Department of HUMAN SERVICES

INFORMATIONAL LETTER NO. 2230-MC-FFS

DATE: April 26, 2021

TO: Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse Practitioners (ARNP), Therapeutically Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics, Skilled Nursing Facilities, Intermediate Care Facilities, Nursing Facilities – Mental Illness, 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, and Physician Assistants

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

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

RE: June 2021 Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: June 1, 2021

1. **Changes to the Preferred Drug List (PDL) Effective June 1, 2021.** Refer to the PDL website[1] to review the complete PDL.

Preferred	Non-Preferred	Non-Recommended
Efavirenz/Emtricitabine/ Tenofovir	Alkindi[1]	Gavreto[1]
Lampit	Asenapine[2]	
Nyvepria[1]	Atripla	
Orladeyo[3]	Deferiprone	
Sunosi[1,4]	Emtricitabine/ Tenofovir	
	Eysuvis	
	Fosfomycin	
	Icosapent	
	Impeklo[1]	
	Ivermectin Lotion	
	Lapatinib	

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

	Levothyroxine Capsules	
	Licart[1]	
	Lubiprostone[1]	
	Lyumjev	
	Lyumjev KwikPen	
	Meloxicam Capsules[1]	
	Metyrosine	
	Mycapssa	
	Naproxen Sodium ER Tab 750mg[1]	
	Nitazoxanide	
	Oriahnn[1]	
	Phexxi	
	Reditrex[1]	
	Rufinamide	
	Sapropterin[1]	
	Sumansetron[1]	
	Sutab	
	Tavaborole[1]	
	Thyquidity	
	Timolol Maleate PF Ophth Soln	
	Tobramycin Neb 300mg/4mL	
	Trilociclo	
	Tyblume	
	Verquvo	
	Xywav[1]	

[1]Clinical PA criteria apply
[2]Step 3
[3]PA for diagnosis confirmation
[4]Step through armodafinil or modafinil

2. New Drug Prior Authorization Criteria. See complete prior authorization criteria under the Prior Authorization Criteria tab[2].

- **Satralizumab (Enspryng):**
  Prior authorization (PA) is required for satralizumab (Enspryng). Payment will be considered under the following conditions:

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

1. Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and
2. Patient is anti-aquaporin 4 (AQP4) seropositive (attach documentation); and
3. Patient meets the FDA approved age and dosing; and
4. Patient has a history of at least 1 relapse in the previous 12 months prior to initiation of therapy; and
5. Patient has been tested for tuberculosis prior to the initiation of therapy and does not have active or untreated latent tuberculosis; and
6. Patient has been tested for hepatitis B virus (HBV) prior to the initiation of therapy and confirmed negative for active HBV; and
7. Prescribed by a neurologist.

If criteria for coverage are met, initial requests will be given for 1 year. Additional authorizations will be considered upon documentation of clinical response to therapy (i.e. a reduction in the frequency of relapse).

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

- **Elagolix Products [formerly Elagolix (Orilissa)]:**
  Prior authorization (PA) is required for *elagolix containing drugs*. Payment will be considered for patients when the following is met:
  5. *Requests for elagolix (Orilissa) will be considered under the following conditions:*
     a. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
     b. 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
     c. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
     d. Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.
     e. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose~~.~~*; or*
  6. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) will be considered under the following conditions:*
     a. *Patient is premenopausal; and*

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

b. *Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and*
c. *Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and*
d. *Patient has documentation of a previous trial and therapy failure with tranexamic acid.*
e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
f. *Requests will be considered for a maximum of 24 months of treatment.*

- **Select Anticonvulsants [formerly Cannabidiol (Epidiolex]:**
  Prior authorization (PA) is required for select anticonvulsants. Payment will be considered under the following conditions:
  1. Patient meets the FDA approved age for submitted diagnosis and drug; and
  2. Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, with documentation of an adequate trial and inadequate response with at least two preferred concomitant antiepileptic drugs (AEDs), if available; and
  3. Is prescribed by or in consultation with a neurologist; and
  4. Patient's current weight is provided; and
  5. Follows FDA approved dosing for indication and drug. The total daily dose does not exceed the following:

  a. Cannabidiol
     i. Lennox-Gastaut syndrome or Dravet syndrome: 20 mg/kg/day; or
     ii. Tuberous sclerosis complex: 25 mg/kg/day; or
  b. Fenfluramine
     i. With concomitant stiripentol (plus clobazam): 0.4 mg/kg/d with a maximum of 17 mg per day; or
     ii. Without concomitant stiripentol: 0.7 mg/kg/day with a maximum of 26 mg per day; or
  c. Stiripentol
     i. Prescribed concomitantly with clobazam; and
     ii. 50 mg/kg/day with a maximum of 3,000 mg/day.

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

4. Removal of Existing Prior Authorization Criteria:
Due to voluntary withdrawal by the manufacturer Smith & Nephew (labeler code 50484) from the Medicaid Drug Rebate Program, Regranex has been removed from coverage, thus prior authorization criteria are no longer applicable.

5. Point of Sale Billing Updates:

a. Automatic Refill Programs: Rules became effective March 1, 2021, which establishes pharmacy policies and procedures for Medicaid coverage and reimbursement of prescription drug refills through an automatic refill program. Requirements can be found in 441 Iowa Administrative Code 78.2(6) and below:

1. Automatic refills are allowed. Participation in an automatic refill program is voluntary and opt-in only, on a drug-by-drug basis.
2. The program must have:
- Easy-to-locate contact information through telephone, the program's website, or both;
- Easy-to-understand patient materials on how to select or unselect drug(s) for inclusion and how to disenroll;
- Confirmation that the member wants to continue in the automatic refill program at least annually;
- Confirmation of continued medical necessity provided by the Medicaid member or person acting as an authorized representative of the member, before the member receives the medication at the pharmacy or before the medication is mailed or delivered to the member, without which confirmation the drug(s) must be credited back to the Medicaid program; and
- Records of all consents, which must be in electronic or written format and must be available for review by auditors

<u>Important Requirements:</u>
1. A member is required to **agree** to participate in the program and on a drug-by-drug basis. The member should be able to easily stop this service at any time.
2. Continued medical necessity must be verified **before** providing each prescription refill.
3. Programs should be utilized to **improve medication compliance** for chronic medical conditions.
4. Medication stockpiling, continued filling of discontinued medications, and any other forms of **fraud, waste and abuse must be discouraged and monitored.**
5. **Documentation** of all required consents must be adequately maintained and easily retrievable for audit purposes.

b. **ProDUR Edits:** A maximum milligram per day edit will be placed on gabapentin (3600 mg) and pregabalin immediate release (600 mg), limiting each medication to the maximum milligram per day across all strengths.

6. **DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website[4] under the "Newsletters" link. We encourage providers to go to the PDL website[5] to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization helpdesk by phone at 877-776-1567 or 515-256-4607 (locally in Des Moines), or by e-mail at info@iowamedicaidpdl.com.

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