IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
1305 East Walnut – 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.
Lisa Todd, R.Ph.

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

November 3, 2021

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
1305 East Walnut
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 3, 2021. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Topical Acne and Rosacea Products; Omalizumab (Xolair); Vericiguat (Verquvo); Viloxazine (Qelbree); Non-Biologic Agents for Ulcerative Colitis; and Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral. In addition, the DUR Commission discussed ProDUR quantity limits for viloxazine (Qelbree). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an August 9, 2021 letter that was sent to them detailing the proposed criteria for Topical Acne and Rosacea Products; Omalizumab (Xolair); Vericiguat (Verquvo); Viloxazine (Qelbree); Non-Biologic Agents for Ulcerative Colitis; and Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral and ProDUR quantity limits for viloxazine (Qelbree).

Topical Acne and Rosacea Products

Current Clinical Prior Authorization Criteria

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.
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.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is *not* required for *preferred* topical acne agents (topical antibiotics and topical retinoids) ~~or topical rosacea agents~~ *for members under 21 years of age*. ~~Payment~~ *PA is required* for *preferred topical acne agents for members 21 years or older,* non-*preferred* topical acne *agents* and *all* topical rosacea agents*. Payment* will be considered under the following conditions:

1. Documentation of diagnosis*; and*
2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid*; and*
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)*; and*
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*; and*
5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products~~.~~*; and*
6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis*; and*
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.

Omalizumab (Xolair) Prefilled Syringe

Previous Prior Authorization Criteria (prior to removal from PDL in October 2017)
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.

<u>Chronic Idiopathic Urticaria</u>

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.

Newly Proposed Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization *(PA)* is required for omalizumab *(*Xolair*) prefilled syringe*. *Requests for omalizumab (Xolair) lyophilized powder for reconstitution will not be considered through the pharmacy benefit.* Payment for omalizumab *(*Xolair*) prefilled syringe* will be *considered for FDA approved and compendia indications under the following conditions* ~~authorized when the following criteria are met~~:

1. *Patient meets the FDA approved age; and*
2. *Therapy will be initiated in a healthcare setting, under the guidance of a healthcare provider, where the patient can be closely observed for anaphylaxis and safety of therapy has been established after a minimum of 3 doses of omalizumab; and*
3. *The healthcare provider has determined self-administration with omalizumab is appropriate based on careful assessment of risk for anaphylaxis and mitigation strategies, as outlined in the label; and*
4. *Dose follows the FDA approved dosing for indication; and*
5. Prescriber is an allergist, *dermatologist,* immunologist, *otolaryngologist* or pulmonologist; and
6. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of *omalizumab (*Xolair*); and*
7. *Prescriber and dispensing pharmacy will educate patient on proper storage and administration. Improperly stored medications will not be replaced.*

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 150 kg; 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. *Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

~~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 *omalizumab (*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. *Requests for continuation of therapy will not be granted for patients who have not shown adequate response to omalizumab (Xolair) therapy.*

Nasal Polyps

1. *Patient has a diagnosis of nasal polyps; and*
2. *Pretreatment IgE level is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 IU/mL to 1500 IU/mL; and*
3. *Patient's weight is within the following range:*
    a. *Adults and adolescent patients 12 years of age or older - 30 kg to 150 kg; and*
4. *Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and*
5. *Will be used concurrently with a nasal corticosteroid; and*
6. *Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight. Note: according to the label, there is insufficient data to recommend a dose for certain pretreatment serum IgE levels and body weight. PA requests will be denied in these instances.*

If criteria for coverage are met, the initial authorization will be given for 24 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 omalizumab (Xolair) therapy and for patients who do not continue concurrent use with a nasal corticosteroid.

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

Vericiguat (Verquvo)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for vericiguat (Verquvo). Payment will be considered under the following conditions:

1. Patient has a diagnosis of symptomatic chronic heart failure (NYHF class II-IV) with a left ventricular ejection fraction (LVEF) ≤ 45%; and
2. Patient meets one of the following:
    a. Recent hospitalization for heart failure (within the last 6 months); or
    b. Recent need for outpatient intravenous diuretics (within the last 3 months); and
3. Patient is within the FDA labeled age for indication; and
4. Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after the last dose; and
5. Will not be used concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g., riociguat) or phosphodiesterase type 5 (PDE-5) inhibitors (e.g., sildenafil, tadalafil, vardenafil); and
6. Documentation of prior or current therapy, at a maximally tolerated dose, with one drug from each category below:
    a. Renin-angiotensin system inhibitor (angiotensin converting enzyme [ACEI], angiotensin receptor blocker [ARB], or angiotensin receptor-neprilysin inhibitor [ARNI]); and
    b. Evidence-based beta-blocker (carvedilol, metoprolol succinate, or bisoprolol); and
7. Is dosed based on FDA approved dosing; and
8. Initial requests for Verquvo 2.5 mg and 5 mg tablets will be limited to one 14-day supply for each strength.

