IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, April 6, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for PCSK9 Inhibitors, with quantity limits; Valsartan/Sacubitril (*Entresto*); Sodium Oxybate (*Xyrem*); and Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products. The DUR Commission also discussed and made recommendations to update the current Public Comment policy. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a December 7, 2015 letter that was sent to them detailing the proposed criteria for PCSK9 Inhibitors, with quantity limits; Valsartan/Sacubitril (*Entresto*); Sodium Oxybate (*Xyrem*); and Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products.

PCSK9 Inhibitors

Newly Proposed Prior Authorization Criteria

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% reduction in untreated baseline LDL-C.
11. Is prescribed for one of the following diagnoses:

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)

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 3 months (third dose) and every 6 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™)

Newly Proposed Prior Authorization Criteria

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 3 months. Requests for continuation of therapy may be provided if prescriber documents adequate response to therapy.

Sodium Oxybate (Xyrem®)

Current Prior Authorization Criteria

Prior authorization is required for sodium oxybate (Xyrem®). Payment will be considered for patients 16 years of age or older under the following conditions:

1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline.
2. Patient is enrolled in the Xyrem® Success Program.
3. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.
4. Patient has been instructed to not drink alcohol when using Xyrem®.
5. Patients with and without a history of substance abuse have been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence.
6. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered.
7. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ prior to requesting prior authorization.

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

Proposed Prior Authorization Criteria (*changes are italicized*)

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

1. A diagnosis of cataplexy associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trial and therapy failure with one of the following tricyclic antidepressants: clomipramine, imipramine, or protriptyline; *or*
2. A diagnosis of excessive daytime sleepiness associated with narcolepsy verified by a recent sleep study (including PSG, MSLT, and ESS) and previous trials and therapy failures at a therapeutic dose with a preferred amphetamine and non-amphetamine stimulant.
3. Patient is enrolled in the Xyrem® *REMS* Program.
4. Patient has been instructed to not drink alcohol when using Xyrem®.
5. Patients with and without a history of substance abuse have been counseled regarding the potential for abuse and dependence and will be closely monitored for signs of abuse and dependence.
6. Requests for patients with concurrent use of a sedative hypnotic or a semialdehyde dehydrogenase deficiency will not be considered.
7. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ prior to requesting prior authorization.

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

Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products
(Removal of PA criteria for nocturnal enuresis)

Current Prior Authorization Criteria
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

Payment for oral vasopressin derivatives of posterior pituitary hormone products used in the treatment of primary nocturnal enuresis will be authorized for patients who are six years of age or older for periods of six months. Approvals will be granted for subsequent six-month periods only after a drug-free interval to assess the need for continued therapy. 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).

Proposed Prior Authorization Criteria (*changes italicized*)
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.*

The DUR Commission also discussed the current Public Comment policy which allows individuals attending the meeting the opportunity to address the Commission twice during the open portion of the meeting with a limit of 5 minutes or less for comment. The DUR Commission made a recommendation to decrease the number of public comment periods from two to one, with no change to the time limit.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for PCSK9 Inhibitors, with quantity limits; Valsartan/Sacubitril (*Entresto*); Sodium Oxybate (*Xyrem*); and Non-Parenteral Vasopressin Derivatives of Posterior Pituitary Hormone Products, in addition to the recommendation for Public Comment policy.

Sincerely,

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Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME