IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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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 3, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Topical Acne and Rosacea Products; Novel Oral Anticoagulants (NOACs); Patiromer (Veltassa); and Mepolizumab (Nucala). The DUR Commission members also made a recommendation to implement a ProDUR quantity limit on all strengths of rivaroxaban (Xarelto). 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 6, 2016 letter that was sent to them detailing the proposed criteria for Topical Acne and Rosacea Products; NOACs; Patiromer (Veltassa); and Mepolizumab (Nucala) as well as the proposed quantity limits for rivaroxaban (Xarelto).

Topical Acne and Rosacea Products (replaces Anti-Acne Topical Products and Topical Retinoids for Acne prior authorizations)

Newly Proposed Prior Authorization Criteria (combined for topical antibiotics and topical retinoids)

Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions:

1. Documentation of diagnosis.
2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid for moderate to severe acne.
3. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid).

4. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent.
5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products.
6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis.
7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.
8. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.

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

Novel Oral Anticoagulants (removal of PA criteria for Pradaxa and Xarelto and combination of existing criteria for remaining non-preferred agents)

Newly Proposed Prior Authorization Criteria for Non-Preferred NOACs
Prior authorization is not required for preferred novel oral anticoagulants (NOACs). Prior authorization is required for non-preferred NOACs. Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications under the following conditions:

1. Patient does not have a mechanical heart valve; and
2. Patient does not have active bleeding; and
3. 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
4. A recent creatinine clearance (CrCl) is provided; and
5. A recent Child-Pugh score is provided; and
6. Patient's current body weight is provided; and
7. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred NOACs.
8. For requests for edoxaban, documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).

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

In addition to the above PA criteria the DUR Commission made the recommendation to implement the following ProDUR quantity limits on rivaroxaban (Xarelto):

- 10mg tablet – 30 tablets per 30 days
- 15mg tablets – allow twice daily dosing for 21 days followed by once daily dosing
- 20mg tablets – 30 tablets per 30 days

Potassium Binders

Newly Proposed Prior Authorization Criteria

Prior authorization (PA) is required for non-preferred potassium binders. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of chronic hyperkalemia; and
3. Patient has documentation of a recent trial and therapy failure with sodium polystyrene sulfonate.

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

Mepolizumab (Nucala)

Newly Proposed Prior Authorization Criteria

Prior authorization is required for mepolizumab (Nucala). Requests will not be considered with concurrent use of omalizumab. Payment will be considered under the following conditions:

1. Patient is 12 years of age or older; and
2. Patient has a diagnosis of severe asthma with an eosinophilic phenotype; and
3. Patient has a pretreatment blood eosinophil count of ≥150 cells per mcL within the previous 6 weeks or blood eosinophils of ≥300 cells per mcL within 12 months prior to initiation of therapy; and
4. 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
5. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus an LABA and LTRA; and
6. A pretreatment forced expiratory volume in 1 second (FEV_1) <80% predicted; and
7. Prescriber is an allergist, immunologist, or pulmonologist; and
8. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.

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 the following criteria are met:

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.

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

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Topical Acne and Rosacea Products; NOACs; Patiromer (Veltassa); Mepolizumab (Nucala) as well as the recommended quantity limits for rivaroxaban (Xarelto).

Sincerely,

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Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
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