

INFORMATIONAL LETTER NO. 2013-MC-FFS

DATE: April 30, 2019

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 (FQHC), Indian Health Service, Maternal Health Centers, Certified Nurse Midwife, Community Mental Health, Family Planning, Residential Care Facilities, ICF/ID State and Community Based ICF/ID Providers, Physician Assistants

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

FROM: Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: June 1, 2019

- Changes to the Preferred Drug List (PDL) Effective January 1, 2019.** Refer to the [PDL website](#)¹ to review the complete PDL.

<u>Preferred</u>	<u>Non-Preferred</u>	<u>Recommended</u>	<u>Non-Recommended</u>
Clobazam	Abilify MyCite ²	Tibsovo ¹	Abiraterone ¹
Galafold ³	Albendazole		Braftovi ¹
Krintafel	Altreno Lotion ¹		Copiktra ¹
Movantik ¹	Amphetamine Sulfate Tablets ¹		Daurismo ¹
Sofosbuvir/Velpatasvir ¹	Azelaic Acid Gel 15% ¹		Lorbrena ¹
	Bryhali Lotion ¹		Mektovi ¹
	Cequa		Talzenna ¹
	Cinacalcet		Vizimpro ¹
	D-penamamine		Xospata ¹
	Doptelet ¹		
	Emgality ¹		
	Epclusa ¹		

¹ <http://www.iowamedicaidpdl.com/>

<u>Preferred</u>	<u>Non-Preferred</u>	<u>Recommended</u>	<u>Non-Recommended</u>
	Epidiolex		
	Farxiga ¹		
	Jivi		
	Ledipasvir/ Sofosbuvir ¹		
	Lexette Foam ¹		
	Mafenide Acetate Packet for Topical Solution		
	Miconazole-Zinc Oxide-White Petrolatum Ointment ¹		
	Nivestym ¹		
	Nocdurna ¹		
	Pimecrolimus ¹		
	Promacta Powder ¹		
	Qbrexza		
	Silodosin		
	Tegsedi		
	Testosterone Gel 1.62% ¹		
	Tiglutik Oral Suspension		
	Tolsura ¹		
	Toremifene		
	Ventolin HFA		
	Xarelto 2.5mg		
	Xelpros Emulsion		
	Xigduo XR ¹		
	Xofluza		
	Xyosted ¹		
	Yupelri		
	Zolpidem SL Tablets ¹		

¹Clinical PA Criteria Apply

²Step 3

³PA required for diagnosis confirmation

- 2. Pharmacy Benefit Policy Changes-** Effective June 1, 2019, coverage for the drugs listed below will be removed under the pharmacy benefit. Coverage will continue however, to be available through the medical benefit for Exondys 51, Gablofen, Inflectra, Lidocaine 2% Gel, Lioresal Intrathecal, Nucala and Remicade.

3. **New Drug Prior Authorization Criteria-** See complete prior authorization criteria under the [Prior Authorization Criteria tab](#)².

▪ **Desmopressin Acetate (Noctiva):**

Prior authorization is required for Noctiva (desmopressin acetate). Payment will be considered for patients when the following criteria are met:

1. Patient is 50 years of age or older; and
2. Patient has a diagnosis of nocturnal polyuria as confirmed by a 24-hour collection which notes the presence of greater than 33% of 24-hour urine production occurring at night; and
3. Patient awakens at least 2 times at night to void; and
4. Patient has attempted fluid restriction in the evenings without improvement in nocturnal polyuria; and
5. Patient is not taking a diuretic in the evening; and
6. Patient does not have any of the following contraindications:
 - a) Current or previous history of hyponatremia; and
 - b) Primary nocturnal enuresis; and
 - c) Polydipsia; and
 - d) Concomitant use with loop diuretics, systemic or inhaled glucocorticoids; and
 - e) Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion; and
 - f) Estimated glomerular filtration rate < 50 mL/min/1.73 m²; and
 - g) Illnesses that can cause fluid or electrolyte imbalance; and
 - h) New York Heart Association (NYHA) Class II-IV congestive heart failure; and
 - i) Uncontrolled hypertension.

Initial requests will be considered for 3 months. Requests for continuation of therapy will require the following:

1. Patient continues to meet above criteria; and
2. Patient has experienced a decrease in nocturnal voiding; and
3. There is no evidence of toxicity (e.g., hyponatremia, fluid retention, or electrolyte imbalances).

▪ **Elagolix (Orilissa)**

Prior authorization is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
2. Pregnancy has been ruled out; and
3. Patient does not have osteoporosis; and

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

4. Patient does not have severe hepatic impairment; and
5. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine and gemfibrozil); and
6. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and
7. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
8. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose.

Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.

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

4. **Changes to Existing Prior Authorization Criteria- *Changes are italicized or stricken.*** See complete prior authorization criteria under the [Prior Authorization Criteria tab](#)³.

▪ **Hematopoietics/Chronic ITP (formerly Thrombopoietin Receptor Agonists):**

~~Payment~~ Prior authorization is required for *hematopoietics/chronic ITP agents* a preferred thrombopoietin receptor agonist. *Request must adhere to all FDA approved labeling.* ~~Payment for a non-preferred hematopoietic/chronic ITP agent thrombopoietin receptor agonist will be considered following documentation of a recent trial and therapy failure with a preferred hematopoietic/chronic ITP agent thrombopoietin receptor agonist, when applicable, unless such a trial would be medically contraindicated. Payment will only be considered under the following conditions: for cases in which there is~~

1. A diagnosis of *thrombocytopenia with chronic immune thrombocytopenia* thrombocytopenic purpura (ITP) (Promacta, Nplate, or Tavalisse)
 - a. *Patient has documentation of an insufficient response to a corticosteroid, an immunoglobulin, or the patient has undergone a splenectomy.*
2. ~~Payment for eltrombopag (Promacta[®]) for the treatment of chronic hepatitis C associated thrombocytopenia will only be considered to allow for initiation and/or maintenance of interferon-based therapy with ribavirin when the patient has a baseline platelet count less than 75×10^9 L. Requests will not be considered under the following conditions:~~
 - a. ~~Patient taking direct acting antiviral agents for the treatment of chronic hepatitis C genotype 1 infection in addition to interferon-based therapy~~

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

with ribavirin.

