IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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August 6, 2015

Susan L. Parker, R.Ph., Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 5, 2015. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Topical Corticosteroids, Ivacaftor (Kalydeco®), Idiopathic Pulmonary Fibrosis, Select Oncology Agents and Edoxaban (Savaysa®). 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 June 10, 2015 letter that was sent to them detailing the proposed criteria for Topical Corticosteroids, Ivacaftor (Kalydeco®), Idiopathic Pulmonary Fibrosis, Oral Oncology agents, and Edoxaban (Savaysa®).

Topical Corticosteroids

Newly Proposed Prior Authorization Criteria

Prior authorization is required for non-preferred topical corticosteroids. Payment will be considered for patients when there is documentation of adequate trials and therapy failures with at least two preferred, chemically distinct, topical corticosteroid agents within the same potency class or a higher potency class in the past 12 months. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Ivacaftor (Kalydeco®)

Proposed Prior Authorization Criteria (*changes italicized*)

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

1. Patient is *2* years of age or older; and

2. Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and *R117H* as detected by a FDA-cleared CF mutation test; and
3. Prescriber is a CF specialist or pulmonologist; and
4. *Baseline liver function tests (AST/ALT) and FEV_1, if age appropriate, are provided; and*
5. Patient does not have one of the following infections: *Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus.*

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. *Adherence to ivacaftor therapy is confirmed; and*
2. *Response to therapy is documented by prescriber (e.g., improved FEV_1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and*
3. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.*

Idiopathic Pulmonary Fibrosis

Newly Proposed Prior Authorization Criteria

Prior authorization is required for pirfenidone (Esbriet®) and nintedanib (Ofev®). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient is 40 years of age or older; and
2. Is prescribed by a pulmonologist; and
3. Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation):
    - Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
    - A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and
4. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and
5. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and
6. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; and
7. Patient does not have hepatic impairment as defined below:
    - Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
    - Pifenidone - Patient does not have severe hepatic impairment (Child Pugh C); and
8. Patient does not have renal impairment as defined below:
    - Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or
    - Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
9. Patient is a nonsmoker or has been abstinent from smoking for at least six weeks.

If the criteria for coverage are met, initial requests will be given for 6 months. Additional

authorizations will be considered at 6 month intervals when the following criteria are met:

1. Adherence to pirfenidone (Esbriet®) and nintedanib (Ofev®) is confirmed; and
2. Patient is tolerating treatment defined as improvement or maintenance of disease (<10% decline in percent predicted FVC or < 200 mL decrease in FVC); and
3. Documentation is provided that the patient has remained tobacco-free; and
4. ALT, AST, and bilirubin are assessed periodically during therapy.

Edoxaban (Savaysa®)

Newly Proposed Prior Authorization Criteria

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

1. Patient does not have a mechanical heart valve; and
2. Patient does not have moderate to severe mitral stenosis; and
3. Patient does not have active pathological bleeding; and
4. A recent creatinine clearance (CrCl) is provided and is within specified range listed below; and
5. Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); and
6. Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and
7. Patient has documentation of a previous trial and therapy failure with apixaban or rivaroxaban, where applicable.

Atrial Fibrillation

1. Patient has documentation of a diagnosis of non-valvular atrial fibrillation; with
2. Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥1; and
3. Patient does not have a creatinine clearance (CrCl) > 95 mL/min.
4. Requests will be considered for the following dosing:
    a. 60mg once daily in patients with a CrCl of > 50 mL/min to ≤ 95 mL/min; or
    b. 30mg once daily in patients with a CrCl of 15 to 50 mL/min

Treatment of Deep Vein Thrombosis or Pulmonary Embolism

1. Patient has documentation of a current deep vein thrombosis or pulmonary embolism; with
2. Documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).
3. Requests will be considered for the following dosing:
    a. 60mg once daily; or
    b. 30mg once daily in patients with any of the following:
        i. CrCl 15 mL/min to 50 mL/min
        ii. Body weight ≤60 kg

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

The DUR Commission discussed the proposed prior authorization criteria for Select Oncology Agents in addition to reviewing written comments received on this topic. The DUR Commission made changes to the proposed prior authorization criteria and asked the criteria be sent out to the medical and pharmacy associations for their review and comment.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Topical Corticosteroids, Ivacaftor (Kalydeco®), Idiopathic Pulmonary Fibrosis, and Edoxaban (Savaysa®).

Sincerely,

Pamela Smith R.Ph.

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Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph., IME
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