



Iowa Department of Human Services

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INFORMATIONAL LETTER NO.1824-MC-FFS

DATE: August 28, 2017

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

APPLIES TO: Managed Care, Fee-for-Service

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

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: October 1, 2017

1. **Changes to the Preferred Drug List (PDL) Effective October 1, 2017.** Refer to the [PDL website](#)¹ to review the complete PDL.

<u>Preferred</u>	<u>Non-Preferred</u>	<u>Recommended</u>
Acyclovir Oral Suspension	Airduo RespiClick	Kisqali ¹
Atomoxetine ^{1,6}	Arymo ER ¹	Kisqali Pak Femara ¹
Atovaquone	Baraclude	
Atovaquone/Proguanil	Buprenorphine Patch ¹	
Clobetasol Propionate Cream, Foam & Ointment	Depakote Sprinkles ²	
Divalproex Sprinkle Capsules	Dupixent	
Dofetilide	Epinephrine Auto-Injector ⁴	
Entecavir	Eucrisa ¹	
Epinephrine Auto-Injector ⁵	Ezetimibe/ Simvastatin	
Lantus SoloSTAR	Fluticasone/ Salmeterol	
Levemir FlexTouch	Imitrex Nasal Spray ¹	
Mavyret ¹	Malarone	

¹ <http://www.iowamedicaidpdl.com/>

Methylphenidate ER Capsules (LA) ¹	Mepron	
Nitrofurantoin Monohydrate Macrocrystals	Micardis ¹	
Sumatriptan Nasal Spray ¹	Micardis HCT ¹	
Temozolomide ¹	MorphaBond ER ¹	
Valganciclovir	Olux ¹	
	Olux-E ¹	
	Ritalin LA ¹	
	Strattera ¹	
	Synjardy XR ¹	
	Tazarotene ¹	
	Temodar ¹	
	Temovate ¹	
	Tikosyn	
	Trulance ¹	
	Valcyte	
	Xadago	
	Xatmep	
	Xultophy ¹	
	Zovirax Oral Suspension	

¹Clinical PA Criteria Apply

²Grandfather Existing Users with Seizure Diagnosis

³Authorized Generic Only

⁴Labeler 54505

⁵Labeler 49502

⁶Labeler 66993

2. Pharmacy Benefit Policy Changes- Effective October 1, 2017, 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 Aplisol, Botox, Cortrosyn, Cosyntropin, Dysport, Myobloc, Sylvant, Thyrogen, Vivitrol, Xeomin, Xiaflex, and Xolair.

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

▪ **Calcifediol (Ryaldee):**

Prior authorization is required for calcifediol (Ryaldee). Initial requests will be considered for patients when the following criteria are met:

1. Patient is 18 years of age or older; and
2. Patient is being treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) as documented by a current glomerular filtration rate (GFR); and

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

3. Patient is not on dialysis; and
4. Patient has a serum total 25-hydroxyvitamin D level less than 30 ng/mL and a serum corrected total calcium below 9.8 mg/dL within the past three months; and
5. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with a preferred vitamin D analog for a minimum of three months.
6. Initial requests will be considered for a dose of 30 mcg once daily for three months.

Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to need to be treated for secondary hyperparathyroidism associated with a diagnosis of stage 3 or stage 4 chronic kidney disease (CKD) documented by a current glomerular filtration rate (GFR); and
2. Patient has a serum total 25-hydroxyvitamin D level between 30 and 100 ng/mL, a serum corrected total calcium below 9.8 mg/dL, and a serum phosphorus below 5.5 mg/dL.

▪ **Crisaborole (Eucrisa):**

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

1. Patient has a diagnosis of mild to moderate atopic dermatitis; and
2. Patient is within the FDA labeled age; and
3. Patient has failed to respond to good skin care and regular use of emollients; and
4. Patient has documentation of an adequate trial and therapy failure with two preferred medium to high potency topical corticosteroids for a minimum of two consecutive weeks; and
5. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of four weeks; and
6. Patient will continue with skin care regimen and regular use of emollients.
7. Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.

