IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

611 5th Avenue – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O
Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Jason Wilbur, M. D.
Charles Wadle, D.O.
John Ellis, Pharm.D.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

August 6, 2020

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
611 5th Avenue
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 5, 2020. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Cystic Fibrosis Agents, Oral; Valsartan/Sacubitril (Entresto); Direct Oral Anticoagulants; Voxelotor (Oxbryta); IL-5 Antagonists; and removal of PA criteria for Insulin, Pre-Filled Insulin Pens. Additionally, the DUR Commission members recommended changes to the DUR Public Comment Policy that will be reflected on the DUR website, www.iadur.org, and in the DUR Policy and Procedures. The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to a March 17, 2020 letter that was sent to them detailing the proposed criteria for Cystic Fibrosis Agents, Oral; Valsartan/Sacubitril (Entresto); Direct Oral Anticoagulants; Voxelotor (Oxbryta); IL-5 Antagonists; and removal of PA criteria for Insulin, Pre-Filled Insulin Pens.

Cystic Fibrosis Agents, Oral (Applies to Kalydeco, Orkambi, Symdeko, and Trikafta)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for oral cystic fibrosis agents. Payment will be considered for patients when the following criteria are met:

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of cystic fibrosis (CF); and
3. Patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene confirmed by an FDA-cleared CF mutation test (attach test results) for which the requested drug is indicated; and
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST, ALT, and bilirubin) are provided; and

6. Requests for Trikafta will not be considered for patients with severe hepatic impairment (Child-Pugh Class C); and
7. Will not be used with other CFTR modulator therapies.

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. Adherence to oral cystic fibrosis therapy is confirmed; and
2. Liver function tests (AST, ALT, and bilirubin) are assessed every 3 months during the first year of treatment and annually thereafter.

Valsartan/Sacubitril (Entresto)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) 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 within the FDA labeled age for indication; and*
2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
   ~~a. Patient is 18 years of age or older; and~~
   b. Patient has a left ventricular ejection fraction (LVEF) ≤40%; and
   c. Patient is currently tolerating treatment with an ACE inhibitor or angiotensin ll receptor blocker (ARB) at a therapeutic dose, where replacement with valsartan/sacubitril is recommended to further reduce morbidity and mortality; and
   d. 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); *or* ~~and~~
3. *Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class II to IV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤ 40%; and*
4. Will not be used in combination with an ACE inhibitor or ARB; and
5. Will not be used in combination with aliskiren (Tekturna) in diabetic patients; and
6. Patient does not have a history of angioedema associated with the use of ACE inhibitor or ARB therapy; and
7. Patient is not pregnant; and
8. Patient does not have severe hepatic impairment (Child Pugh Class C)*.*~~; and~~
~~9. 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.

Direct Oral Anticoagulants (formerly Novel Oral Anticoagulants)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is not required for preferred ~~novel~~ *direct* oral anticoagulants (~~N~~*DOACs*). PA is required for non-preferred ~~N~~*D*OACs. *Requests will be considered for FDA approved dosing and length of therapy for submitted diagnosis* Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications *for the requested drug* under the following conditions:

1. *Patient is within the FDA labeled age for indication; and*
2. Patient does not have a mechanical heart valve; and
3. Patient does not have active bleeding; and
4. For a diagnosis of atrial fibrillation or stroke prevention, patient has the presence of at least one additional risk factor for stroke, with a CHA_2DS_2-VASc score ≥1; and
5. A recent creatinine clearance (CrCl) is provided; and
6. A recent Child-Pugh score is provided; and
7. Patient's current body weight is provided; and
8. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred ~~N~~*NDOACs; and*~~.~~
9. For requests for edoxaban, *when prescribed for the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE),* documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin) *is provided*.

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

Voxelotor (Oxbryta)

Newly Proposed Clinical Prior Authorization Criteria
Prior authorization is required for Oxbryta (voxelotor). Payment will be considered for patients when the following criteria are met:

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of sickle cell disease (SCD); and
3. Requested dose is within the FDA approved dosing; and
4. Patient has experienced at least two sickle cell-related vasoocclusive crises within the past 12 months (documentation required); and
5. Patient has documentation of an adequate trial and therapy failure with hydroxyurea; and
6. Baseline hemoglobin (Hb) range is ≥5.5 to ≤10.5 g/dL; and
7. Is prescribed by or in consultation with a hematologist; and
8. Patient is not receiving concomitant blood transfusion therapy.

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. Documentation of an increase in hemoglobin by ≥1 g/dL from baseline; and
2. Documentation of a decrease in the number of sickle cell-related vasoocclusive crises.

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

IL-5 Antagonists

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)

Prior authorization is required for *IL-5 antagonists* ~~mepolizumab (Nucala)~~. Requests will not be considered with concurrent use *with another monoclonal antibody* ~~of omalizumab~~. Payment will be considered under the following conditions:

1. Patient meets the FDA approved age *for submitted diagnosis*; and
2. *Is dosed within FDA approved dosing for submitted diagnosis and age; and*
3. Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and
    a. Patient has a pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells per mcL within 12 months prior to initiation of therapy; and
    b. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and
    c. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and
    d. A pretreatment forced expiratory volume in 1 second (FEV_1) < 80% predicted *in adults and < 90% in adolescents*; *or* ~~and~~
4. *Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and*
    a. *Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and*
    b. *One of the following:*
        i. *Eosinophil count greater than 1000 cells/mcL; or*
        ii. *Eosinophil count greater than 10% of the total leukocyte count; and*
5. *Prescribed~~r~~ by or in consultation with* ~~is~~ an allergist, immunologist, ~~or~~ pulmonologist*, or rheumatologist.*~~; and~~

If criteria for coverage are met, an initial authorization will be given for 3 months to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered ~~if one or more of~~ *when* the following criteria are met:

Severe Asthma with an Eosinophilic Phenotype:

1. Patient continues to receive therapy with an ICS, LABA and LTRA; and
2. Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or
3. Patient has experienced a decrease in administration of rescue medication (albuterol); or
4. Patient has experienced a decrease in exacerbation frequency; or
5. Patient has experienced an increase in predicted FEV_1 from the pretreatment baseline.

Eosinophilic Granulomatosis with Polyangiitis:

1. *Patient has demonstrated a positive clinical response to therapy (increase in remission time).*

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

Insulin, Pre-Filled Pens
Recommendation to remove clinical prior authorization criteria

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for pre-filled insulin pens as designated on the Preferred Drug List (PDL). For pre-filled insulin pens requiring PA where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

1. The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and
2. There is no caregiver available to provide assistance, and
3. Patient does not reside in a long-term care facility, and
4. For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).

For pre-filled insulin pens requiring PA where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

1. Preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and
2. Non-preferred pre-filled insulin pens- Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).

Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Cystic Fibrosis Agents, Oral; Valsartan/Sacubitril (Entresto); Direct Oral Anticoagulants; Voxelotor (Oxbryta); IL-5 Antagonists; and removal of PA criteria for Insulin, Pre-Filled Insulin Pens.

Sincerely,

Pamela Smith R.Ph.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

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