommends implementing the following ProDUR quantity limits:

Drug Product	Quantity	Days' Supply
Eliquis 2.5 mg (apixaban)	60	30
Eliquis 5 mg (apixaban)	74	30

Letermovir (Prevymis)

Current Clinical Prior Authorization

Prior authorization (PA) is required for oral letermovir. Requests for intravenous letermovir should be directed to the member's 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.

Proposed Clinical Prior Authorization (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for oral letermovir. Requests for intravenous letermovir should be directed to the member's medical benefit. Payment will be considered under the following conditions:

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. Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and
3. Patient has received an allogeneic hematopoietic stem cell transplant (HSCT) ~~within the last 28 days (provide date patient received HSCT)~~; and
    a. Patient or donor is CMV-seropositive *[*R+*]* (attach documentation); and
    b. *Treatment is initiated between day 0 and day 28 post-transplantation with IV and/or oral therapy (before or after engraftment); and*
    c. *Therapy duration will not exceed 100 days post-transplantation or up to 200 days if patient is at high risk for late CMV infection (attach documentation); or*
4. *Patient is a kidney transplant recipient; and*
    a. Donor is CMV-seropositive/recipient is CMV seronegative [D+/R-] (attach documentation); and
    b. Treatment is initiated between day 0 and day 7 post-transplantation with IV and/or oral therapy (before or after engraftment); and
    c. Therapy will not exceed 200 days post-transplantation; and
5. Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and
6. *Date of transplant is provided; and*
7. *Patients weight (in kg) is provided.*
8. ~~Patient is 18 years of age or older; and~~
9. ~~Dose does not exceed:~~
    ~~a. 240mg once daily when co-administered with cyclosporine;~~
    ~~b. 480mg once daily; and~~
10. ~~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~~
11. ~~Patient does not have severe (Child-Pugh Class C) hepatic impairment (provide score); and~~
12. ~~Therapy duration will not exceed 100 days post-transplantation.~~

Peanut Allergen Powder-dnfp (Palforzia)

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for Peanut (*Arachis hypogaea*) Allergen Powder-

dnfp (Palforzia). Payment will be considered under the following conditions:

1. Patient has a confirmed diagnosis of peanut allergy, as documented by a skin prick test to peanut ≥ 3 mm compared to control or a peanut-specific serum IgE ≥ 0.35 kUA/L (kilos of allergen-specific units per liter); and
2. Patient is 4 to 17 years of age at initiation of therapy or 4 years of age and older for continued up-dosing and maintenance therapy; and
3. Prescribed by or in consultation with an allergist or immunologist; and
4. Patient has access to injectable epinephrine; and
5. Will be used in conjunction with a peanut-avoidant diet; and
6. Patient does not have any of the following:
    a. Uncontrolled asthma; and/or
    b. A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
7. The initial dose escalation and the first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Initial dose escalation and the first dose of all up-dosing levels is not to be billed to the Iowa Medicaid outpatient pharmacy program as the initial dose escalation is administered in the provider office and should be billed via the medical benefit and the first dose of all up-dosing levels is provided via the Office Dose Kit; and
8. Follows FDA approved dosing; and
9. PA is required for all up-dosing dose levels (dose 1 through 11); and
10. Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.

<u>Proposed Clinical Prior Authorization Criteria</u> (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for Peanut (*Arachis hypogaea*) Allergen Powder-dnfp (Palforzia). Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indications, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a confirmed diagnosis of peanut allergy, as documented by a skin prick test to peanut ≥ 3 mm compared to control or a peanut-specific serum IgE ≥ 0.35 kUA/L (kilos of allergen-specific units per liter); and
3. Patient is ~~4~~ *1* to 17 years of age at initiation of therapy or ~~4~~ *1* year~~s~~ of age and older for continued up-dosing and maintenance therapy; and
4. Prescribed by or in consultation with an allergist or immunologist; and
5. Patient has access to injectable epinephrine; and
6. Will be used in conjunction with a peanut-avoidant diet; and
~~7. Patient does not have any of the following:~~
    ~~a. Uncontrolled asthma; and/or~~
    ~~b. A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and~~
8. The initial dose escalation and the first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Initial dose escalation and the first dose of all up-dosing levels is not to be billed to the Iowa Medicaid outpatient pharmacy program as the initial dose escalation is administered in the provider office and should be

billed via the medical benefit and the first dose of all up-dosing levels is provided via the Office Dose Kit; and

~~9. Follows FDA approved dosing; and~~

10. PA is required for all up-dosing dose levels (dose 1 through 11); and
11. Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.

Oxybate Products (formerly Sodium Oxybate Products)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for sodium oxybate (Xyrem). Payment will be considered 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 prescriber are enrolled in the Xyrem® REMS Program; and
6. Patient has been instructed to not drink alcohol when using Xyrem; and
7. Patient 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.
9. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website prior to requesting PA.

