IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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December 8, 2016

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, December 7, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Omalizumab (Xolair); Oral Constipation Agents; and Multiple Sclerosis Agents, Oral. Additionally, the DUR Commission members also made a recommendation to implement the following ProDUR edits: a morphine milligram equivalent (MME) per day limit across the opioid drug class and a quantity limit on Narcan Nasal Spray. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an October 7, 2016 letter that was sent to them detailing the proposed criteria for Omalizumab (Xolair); Oral Constipation Agents; and Multiple Sclerosis Agents, Oral as well as the proposed morphine milligram equivalent (MME) per day limit across the opioid drug class and the quantity limit on Narcan Nasal Spray.

Omalizumab (Xolair)

Proposed Clinical Prior Authorization Criteria (*changes italicized*)
Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

Moderate to Severe Persistent Asthma

1. Patient has a diagnosis of moderate to severe persistent asthma for at least one year; and
2. Patient is *6* years of age or older; and
3. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
4. Pretreatment IgE level is *within the following range*:

a. *Adults and adolescent patients 12 years of age or older* - 30 IU/mL *to* 700 IU/mL; *or*
b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*

5. Patient's weight *is within the following range:*
   a. *Adults and adolescent patients 12 years of age or older* - 30 kg *to* 150 kg; *or*
   b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150kg; and*
6. History of positive skin or RAST test to a perennial aeroallergen; and
7. Prescriber is an allergist, immunologist, or pulmonologist; and
8. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, *AND a leukotriene receptor antagonist, and* is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy*; and*
9. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight.*
10. Patient has access to an *epinephrine injection* to treat allergic reactions that may occur after administration of Xolair®.

If the criteria for coverage are met, the initial authorization will be given for 16 weeks to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, *and leukotriene receptor antagonist.*

Chronic Idiopathic Urticaria

1. Patient has a diagnosis of moderate to severe chronic idiopathic urticaria; and
2. Patient is 12 years of age or older; and
3. *Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and*
4. Patient has documentation of a trial and therapy failure with at least one *preferred* second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and
5. Patient has documentation of a trial and therapy failure with at least one *preferred* first-generation antihistamine; and
6. Patient has documentation of a trial and therapy failure with at least one *preferred* potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
7. Patient has documentation of a trial and therapy failure with a preferred leukotriene receptor antagonist in combination with a first- or second-generation antihistamine.

If criteria for coverage are met, the initial authorization will be given for 12 weeks to assess the need for continued therapy.

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

Oral Constipation Agents

Proposed Clinical Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for *oral constipation agents*. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient must have documentation of adequate trials and therapy failures with *both of* the following:
    a. *Stimulant laxative (senna) plus* saline laxative (milk of magnesia); and
    b. *Stimulant laxative (senna) plus* osmotic laxative (polyethylene glycol or lactulose).
3. Patient does not have a known or suspected mechanical gastrointestinal obstruction; and
4. Patient has one of the following diagnoses:
    a. A diagnosis of chronic idiopathic constipation (Amitiza® or Linzess™)
        i. Patient has less than 3 spontaneous bowel movements (SBMs) per week; and
        ii. Patient has two or more of the following symptoms within the last 3 months:
            1. Straining during at least 25% of bowel movements;
            2. Lumpy or hard stools for at least 25% of bowel movements; and
            3. Sensation of incomplete evacuation for at least 25% of bowel movements; and
        iii. Documentation the patient is not currently taking constipation causing therapies
    b. A diagnosis of irritable bowel syndrome with constipation (Amitiza® or Linzess™)
        i. Patient is female (Amitiza® only); and
        ii. Patient has abdominal pain or discomfort at least 3 days per month in the last 3 months associated with two (2) or more of the following:
            1. Improvement with defecation;
            2. Onset associated with a change in stool frequency; and/or
            3. Onset associated with a change in stool form.
    c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™ or *Relistor*®)
        i. Patient has been receiving stable opioid therapy for at least 30 days as seen in the patient's pharmacy claims; and
        ii. Patient has less than 3 spontaneous bowel movements (SBMs) per week, with at least 25% associated with one or more of the following:
            1. Hard to very hard stool consistency;
            2. Moderate to very severe straining; and/or
            3. Having a sensation of incomplete evacuation.
        iii. Patient has documentation of an adequate trial and therapy failure with Amitiza®, if prior authorization request is for a different oral constipation agent.

If the criteria for coverage are met, initial authorization will be given for 12 weeks to assess the response to treatment. Requests for continuation of therapy may be provided if prescriber documents adequate response to treatment.

Multiple Sclerosis Agents - Oral

Proposed Prior Authorization Criteria (*changes italicized*)
Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions:

1. A diagnosis of relapsing forms of multiple sclerosis; and
2. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis; *and*
3. *Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.*

For patients initiating therapy with fingolimod (Gilenya™), *a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims*, documentation of the following must be provided:

1. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class lll/lV heart failure.
2. Patient does not have a history or presence of Mobitz Type ll 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.
3. Patient does not have a baseline QTc interval ≥ 500ms.
4. Patient is not being treated with Class la or Class lll anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio®), documentation of the following must be provided:

1. Patient does not have severe hepatic impairment.
2. A negative pregnancy test for females of childbearing age.
3. Use of a reliable form of contraception for females of childbearing age.
4. Patient is not taking leflunomide.

For patients initiating therapy with dimethyl fumarate (Tecfidera™), documentation of the following must be provided:

1. Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.
2. Upon renewal, documentation of an updated CBC.

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

Additionally, the DUR Commission made the recommendation to: 1) Implement a morphine milligram equivalent (MME) per day limit across the opioid drug class and 2) Implement a quantity limit on Narcan Nasal Spray. Below are the recommended ProDUR edits:

1. Opioids – 90 morphine milligram equivalents (MME) per day across the opioid drug class. Any claims ≥90 MME per day will require a prior authorization (criteria currently in development by the DUR Commission)
2. Narcan Nasal Spray – one box (2 doses) per 365 days. Quantities greater than 1 box per 365 days will require a prior authorization (criteria currently in development by the DUR Commission)

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Omalizumab (Xolair); Oral Constipation Agents; and Multiple Sclerosis Agents, Oral as well as the recommended morphine milligram equivalent (MME) per day limit across the opioid drug class and quantity limit on Narcan Nasal Spray.

Sincerely,

Pamela Smith R.Ph.

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

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