Iowa Department of Human Services

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

Charles M. Palmer
Director

INFORMATIONAL LETTER NO.1664-MC

DATE: April 29, 2016

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 and Managed Care Organizations (MCOs)

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

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: June 1, 2016

1. **Changes to the Preferred Drug List (PDL) Effective June 1, 2016.** Refer to complete PDL located at www.iowamedicaidpdl.com.

Preferred	Non-Preferred	Non-Recommended
Embeda	Android[1]	Adynovate
Fentanyl 25, 50, 75 & 100 mcg Patches	Aristada[2]	Alecensa[1]
Genvoya	Belbuca[1]	Coagadex
Gleevec[1]	Cresemba[1]	Cotellic[1]
Methyltestosterone[1]	Dutasteride	Lonsurf[1]
Modafinil[1]	Dutasteride-Tamsulosin	Ninlaro[1]
Priftin	Enstilar	Nuwiq
Vigamox	Imatinib[1]	Odomzo[1]
Voriconazole Oral Suspension[1]	Kadian[1] 10, 40, 130 & 150mg	Tagrisso[1]
	Migranal	
	Molindone	
	MS Contin[1]	
	Myambutol	
	Nucala	
	Paliperidone ER[2]	
	Pimozide	

	Prednisolone ODT	
	Provigil[1]	
	Strensiq	
	Testred[1]	
	Tranexamic Acid	
	Tresiba FlexTouch[1]	
	Veltassa	
	Vfend Oral Suspension[1]	
	Vivlodex[1]	

[1]Clinical PA Criteria Apply
[2]Step 3

2. New Drug Prior Authorization Criteria- See complete prior authorization criteria posted at www.iowamedicaidpdl.com under the Prior Authorization Criteria tab.

- **PCSK9 Inhibitors:**

Prior authorization is required for PCSK9 Inhibitors. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older (or, for Homozygous Familial Hypercholesterolemia patient is 13 years of age or older); AND
2. Current use of a statin and documentation of adherence to prescribed lipid lowering medications for the previous 90 days is provided (further defined below, by diagnosis); AND
3. Is to be prescribed as an adjunct to a low fat diet; AND
4. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; AND
5. Documentation patient has been counseled on importance of abstinence from tobacco and, if a current smoker, be encouraged to enroll in a smoking cessation program; AND
6. Is prescribed by a lipidologist, cardiologist, or endocrinologist.
7. The 72-hour emergency supply rule does not apply to PCSK9 Inhibitors.
8. Prescriber and dispensing pharmacy will educate the patient on proper storage and administration. Improperly stored medications will not be replaced.
9. Lost or stolen medication replacement requests will not be authorized.
10. Goal is defined as a 50 percent reduction in untreated baseline LDL-C.
11. Is prescribed for one of the following diagnoses:

<u>Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)</u>

1. Total cholesterol > 290mg/dL or LDL-C > 190mg/dL; AND

a. Presence of tendon xanthomas; OR

b. In first or second degree relative, one of the following:

i. Documented tendon xanthomas; or
ii. MI at age ≤60 years; or
iii. Total cholesterol > 290mg/dL; OR
c. Confirmation of diagnosis by gene or receptor testing (attach results); AND
2. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily, PLUS cholestyramine daily.

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; AND
2. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily, PLUS cholestyramine daily.

Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) – Repatha (evolocumab) only

1. Total cholesterol and LDL-C > 600mg/dL and triglycerides within reference range; OR
2. Confirmation of diagnosis by gene or receptor testing (attach results); AND
3. Unable to reach goal LDL-C with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (including atorvastatin and rosuvastatin), PLUS ezetimibe (Zetia) 10mg daily, PLUS cholestyramine daily.

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

Initial and Renewal Authorizations HeFH or ASCVD

- Initial
    - Praluent 75mg or Repatha 140mg every 2 weeks for 8 weeks (4 doses).
- Renewal
    - Lipid profile required at week 8, week 24, and every 6 months thereafter; and
    - Patient continues therapy with a maximally tolerated statin dose and remains at goal; and
    - Patient has continued compliance with a low fat diet; and

Praluent

- If LDL-C at goal, continue therapy at 75mg every 2 weeks for 24 weeks.
- If LDL-C not at goal, dose increase to 150mg every 2 weeks for 8 weeks (4 doses) and repeat LDL-C in 8 weeks.
  - If repeat LDL-C not at goal, discontinue Praluent.
  - If repeat LDL-C at goal, continue therapy at 150mg every 2 weeks for 24 weeks; or

Repatha

- If LDL-C at goal, continue therapy at 140mg every 2 weeks for 24 weeks.
- If LDL-C not at goal, discontinue Repatha.

