IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 6, 2024. At this meeting, the DUR Commission members discussed updated prior authorization (PA) criteria for Biologicals for Inflammatory Bowel Disease; Janus Kinase Inhibitors; Maralixibat (Livmarli); Omalizumab (Xolair); Oral Glucocorticoids for Duchenne Muscular Dystrophy; Tralokinumab (Adbry); and new PA criteria for Zuranolone (Zurzuvae). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an August 19, 2024 letter that was sent to them detailing the updated PA criteria for Biologicals for Inflammatory Bowel Disease; Janus Kinase Inhibitors; Maralixibat (Livmarli); Omalizumab (Xolair); Oral Glucocorticoids for Duchenne Muscular Dystrophy; Tralokinumab (Adbry); and new PA criteria for Zuranolone (Zurzuvae).

Biologicals for Inflammatory Bowel Disease

Current Clinical Prior Authorization

Prior authorization (PA) is required for biologicals used for inflammatory bowel disease. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and
2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and
3. Patient has a diagnosis of Crohn's Disease – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or

methotrexate; or
4. Patient has a diagnosis of Ulcerative Colitis (moderate to severe) – Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine; and

In addition to the above:
Requests for TNF Inhibitors:
1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and
2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less; and

Requests for Interleukins:
1. Medication will not be given concurrently with live vaccines.

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 highlighted/italicized and/or stricken)
Prior authorization (PA) is required for biologicals used for inflammatory bowel disease. Request must adhere to all FDA approved labeling *for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations*. Payment for non-preferred biologicals for inflammatory bowel disease will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

~~1. Patient has been screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and~~
~~2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and~~
3. Patient has a diagnosis of *moderate to severe* Crohn's Disease*; or*
    a. ~~Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates (mesalamine, sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; or~~
4. Patient has a diagnosis of *moderate to severe* Ulcerative Colitis ~~(moderate to severe)~~*; and*
    a. ~~Payment will be considered following an inadequate response to two preferred conventional therapies including aminosalicylates and azathioprine/6-mercaptopurine; and~~
5. *Medication will be administered in the patient's home by patient or patient's caregiver.*

~~In addition to the above:~~
~~Requests for TNF Inhibitors:~~
~~1. Patient has not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and~~
~~2. Patient does not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class lll or lV and with an ejection fraction of 50% or less; and~~

~~Requests for Interleukins:~~
~~1. Medication will not be given concurrently with live vaccines.~~

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

Janus Kinase Inhibitors

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug, excluding requests for the FDA approved indication of alopecia areata, vitiligo, or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules when the following conditions are met:

1. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and
2. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
3. Patient has a diagnosis of:
    a. Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
        ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR
    b. Psoriatic arthritis (tofacitinib, upadacitinib); with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR
    c. Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with
        i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
        iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR
    d. Moderately to severely active Crohn’s disease (upadacitinib); with
        i. A documented trial and inadequate response to two preferred conventional therapies including aminosalicylates (sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; OR
    e. Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with
        i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and

ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
iii. A documented trial and inadequate response with a preferred TNF inhibitor; OR

f. Axial spondyloarthritis conditions (e.g., *a*nkylosing spondylitis or nonradiographic axial spondyloarthritis) (tofacitinib, upadacitinib); with
   i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and
   ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR
g. Atopic dermatitis; with
   i. Documentation patient has failed to respond to good skin care and regular use of emollients; and
   ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
   iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
   iv. For mild to moderate atopic dermatitis (ruxolitinib)
      a. A documented trial and therapy failure with crisaborole; and
      b. Affected area is less than 20% of body surface area (BSA); and
      c. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or
   v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):
      a. A documented trial and therapy failure with cyclosporine or azathioprine; and
      b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.