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

Viloxazine (Qelbree)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for viloxazine (Qelbree). Payment will be considered under the following conditions:

1. Patient has a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV); and
2. Patient is between 6 and 17 years of age; and
3. Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational) and
4. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred amphetamine stimulant; and

5. Documentation of a previous trial and therapy failure at a therapeutic dose with at least one preferred methylphenidate stimulant; and
6. Documentation of a previous trial and therapy failure at a therapeutic dose with atomoxetine; and
7. Is dosed based on FDA approved dosing, and dose does not exceed 400 mg per day; and
8. Documentation of a recent clinical visit that confirms improvement in symptoms from baseline will be required for renewals or patients newly eligible that are established on medication to treat ADHD.

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

Select Non-Biologics for Ulcerative Colitis

Newly Proposed Clinical Prior Authorization
Prior authorization is required for select non-biologicals for ulcerative colitis (UC). Payment for non-preferred select non-biologics for UC may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment will be considered under the following conditions:

1. Patient has a diagnosis of moderately to severely active ulcerative colitis (UC) and
2. Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications; and
3. A documented trial and inadequate response to two preferred conventional therapies (immunomodulators) including aminosalicylates and azathioprine/6-mercaptopurine; and
4. A documented trial and inadequate response with a preferred biological DMARD; and
5. Will not be taken concomitantly with immunomodulators or biologic therapies.

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

Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral (Formerly Elagolix Products)

Current Clinical Prior Authorization Criteria (Elagolix Products)
Prior authorization (PA) is required for elagolix containing drugs. Payment will be considered for patients when the following is met:

1. Pregnancy has been ruled out; and
2. Patient does not have osteoporosis; and
3. Patient does not have severe hepatic impairment; and
4. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g., cyclosporine and gemfibrozil); and
5. Requests for elagolix (Orilissa) will be considered under the following conditions:
    a. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
    b. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and

c. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
d. Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.
e. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose; or

6. Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) will be considered under the following conditions:
    a. Patient is premenopausal; and
    b. Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and
    c. Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and
    d. Patient has documentation of a previous trial and therapy failure with tranexamic acid.
    e. Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.
    f. Requests will be considered for a maximum of 24 months treatment.

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

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization (PA) is required for ~~elagolix containing drugs~~ *oral gonadotropin-releasing hormone (GnRH) antagonists*. *Payment for non-preferred oral GnRH antagonists may be considered only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent.* Payment will be considered for patients when the following is met:

1. Pregnancy has been ruled out; and
2. Patient does not have osteoporosis; and
3. *Request adheres to all FDA approved labeling for requested drug, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
4. ~~Patient does not have severe hepatic impairment; and~~
5. ~~Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and~~
6. Requests for elagolix (Orilissa) will be considered under the following conditions:
    a. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
    b. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and
    c. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
    d. Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.
    e. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose; or
7. Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) *or relugolix, estradiol, norethindrone acetate (Myfembree)* will be considered under the following conditions:

a. Patient is premenopausal; and
b. Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and
c. Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and
d. Patient has documentation of a previous trial and therapy failure with tranexamic acid.
e. Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.
f. Requests will be considered for a maximum of 24 months treatment.

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

ProDUR Edit(s)

The DUR Commission recommends implementing the following ProDUR quantity limits:

Drug Product	**Proposed Quantity Limit per 30 Days**
Qelbree 100 mg	30 capsules
Qelbree 150 mg	60 capsules
Qelbree 200 mg	60 capsules

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; Omalizumab (Xolair); Vericiguat (Verquvo); Viloxazine (Qelbree); Non-Biologic Agents for Ulcerative Colitis; and Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist, Oral; and ProDUR quantity limits for viloxazine (Qelbree).

Sincerely,

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

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