



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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November 4, 2022

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

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 2, 2022. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Sedative/Hypnotics, Non-Benzodiazepine; Vericiguat (Verquvo); Maralixibat (Livmarli); Alpelisib (Vijoice); Mavacamten (Camzyos); Dupilumab (Dupixent); Viloxazine (Qelbree); and CNS Stimulants and Atomoxetine. The DUR Commission members also discussed ProDUR quantity limits for select drugs (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 an August 11, 2022 letter that was sent to them detailing the proposed criteria for Sedative/Hypnotics, Non-Benzodiazepine; Vericiguat (Verquvo); Maralixibat (Livmarli); Alpelisib (Vijoice); Mavacamten (Camzyos); Dupilumab (Dupixent); Viloxazine (Qelbree); and CNS Stimulants and Atomoxetine. Also included were details regarding proposed ProDUR quantity limits for select drugs (as detailed below).

Sedative/Hypnotics, Non-Benzodiazepine

Current Clinical Prior Authorization Criteria

Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. Requests for doses above the manufacturer recommended dose will not be considered.

PA is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when the following criteria are met:

1. A diagnosis of insomnia; and

2. Medications with a side effect of insomnia (i.e., stimulants) are decreased in dose, changed to a short acting product, and/or discontinued; and
3. Enforcement of good sleep hygiene is documented; and
4. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses.
5. In addition to the above criteria, requests for suvorexant (Belsomra) will require documentation of a trial and therapy failure with at least one non-preferred agent, other than suvorexant, prior to consideration of coverage.
6. Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.

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 italicized/highlighted and stricken)

Preferred agents are available without prior authorization (PA) when dosed within the established quantity limits. ~~Requests for doses above the manufacturer recommended dose will not be considered.~~ PA is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for ~~a non-preferred agent non-benzodiazepine sedative/hypnotics~~ will be authorized only for cases in which there is documentation of previous trials and therapy failures with, at a minimum, three (3) preferred agents. Payment for a non-preferred ~~agent non-benzodiazepine sedative/hypnotics~~ 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. A diagnosis of insomnia; and
3. Medications with a side effect of insomnia (~~i.e., stimulants~~) are decreased in dose, changed to a short acting product, and/or discontinued; and
4. Enforcement of good sleep hygiene is documented; and
5. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses; *and*
6. *Will not be used concurrently with a benzodiazepine sedative/hypnotic agent.*
7. In addition to the above criteria, requests for *an orexin receptor antagonist suvorexant (Belsomra)* will require documentation of a trial and therapy failure with at least one non-preferred agent, ~~other than suvorexant~~, prior to consideration of coverage.
8. Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.

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

Vericiguat (Verquvo)

Current Clinical Prior Authorization Criteria

Prior authorization is required for vericiguat (Verquvo). Payment will be considered under the following conditions:

1. Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) \leq 45%; and
2. Patient meets one of the following:
 - a. Recent hospitalization for heart failure (within the last 6 months); or
 - b. Recent need for outpatient intravenous diuretics (within the last 3 months); and
3. Patient is within the FDA labeled age for indication; and
4. Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and
5. Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and
6. Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:
 - a. Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and
 - b. Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and
7. Is dosed based on FDA approved dosing; and
8. Initial requests for Verquvo 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.

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

Proposed Clinical Prior Authorization Criteria (changes stricken/italicized and/or highlighted)
 Prior authorization is required for vericiguat (Verquvo). Payment will be considered *when patient has an FDA approved or compendia indication for the requested drug* 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. Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) \leq 45%; and
3. Patient meets one of the following:
 - a. Recent hospitalization for heart failure (within the last 6 months); or
 - b. Recent need for outpatient intravenous diuretics (within the last 3 months); and
- ~~4. Patient is within the FDA labeled age for indication; and~~
5. Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and
6. Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g. sildenafil, tadalafil, vardenafil); and
7. Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:
 - a. Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and

- b. Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and
 - c. *Mineralocorticoid receptor antagonist (MRA); and*
 - d. *Sodium-glucose cotransporter 2 inhibitor (SGLT2i) indicated for the treatment of heart failure (empagliflozin or dapagliflozin); and*
8. ~~Is dosed based on FDA approved dosing; and~~
9. Initial requests for *vericiguat (Verquvo)* 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.

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

Maralixibat (Livmarli)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for maralixibat (Livmarli). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) 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 Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a *JAG1* or *NOTCH2* mutation or deletion; and
3. Patient has cholestasis with moderate to severe pruritus; and
4. Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS; and
5. Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:
 - a. Ursodeoxycholic acid (ursodiol)
 - b. Cholestyramine
 - c. Rifampin; and
6. Patient's current weight in kilograms (kg) is provided.

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

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritus symptoms and patient's current weight in kg.

PIK3CA-Related Overgrowth Spectrum (PROS) Treatments

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for alpelisib (Vijoice). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) 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 PIK3CA-Related Overgrowth Spectrum (PROS) confirmed by genetic testing demonstrating a *PIK3CA* mutation; and
3. Patient's condition is severe or life-threatening requiring systemic therapy as determined by treating prescriber; and
4. Patient has at least one target lesion identified on imaging.

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

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will be considered with documentation of a positive response to therapy as evidenced by a reduction in sum of measurable lesion volume assessed across 1 to 3 target lesions.

