Iowa Medicaid
IOWA HHS

**INFORMATIONAL LETTER NO. 2405-MC-FFS**

**DATE:** November 29, 2022

**TO:** Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse Practitioners, Therapeutically-Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics, Skilled Nursing Facilities, Intermediate Care Facilities, Nursing Facilities – Mental ILL, Federally Qualified Health Centers, Indian Health Service, Maternal Health Centers, Certified Nurse Midwife, Community Mental Health, Family Planning, Residential Care Facilities, Intermediate Care Facilities for Individuals with Intellectual Disability (ICF/ID) State and Community-Based ICF/ID Providers, Physician Assistants

**APPLIES TO:** Managed Care (MC), Fee-for-Service (FFS)

**FROM:** Iowa Department of Health and Human Services (HHS), Iowa Medicaid

**RE:** January 2023 Iowa Medicaid Pharmacy Program Changes

**EFFECTIVE:** January 1, 2023

1. **Changes to the preferred drug list (PDL) effective January 1, 2023.** Refer to the PDL website[1] to review the complete PDL.

| Preferred | Non-Preferred |
|---|---|
| Adynovate | Adlarity[1] |
| Chlorpromazine Tabs | Aspruzyo[1] |
| Clenpiq | Byetta[3] |
| Clindamycin 300mg Caps | Camzyos[1] |
| Dermotic | Dabigatran[1] |
| Descovy | Dyanavel XR Chew Tabs[1] |
| Fluocinolone Acetonide Topical Oil | Esperoct[3] |
| Fluticasone / Salmeterol Aer Powder BA | Fesoterodine |
| Glatiramer | Flavoxate |

[1] http://www.iowamedicaidpdl.com/

| | |
|---|---|
| Glatopa | Idelvion[3] |
| Ixinity | Kogenate FS[3] |
| Jivi | Methylphenidate TD Patch[1] |
| Lacosamide Oral Solution | Mounjaro[1] |
| Moviprep | Quviviq[1] |
| Myfembree[1] | Rhopressa[3] |
| Nebivolol[1] | Rocklatan[3] |
| Nexavar[1] | Sorafenib[1] |
| Ozempic[1] | Suprep |
| Paliperidone ER[4] | Tascenso ODT[1] |
| Rixubis | Theo-24 |
| Sod Sulfate- Pot Sulf-Mg Sulf Oral Soln | Vilazodone[1] |
| Sumatriptan Nasal Spray[1] | Vimpat Oral Soln[2] |
| Xolair Prefilled Syringe[1] | Vtama |
| | Winlevi[1] |
| | Zolmitriptan Nasal Spray[1] |

[1] Clinical prior authorization (PA) criteria apply
[2] Grandfather-established users with seizure diagnosis
[3] Grandfather-established users
[4] Step 2

2. **New Drug PA Criteria** – See complete PA criteria under the Prior Authorization Criteria tab[2].

   - **Alpelisib (Vijoice):**
     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 a Food and Drug Administration (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

[2] http://www.iowamedicaidpdl.com/pa_criteria

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.

- **Maralixibat (Livmarli):**

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.

- **Mavacamten (Camzyos):**
  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) ≥ 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.

3. **Changes to Existing PA Criteria** – *Changes are italicized or stricken.* See complete PA criteria under the Prior Authorization Criteria tab[3].

   - **CNS Stimulants and Atomoxetine:**
     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

[3] http://www.iowamedicaidpdl.com/pa_criteria

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.*

- **Dupilumab (Dupixent):**
  PA 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*
  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*

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

- **Sedative/Hypnotics, Non-Benzodiazepine:**

Preferred agents are available without 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*
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
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.

- **Vericiguat (Verquvo):**

PA 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*

~~4. Patient is within the FDA labeled age for indication; and~~

7. Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:
   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.

4. **Point of Sale Billing Updates:**

   **ProDUR Quantity Limits:** The following quantity limit edits will be implemented. A comprehensive list of all quantity limit edits appears on the Quantity Limit Chart[4].

| Drug Product | Quantity | Days' Supply |
|---|---|---|
| Camzyos 2.5 MG, 5 MG, 10 MG, 15 MG | 30 | 30 |
| Lamotrigine 25 MG tab & ODT, 50 MG ODT, 100 MG tab & ODT | 120 | 30 |
| Lamotrigine 150 MG tab | 60 | 30 |
| Livmarli 9.5 mg/mL | 90 mL | 30 |
| Qelbree 200 MG | 90 | 30 |
| Vijoice 50 MG & 125 MG blister pack | 1 pack (28 tabs) | 28 |
| Vijoice 250 MG blister pack | 1 pack (56 tabs) | 28 |

5. **DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website[5] under the "Newsletters" link.

We encourage providers to visit the PDL website[6] to view all recent changes to the PDL. If you have questions, please contact the pharmacy prior authorization helpdesk at 1-877-776-1567, locally in Des Moines at 515-256-4607, or by e-mail at info@iowamedicaidpdl.com.

[4] http://www.iowamedicaidpdl.com/billing_quantity_limits
[5] http://www.iadur.org/
[6] http://www.iowamedicaidpdl.com/