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

▪ **Deflazacort (Emflaza):**

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

1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and
2. Patient is within the FDA labeled age; and
3. Patient experienced onset of weakness before five years of age; and
4. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and
5. Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (significant weight gain defined as one standard deviation above baseline percentile rank weight for height) while on prednisone at a therapeutic dose; and
6. Is dosed based on FDA approved dosing.

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

▪ **GLP-1 Agonist/Basal Insulin Combinations:**

Prior authorization is required for GLP-1 agonist receptor/basal insulin combination products. Payment will be considered for patients when the following criteria are met:

1. A diagnosis of type 2 diabetes mellitus; and
2. Patient is 18 years of age or older; and
3. The patient has not achieved HgbA1C goals after a minimum three-month trial with metformin at a maximally tolerated dose, unless evidence is provided that use of this agent would be medically contraindicated; and
4. Documentation of an adequate trial and inadequate response with at least one preferred GLP-1 receptor agonist and one preferred long-acting insulin agent concurrently; and
5. Will not be used concurrently with prandial insulin; and
6. Clinical rationale is provided as to why the patient cannot use a preferred GLP-1 receptor agonist and a preferred long-acting insulin agent concurrently; and
7. Medication will be discontinued and alternative antidiabetic products will be used if patients require a daily dosage of:
 - a. Soliqua below 15 units or over 60 units, or
 - b. Xultophy persistently below 16 units or over 50 units.

▪ **Lesinurad (Zurampic):**

Prior authorization is required for lesinurad (Zurampic). Requests for doses above the FDA approved dose will not be considered. Requests will be considered for patients when the following criteria are met:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of hyperuricemia associated with gout; and

3. Patient has not achieved target serum uric acid levels or patient remains symptomatic with a maximally tolerated dose of a xanthine oxidase inhibitor (allopurinol or febuxostat) for at least three months; and
4. Patient has documentation of a previous trial and therapy failure with probenecid in combination with a xanthine oxidase inhibitor; and
5. Patient has an estimated creatinine clearance (eCrCl) > 45 mL/min; and
6. Documentation is provided lesinurad will be used in combination with a xanthine oxidase inhibitor.
 - a. If taking allopurinol, dose should be ≥ 300 mg per day (or ≥ 200 mg per day in patients with an eCrCl < 60 mL/min); and
7. Patient does not have a contraindication to therapy including any of the following:
 - a. Severe renal impairment (eCrCl <30 mL/min),
 - b. End stage renal disease,
 - c. Kidney transplant recipient,
 - d. On dialysis,
 - e. Tumor lysis syndrome, or
 - f. Lesch-Nyhan syndrome.

If criteria for coverage are met, initial requests will be given for six months.

Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to take medication in combination with a xanthine oxidase inhibitor.
 - a. If allopurinol, dose should be ≥ 300 mg per day (or ≥ 200 mg per day in patients with an eCrCl < 60 mL/min)
2. Patient has an eCrCl > 45 mL/min; and
3. Patient does not have a contraindication to therapy including any of the following:
 - a. Severe renal impairment (eCrCl <30 mL/min),
 - b. End stage renal disease,
 - c. Kidney transplant recipient,
 - d. On dialysis,
 - e. Tumor lysis syndrome, or
 - f. Lesch-Nyhan syndrome.
4. Documentation of a positive clinical response to lesinurad.

The required trials may be overridden when documented evidence is provided that use of the agent(s) would be medically contraindicated.

▪ **New to Market Drugs:**

Prior authorization is required for newly marketed drugs. Payment will be considered for patients when the following criteria are met:

1. Patient has an FDA approved or compendia indication for the requested drug; and
2. If the requested drug falls in a therapeutic category/class with existing prior authorization criteria, the requested drug must meet the criteria for the same indication; or
3. If no clinical criteria are established for the requested drug, patient has tried and failed at least two preferred drugs, when available, from the Iowa Medicaid Preferred Drug List (PDL) for the submitted indication; and
4. Request must adhere to all FDA approved labeling.

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

Once newly marketed drugs are reviewed by the Pharmaceutical & Therapeutics Committee, they will be placed on the PDL which will dictate ongoing PA criteria, if applicable.