Mavacamten (Camzyos)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for mavacamten (Camzyos). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) 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 obstructive hypertrophic cardiomyopathy (HCM); and
3. Patient exhibits symptoms of New York Heart Association (NYHA) class II or III symptoms; and
4. Is prescribed by or in consultation with a cardiologist; and
5. Patient has a left ventricular ejection fraction (LVEF) $\geq 55\%$; and
6. Patient has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation; and
7. Documentation of a previous trial and therapy failure, at a maximally tolerated dose, with all of the following:
 - a. Non-vasodilating beta-blocker (atenolol, metoprolol, bisoprolol, propranolol); and
 - b. Non-dihydropyridine calcium channel blocker (verapamil, diltiazem); and
 - c. Combination therapy with disopyramide plus beta-blocker or disopyramide plus a non-dihydropyridine calcium channel blocker.

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

Request for continuation of therapy will be considered with documentation of a positive response to therapy as evidenced by improvement in obstructive HCM symptoms.

Dupilumab (Dupixent)

Current Prior Authorization Criteria

Prior authorization is required for Dupixent (dupilumab). Payment will be considered under the following conditions:

1. Patient is within the FDA labeled age for indication; and
2. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
 - a. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
 - b. Patient has failed to respond to good skin care and regular use of emollients; and
 - c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
 - d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
 - e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
 - f. Patient will continue with skin care regimen and regular use of emollients; or
3. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and
 - a. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
 - b. Has a pretreatment forced expiratory volume in 1 second (FEV₁) $\leq 80\%$ predicted; and
 - c. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long acting beta₂ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
 - d. Patient must have one of the following, in addition to the regular maintenance medications defined above:
 - i. Two (2) or more exacerbations in the previous year or
 - ii. Require daily oral corticosteroids for at least 3 days; ~~and~~ **or**
4. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
 - a. Documentation dupilumab will be used as an add-on maintenance treatment; and
 - b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
 - i. Nasal corticosteroid spray; and
 - ii. Oral corticosteroid; and
5. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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

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

Prior authorization is required for Dupixent (dupilumab). *Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug* 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* Patient is within the FDA labeled age for indication; and
2. *Patient's current weight in kilograms (kg) is provided; and*
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
 - a. Is prescribed by or in consultation with a dermatologist, allergist, or immunologist; and
 - b. Patient has failed to respond to good skin care and regular use of emollients; and
 - c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
 - d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
 - e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
 - f. Patient will continue with skin care regimen and regular use of emollients; or
4. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and
 - a. Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and
 - b. Has a pretreatment forced expiratory volume in 1 second (FEV₁) $\leq 80\%$ predicted; and
 - c. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g., long acting beta₂ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
 - d. Patient must have one of the following, in addition to the regular maintenance medications defined above:
 - i. Two (2) or more exacerbations in the previous year or
 - ii. Require daily oral corticosteroids for at least 3 days; ~~and~~ *or*
5. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
 - a. Documentation dupilumab will be used as an add-on maintenance treatment; and
 - b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
 - i. Nasal corticosteroid spray; and
 - ii. Oral corticosteroid; ~~and~~ *or*

6. Patient has a diagnosis of eosinophilic esophagitis (EoE); and
 - a. Is prescribed by, or in consultation with, an allergist, gastroenterologist, or immunologist; and
 - b. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
 - c. Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and
 - d. Documentation of previous trials and therapy failures with all of the following:
 - i. High dose proton pump inhibitor (PPI) for at least 8 weeks; and
 - ii. Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension); and
 - iii. Dietary therapy; and
7. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for ~~16 weeks~~ **6 months** to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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

Viloxazine (Qelbree)

Current Clinical Prior Authorization Criteria

Prior authorization is required for viloxazine (Qelbree). Payment will be considered under the following conditions:

1. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
2. Patient is between 6 and 17 years of age; and
3. 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) and
4. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and
5. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and
6. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and
7. Is dosed based on FDA approved dosing, and dose does not exceed 400 mg per day; and
8. 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.

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

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

Prior authorization is required for viloxazine (Qelbree). Payment will be considered *when patient has an FDA approved or compendia indication for the requested drug* 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. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
- ~~3. Patient is between 6 and 17 years of age; and~~
4. 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) and
- ~~5. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and~~
- ~~6. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and~~
7. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and
8. ~~Is dosed based on FDA approved dosing, and~~ *Dose does not exceed 400 mg per day for pediatric patients (< 18 years of age) and 600 mg per day for adult patients;* and
9. 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.

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

CNS Stimulants and Atomoxetine

Current Clinical Prior Authorization Criteria for ADHD

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. Requests will be considered for an FDA approved age for the submitted diagnosis. Payment for CNS stimulants and atomoxetine will be considered under the following conditions:

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.

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 extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.

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 for ADHD (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. ~~Requests will be considered for an FDA approved age for the submitted diagnosis.~~

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 the requested drug* under the following conditions:

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.*

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 extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.

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

Proposed ProDUR Quantity Limits

Drug	Proposed Quantity Limit per 30 Days (unless otherwise stated)
Livmarli 9.5 mg/mL (maralixibat)	90 mL
Vioice 50 mg blister pack (alpelisib)	1 pack (28 tabs) per 28 days
Vioice 125 mg blister pack (alpelisib)	1 pack (28 tabs) per 28 days
Vioice 250 mg blister pack (alpelisib)	1 pack (56 tabs) per 28 days
Camzyos 2.5 mg, 5 mg, 10 mg, 15 mg (mavacamten)	30
Qelbree 200 mg (viloxazine)	90

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Sedative/Hypnotics, Non-Benzodiazepine; Vericiguat (Verquvo); Maralixibat (Livmarli); Alpelisib (Vioice); Mavacamten (Camzyos); Dupilumab (Dupixent); Viloxazine (Qelbree); CNS Stimulants and Atomoxetine; and the Proposed ProDUR quantity limits detailed above.

Sincerely,



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

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