- ~~b. Patients taking direct acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.~~
- ~~c. Patients with decompensated liver disease with a Child-Pugh score > 6 (Class B & C).~~
- ~~d. Patients with a history of ascites.~~
- ~~e. Patients with hepatic encephalopathy.~~
- 3. Payment for eltrombopag (Promacta[®]) for the treatment of a diagnosis of severe aplastic anemia (Promacta) will only be considered under the following conditions:
 - a. Patient has documentation of an insufficient response or intolerance to at least one prior immunosuppressive therapy; and
 - b. Patient has a platelet count less than or equal to $30 \times 10^9/L$.
 - c. If criteria for coverage are met, initial authorization will be given for 16 weeks. Documentation of hematologic response after 16 weeks of therapy will be required for further consideration.
- 4. A diagnosis of thrombocytopenia with chronic liver disease in patients who are scheduled to undergo a procedure (Doptelet, Mulpleta)
Documentation of the following:
 - a. *Pre-treatment platelet count; and*
 - b. *Scheduled dosing prior to procedure; and*
 - c. *Therapy completion prior to scheduled procedure; and*
 - d. *Platelet count will be obtained prior to procedure.*

▪ **Kalydeco (Ivacaftor):**

Prior authorization is required for Kalydeco[™] (ivacaftor). Payment will be considered for patients when the following criteria are met:

- 1. Patient ~~meets the FDA approved age is 2 years of age or older;~~ and

▪ **Oral Constipation Agents:**

Prior authorization is required for oral constipation agents *subject to clinical criteria. Payment for non-preferred oral constipation agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred oral constipation agent.* Payment will be considered under the following conditions:

- 1. Patient ~~meets the FDA approved age is 18 years of age or older;~~ and
- 4. Patient has one of the following diagnoses:
 - b. A diagnosis of irritable bowel syndrome with constipation (Amitiza[®], Linzess[™], Trulance[®])
 - i. Patient is female (Amitiza[®] only); and
 - ii. Patient has ~~recurrent abdominal pain or discomfort at least 3 on average at least 1 days per week month~~ in the last 3 months associated with two (2) or more of the following:
 - 1. ~~Improvement with~~ *Related to* defecation;
 - 2. ~~Onset~~ *Associated* with a change in stool frequency; and/or

- 3. ~~Onset~~ Associated with a change in stool form
 - c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza[®], Movantik[™], Relistor[®], or Symproic[®])
 - iii. ~~Patient has documentation of an adequate trial and therapy failure with Amitiza[®], if prior authorization request is for a different oral constipation agent.~~
- **Orkambi (Lumacaftor/Ivacaftor)**
 Prior authorization is required for Orkambi[™] (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:
 1. Patient *meets the FDA approved age is 6 years of age or older*; and

5. Point of Sale Billing Issues:

- a. **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
Amphetamine Salt Combo 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg, 30mg Tablets	30	30
Clobazam 2.5mg/mL Oral Suspension	480mL	30
Dextroamphetamine 5mg, 10mg	30	30
Dexmethylphenidate 2.5mg, 5mg, 10mg Tablets	30	30
Krintafel	4	30
Methylphenidate 5mg, 10mg Chew Tablets	30	30
Methylphenidate 5mg, 10mg, 20mg Tablets	30	30
Zenzedi 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg Tablets	30	30

- b. **Fifteen (15) Day Initial Prescription Supply Limit List:** The initial fifteen (15) day prescription limit list will be updated. Please refer to the updated list located at www.iowamedicaidpdl.com under the Preferred Drug Lists link.

⁴ http://www.iowamedicaidpdl.com/billing_quantity_limits

c. ProDUR Age Edits (in addition to PDL requirements): An age edit will be implemented on the following medications:

- Adderall, Adzenys ODT, Desoxyn, Dexedrine, Dyanavel XR, Evekeo, Mydayis, Vyvanse: PA required < 3 years of age and > 20 years of age.
- Adderall XR, Dexedrine ER, Focalin, Focalin XR, Aptensio XR, Concerta, Cotelpla XR ODT, Daytrana, Metadate CD, Methylin, QuilliChew, Quillivant XR, Ritalin IR/LA/SR: PA required < 6 years of age and > 20 years of age.

d. Concurrent Therapy Edit- CNS Stimulants and Atomoxetine: For members under 21 years of age, one unit of a short-acting stimulant with a long-acting stimulant will be allowed. A quantity limit of one unit per day will be placed on all short-acting stimulants.

6. Preferred Brand Name Drugs on the PDL-Pharmacy Clarification

When a status change occurs for a previously preferred brand name drug to non-preferred status, up to a *minimum* of 30 days transition period is given to pharmacies to help utilize existing brand name product in stock in an effort to decrease a pharmacy's remaining brand name drug inventory (see PDL comment section regarding transition periods exceeding 30 days). If additional stock remains beyond this time period, pharmacies may call the POS Helpdesk at 877-463-7671 or 515-256-4608 (local) to request an override for the non-preferred brand name drug with a recent status change.

7. 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 go to the [PDL website](#)⁶ to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or e-mail info@iowamedicaidpdl.com.

⁵ <http://www.iadur.org/>

⁶ <http://www.iowamedicaidpdl.com/>