IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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August 7, 2014

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 6, 2014. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Omalizumab (Xolair®), Apixaban (Eliquis®), and Dabigatran (Pradaxa®) and coverage of Naloxone Auto-injector (Evzio) by Iowa Medicaid. 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 11, 2014 letter that was sent to them detailing the proposed criteria for Omalizumab (Xolair®), Apixaban (Eliquis®), and Dabigatran (Pradaxa®).

Omalizumab (Xolair®)

Changes are 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 12 years of age or older; and
3. Pretreatment IgE level is between 30 IU/mL and 700 IU/mL; and
4. Patient's weight is between 30 kg and 150 kg; and
5. History of positive skin or RAST test to a perennial aeroallergen; and
6. Prescriber is an allergist, immunologist, or pulmonologist; and
7. Patient is currently using a high dose inhaled corticosteroid AND long-acting beta-agonist, is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy.
8. Patient must have access to an EpiPen 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 and long-acting beta-agonist.

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. *Patient has documentation of a trial and therapy failure with at least one second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and*
4. *Patient has documentation of a trial and therapy failure with at least one first-generation antihistamine; and*
5. *Patient has documentation of a trial and therapy failure with at least one potent H1 receptor antagonist (hydroxyzine and/or doxepin); and*
6. *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.

Apixaban (Eliquis®)

Changes are italicized:
Prior authorization is required for apixaban (Eliquis®). Payment will be considered under the following conditions:

1. Patient does not have a mechanical prosthetic heart valve; and
2. Patient does not have active pathological bleeding; and
3. Patient has a diagnosis of non-valvular atrial fibrillation; with
4. 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
5. Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 1; OR
6. *For patients requiring deep vein thrombosis (DVT) prophylaxis undergoing hip or knee replacement. Requests will be considered when the patient has contraindications to use of the preferred agent(s). If patient meets criteria for coverage, requests will be approved for the following doses:*
    - *Hip replacement: 2.5 mg twice daily for up to 35 days following hip replacement; or*
    - *Knee replacement: 2.5 mg twice daily for up to 12 days following knee replacement.*

Dabigatran (Pradaxa®)

Changes are italicized:
Prior authorization is required for dabigatran (Pradaxa®). Payment will be considered for patients under the following conditions:

1. Patient does not have a mechanical prosthetic heart valve; and
2. Patient does not have active pathological bleeding; and
3. *Patient has* documentation of a previous trial and therapy failure with warfarin (TIA, stroke, *recurrence of DVT/PE*, or inability to maintain a therapeutic INR with a minimum 6 month trial).

Non-valvular atrial fibrillation (in addition to the above)

- Patient has the presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥ 1; and
- Patient does not have severe renal impairment (CrCl < 15mL/min) or is not on dialysis.

Treatment and prevention of DVT or PE (in addition to the above)

- *Patient does not have a CrCl < 30mL/min or is not on dialysis.*
- *For patients with current DVT/PE, in addition to warfarin trial, patient must have documentation* of 5 to 10 days of parenteral anticoagulation prior to initiation of dabigatran.

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

The DUR Commission discussed coverage of Naloxone Auto-injector (Evzio). The DUR determined the delivery system used for administration of naloxone was a convenience for the patient or patient's caregiver. Additionally, the DUR determined that the use of intranasal naloxone would be the least costly service which would reasonably meet the medical need of the patient. Since the DUR determined Evzio is a convenience item and there are other cost-effective alternatives to Evzio, the DUR recommends not covering this product.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria Omalizumab (Xolair®), Apixaban (Eliquis®), and Dabigatran (Pradaxa®) and coverage of Naloxone Auto-injector (Evzio).

Sincerely,

Pamela Smith R.Ph.

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Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph., IME
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