▪ **Sapropterin (Kuvan):**

Prior authorization is required for sapropterin (Kuvan). Requests for doses above the FDA approved dose will not be considered. Initial requests will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of phenylketonuria (PKU); and
2. Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and
3. Patient has a baseline blood Phe level ≥ 360 micromol/L while following a Phe restricted diet, obtained within two weeks of initiation of sapropterin therapy (attach lab results); and
4. Patient's current weight is provided; and
5. Request is for an FDA approved starting dose (10mg/kg/day for patients one month to six years and 10-20mg/kg/day for patients seven years and older); and
6. Blood Phe levels will be measured after one week of therapy and at least one other time during the first month of therapy.

Initial requests will be considered for one month to assess response to therapy. Continuation of therapy will be considered when the following criteria are met:

1. Patient's current weight is provided; and

2. Patient continues on a Phe restricted diet; and
3. For patients initiated at a dose of 10mg/kg/day and the blood Phe level did not decrease from baseline, dose may be increased to 20mg/kg/day. Approval will be given for one month to assess response to therapy.
4. For patients initiated at a dose of 20mg/kg/per day or those increased to this dose after one month of therapy at 10mg/kg/day, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30 percent reduction in blood Phe level. If blood Phe level does not decrease after one month at 20mg/kg/day, the patient is considered a non-responder and no further requests will be approved.
5. Maintenance dose requests will be considered for patients that have responded to therapy, based on the above criteria, at six month intervals. Documentation of compliance to diet and updated blood Phe levels documenting continued response to therapy are required for further consideration.

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

- **Eluxadoline (Viberzi):**

Patient does not have any of the following contraindications to therapy:

- *Patient is without a gallbladder.*

- **Hepatitis C Treatments:**

Prior authorization is required for hepatitis C treatments. 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 under the following conditions:

1. Patient has a diagnosis of chronic hepatitis C *and*
2. *Patient's age and/or weight is within the FDA labeled age and/or weight; and*
17. *Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.*

5. **Point of Sale Billing Issues:**

- a. **ProDUR Quantity Limits:** The following quantity limit edits will be implemented effective *October 1, 2017*. A comprehensive list of all quantity limit edits appears on the [Quantity Limit Chart](#)⁴.

Drug Product	Quantity	Days Supply
Enoxaparin (Lovenox)	18mL	30

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

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

30mg/0.3mL		
Enoxaparin (Lovenox) 40mg/0.4mL	24mL	30
Enoxaparin (Lovenox) 60mg/0.6mL	36mL	30
Enoxaparin (Lovenox) 80mg/0.8mL	48mL	30
Enoxaparin (Lovenox) 100mg/mL	60mL	30
Enoxaparin (Lovenox) 120mg/0.8mL	48mL	30
Enoxaparin (Lovenox) 150mg/mL	60mL	30
Enoxaparin (Lovenox) 300mg/3mL	180mL	30
Fragmin 2,500 u/0.2mL	12mL	30
Fragmin 5,000 u/0.2mL	12mL	30
Fragmin 7,500 u/0.3mL	18mL	30
Fragmin 10,000 u/mL	60mL	30
Fragmin 12,500 u/0.5mL	30mL	30
Fragmin 15,000 u/0.6mL	36mL	30
Fragmin 18,000 u/0.72mL	43.2mL	30
Fragmin 25,000 u/mL	60mL	30

b. ProDUR Age Edit Codeine Containing Products: Effective *October 1, 2017*, an age edit will be implemented restricting use in children under 18 years of age and removing the 72-hour emergency supply allowance for this age group.

c. Point of Sale (POS) Pharmacy Claims for Incarcerated Members: Effective *October 1, 2017*, pharmacy claims submitted through POS will reject for members identified as being incarcerated.

d. Morphine Milligram Equivalents (MME) Edit: Effective *spring 2018* prior authorization will be required for use of high-dose opioids ≥ 200 MME per day. Patients undergoing active cancer treatment or end-of-life care will not be subject to prior authorization criteria. The MME edit will gradually be decreased over time to 90 MME per day.

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/>