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

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/or stricken)

Prior authorization (PA) is required for ~~sodium~~ oxybate *products* ~~(Xyrem)~~. *Payment for non-preferred agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.* Payment will be considered under the following conditions:

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. A diagnosis of cataplexy associated with narcolepsy
    a. ~~verified~~ *Confirmed* by a ~~recent~~ sleep study (including PSG, MSLT, and ESS) *and verified by a sleep specialist (attach results);* and
    b. Previous trial and therapy failure with *dextroamphetamine* ~~one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline~~; or

3. A diagnosis of excessive daytime sleepiness associated with narcolepsy
    a. ~~verified~~ *Confirmed* by a ~~recent~~ sleep study (including PSG, MSLT, and

ESS) *and verified by a sleep specialist (attach results);* and
   b. Previous trials and therapy failures at a therapeutic dose with *modafinil* ~~a preferred amphetamine and non-amphetamine stimulant~~; *or*
4. *A diagnosis of idiopathic hypersomnia*
   a. Confirmed by a sleep study (including PSG, MSLT, and ESS) and verified by a sleep specialist (attach results); and
   b. Previous trial and therapy failure at a therapeutic dose with modafinil; and
5. *Will not be used in combination with other oxybate products or with pitolisant and/or solriamfetol; and*
6. ~~Patient meets the FDA approved age; and~~
7. ~~Is prescribed within the FDA approved dosing; and~~
8. ~~Patient and prescriber are enrolled in the Xyrem® REMS Program; and~~
9. ~~Patient has been instructed to not drink alcohol when using Xyrem; and~~
10. Patient has been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence; and
11. ~~Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered.~~
12. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website prior to requesting PA.

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

Incretin Mimetics for Non-Diabetes Indications (adding clinical criteria for OSA)

<u>Proposed Clinical Prior Authorization Criteria</u>

Prior authorization (PA) is required for incretin mimetics not otherwise covered by the Anti-Diabetics Non-Insulin Agents PA criteria for covered FDA approved or compendia indications. Payment for excluded medical use(s) (e.g. weight loss), as defined in the Iowa State Plan and Iowa Administrative Code 441 – 78.2(4) will be denied. Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has been screened for and does not have type 1 or type 2 diabetes mellitus (attach current lab results, obtained within 6 months of request, documenting an A1C < 6.5% or a fasting plasma glucose < 126 mg/dL); and
3. The requested drug will be used to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in an adult with established cardiovascular disease (CVD) and either obesity or overweight; and
   a. Patient has established CVD with history of one of the following (attach chart notes documenting diagnosis):
      i. Prior myocardial infarction (MI);
      ii. Prior stroke (ischemic or hemorrhagic);
      iii. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85

(at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; and

b. Patient has a baseline body mass index (BMI) ≥ 27 kg/m^2 (attach documentation), obtained within 6 months of request; and
c. Patient has been evaluated for cardiovascular standard of care treatment; and
d. For Wegovy:
    i. Patient is ≥ 45 years of age; and
    ii. Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and
    iii. Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment; *or* ~~and~~

4. Patient has a diagnosis of moderate to severe obstructive sleep apnea (OSA); and
    a. Patient has a baseline BMI ≥ 30 kg/m^2; and
    b. Prescriber attests patient has a recent (within prior three years) apnea/hypopnea index (AHI) ≥ 15 events per hour, as documented by a polysomnography (PSG) or at-home sleep study (document AHI); and
    c. For Zepbound:
        i. Patient meets the FDA approved age for OSA; and
        ii. Initiation and escalation dosages will be permitted up to a maximum of 20 weeks prior to reaching the recommended maintenance dosage of 10 mg to 15 mg once weekly; and
        iii. Maintenance dosages other than 10 mg to 15 mg once weekly will not be approved for maintenance treatment; and

5. Patient will use medication in combination with a reduced calorie diet and increased physical activity; and
6. The requested agent will not be used in combination with other incretin mimetics.

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

Requests will be considered for initiation and appropriate dosage escalation. Requests for continuation of therapy, once at an established maintenance dose will be considered at 12-month intervals when:

1. The requested drug will be used to reduce the risk of MACE; and
    ~~a. Patient does not have type 1 or type 2 diabetes; and~~
    b. Patient has been evaluated for cardiovascular standard of care treatment; and
    c. For Wegovy, a maintenance dose of 1.7 mg or 2.4 mg once weekly is requested; ~~and~~ *or*

2. The requested drug will be used to treat moderate to severe OSA; and
    a. Documentation of a positive response to therapy is provided; and
    b. The maintenance dose is requested and maintained (Zepbound 10 mg to 15 mg once weekly); and

3. Patient does not have type 1 or type 2 diabetes; and
4. Patient continues to use medication in combination with a reduced calorie diet and increased physical activity; and
5. The requested agent will not be used in combination with other incretin mimetics.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Aprocitentan (Tryvio); CNS Stimulants and Atomoxetine; Letermovir (Prevymis); Peanut (Arachis hypogaea) Allergen Powder-DNFP (Palforzia); Oxybate Products; Tirzepatide (Zepbound) for OSA; removal of PA criteria for Direct Oral Anticoagulants; and a ProDUR quantity limit for Eliquis.

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