HoFH (Repatha only)

- Initial
  - Repatha 420mg (3x140mg autoinjectors) every month for 3 months.
- Renewal
  - Lipid profile required after three months (third dose) and every six months thereafter; and
  - Continued therapy with a maximally tolerated statin dose.
    - If LDL-C at goal, continue therapy at 420mg every month for six months.
    - If LDL-C not at goal, discontinue Repatha*;* and
  - Patient has continued compliance with a low fat diet.

Quantity Limits

Praluent/Repatha for HeFH or ASCVD

- A quantity limit of one syringe/pen/autoinjector per fill will apply (requires refill every 14 days).

Repatha for HoFH only

- A quantity limit of one three-pack per month

- **Valsartan/Sacubitril (Entresto):**

  Prior authorization is required for valsartan/sacubitril (Entresto™). Requests above the manufacturer recommended dose will not be considered. Payment 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 NYHA Functional Class II, III, or IV heart failure; and
  3. Patient has a left ventricular ejection fraction (LVEF) ≤40%; and
  4. Patient has documentation of a previous trial and therapy failure or intolerance to an ACE inhibitor at a maximally tolerated dose; and
  5. Patient has documentation of a previous trial and therapy failure or intolerance to an angiotensin II receptor blocker (ARB); and
  6. Is to be administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other ARB (list medications patient is currently taking for the treatment of heart failure); and

7. Will not be used in combination with an ACE inhibitor or ARB; and
8. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and
9. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and
10. Patient is not pregnant; and
11. Patient does not have severe hepatic impairment (Child Pugh Class C); and
12. Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).

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

If the criteria for coverage are met, initial authorization will be given for three months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.

3. Changes to Existing Prior Authorization Criteria- *Changes are italicized.* See complete prior authorization criteria posted at www.iowamedicaidpdl.com under the Prior Authorization Criteria tab.

- **Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products:**
  Prior authorization is required for non-parenteral vasopressin derivatives of posterior pituitary hormone products. Payment for preferred non-parenteral vasopressin derivatives of posterior pituitary hormone products will be authorized for the following diagnoses:
  1. Diabetes Insipidus
  2. Hemophilia A
  3. Von Willebrand's disease

  Requests for desmopressin nasal spray for the treatment of nocturnal enuresis will not be considered. Payment for non-preferred non-parenteral vasopressin derivatives will be authorized only for cases in which there is documentation of trial(s) and therapy failure with the preferred agent(s). *Please refer to the Selected Brand-Name Drugs prior authorization form if requesting a non-preferred brand-name product.*

- **Sodium Oxybate (Xyrem):**
  Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients *18* years of age or older under the following conditions:

  3. Patient is enrolled in the Xyrem® *REMS* Program.

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

   a. **ProDUR Quantity Limits:** The following quantity limit edits will be implemented effective *June 1, 2016*. A comprehensive list of all quantity limit edits appears on our website, www.iowamedicaidpdl.com under the heading, “Quantity Limits”.

Drug Product	Quantity	Days Supply
Alprazolam 0.25mg	120	30
Alprazolam 0.5mg	120	30
Alprazolam 1mg	120	30
Alprazolam 2mg	120	30
Amphetamine Salt Combo 12.5mg	90	30
Amphetamine Salt Combo 20mg	90	30
Clonazepam 0.5mg	120	30
Clonazepam 1mg	120	30
Clonazepam 2mg	120	30
Dexmethylphenidate 2.5mg	60	30
Dexmethylphenidate 5mg	60	30
Dexmethylphenidate 10mg	60	30
Embeda 20-0.8mg	60	30
Embeda 30-1.2mg	60	30
Embeda 50-2mg	60	30
Embeda 60-2.4mg	60	30
Embeda 80-3.2mg	60	30
Embeda 100-4mg	60	30
Fentanyl 25mcg	10	30
Fentanyl 50mcg	10	30
Fentanyl 75mcg	10	30
Fentanyl 100mcg	10	30
Focalin XR 5mg	30	30
Focalin XR 10mg	30	30
Focalin XR 15mg	30	30
Focalin XR 20mg	30	30
Focalin XR 25mg	30	30
Focalin XR 30mg	30	30
Lorazepam 0.5mg	120	30
Lorazepam 1mg	120	30
Lorazepam 2mg	120	30
Methylphenidate 5mg	90	30
Methylphenidate 10mg	90	30
Methylphenidate 20mg	90	30
Methylphenidate ER 18mg	30	30
Methylphenidate ER 27mg	30	30

5. **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.

6. **DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website, www.iadur.org under the "Newsletters" link.

We encourage providers to go to the website at www.iowamedicaidpdl.com 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 email info@iowamedicaidpdl.com.