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

<u>Proposed Clinical Prior Authorization Criteria</u> (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug, excluding requests for the FDA approved indication of alopecia areata~~, vitiligo,~~ or other excluded medical use(s), as defined in Section 1927(d)(2) of the Social Security Act, State Plan, and Rules when the following conditions are met:

1. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biological therapies, or potent immunosuppressants (azathioprine or cyclosporine); and
2. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
3. Patient has a diagnosis of:
   a. Moderate to severe rheumatoid arthritis (baricitinib, tofacitinib, upadacitinib); with

i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR

b. Psoriatic arthritis (tofacitinib, upadacitinib); with
i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR

c. Moderately to severely active ulcerative colitis (tofacitinib, upadacitinib); with
~~i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and~~
ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR

d. Moderately to severely active Crohn's disease (upadacitinib); with
~~i. A documented trial and inadequate response to two preferred conventional therapies including aminosalicylates (sulfasalazine), azathioprine/6-mercaptopurine, and/or methotrexate; and~~
ii. A documented trial and inadequate response with a preferred TNF inhibitor; OR

e. Polyarticular Course Juvenile Idiopathic Arthritis (tofacitinib); with
~~i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and~~
ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
iii. A documented trial and inadequate response with a preferred TNF inhibitor; OR

f. Axial spondyloarthritis conditions (e.g., *a*nkylosing spondylitis or nonradiographic axial spondyloarthritis) (tofacitinib, upadacitinib); with
i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and
ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR

g. Atopic dermatitis; with
i. Documentation patient has failed to respond to good skin care and regular use of emollients; and
ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; *or* ~~and~~
iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
iv. For mild to moderate atopic dermatitis (ruxolitinib)*:*
~~a. A documented trial and therapy failure with crisaborole; and~~
b. Affected area is less than 20% of body surface area (BSA); and

c. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or

v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):
   a. A documented trial and therapy failure with *a systemic drug product for the treatment of moderate to severe atopic dermatitis, including biologics* ~~cyclosporine or azathioprine~~; and
   b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg~~.~~*; OR*

h. Nonsegmental vitiligo (ruxolitinib); with
   i. *A documented trial and inadequate response with a potent topical corticosteroid; or*
   ii. *A documented trial and inadequate response with a topical calcineurin inhibitor; and*
   iii. *The patient's body surface area (BSA) is less than or equal to the affected BSA per FDA approved label, if applicable.*

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

Maralixibat (Livmarli)

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for maralixibat (Livmarli). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a *JAG1* or *NOTCH2* mutation or deletion; and
3. Patient has cholestasis with moderate to severe pruritus; and
4. Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS; and
5. Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:
   a. Ursodeoxycholic acid (ursodiol)
   b. Cholestyramine
   c. Rifampin; and
6. Patient's current weight in kilograms (kg) is provided.

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

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritus symptoms and patient's current weight in kg.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted and/or stricken)

Prior authorization (PA) is required for maralixibat (Livmarli). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. *Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS or PFIC; and*
3. Patient has a diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing demonstrating a *JAG1* or *NOTCH2* mutation or deletion; and
    a. Patient has cholestasis with moderate to severe pruritus; and
    ~~b. Is prescribed by or in consultation with a hepatologist, gastroenterologist, or a prescriber who specializes in ALGS; and~~
    c. Documentation of previous trials and therapy failures, at a therapeutic dose, with at least two of the following agents:
        i. Ursodeoxycholic acid (ursodiol)
        ii. Cholestyramine
        iii. Rifampin; *or*
4. *Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) demonstrating a gene mutation affiliated with PFIC (i.e., ATP8B1, ABCB11, ABCB4, TJP2, or MYO5B); and*
    a. Genetic testing does not indicate PFIC type 2 with ABCB11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3); and
    b. Patient has moderate to severe pruritus associated with PFIC; and
5. Patient's current weight in kilograms (kg) is provided.

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

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Request for continuation of therapy will require documentation of an improvement in pruritus symptoms and patient's current weight in kg.

Omalizumab (Xolair)

<u>Current Clinical Prior Authorization Criteria</u>
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:

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. 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
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; or
    b. Pediatric patients 6 to less than 12 years of age - 20 kg to 150 kg; and
4. History of positive skin or RAST test to a perennial aeroallergen; and
5. 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
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 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 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
3. Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and
4. Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
5. 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.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/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. *Request must adhere to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings & precautions, drug interactions, and use in specific populations.* Payment for omalizumab (Xolair) prefilled syringe will be considered ~~for FDA approved and compendia indications~~ under the following conditions:

~~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. *For a diagnosis of asthma, chronic rhinosinusitis with nasal polyps, IgE-mediated food allergy, and any other FDA approved diagnosis where dosing is dependent on serum IgE level and body weight, the pretreatment IgE level and body weight, in kilograms (kg), is provided. 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; and*
7. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab; and
8. 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. ~~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~~
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; or~~
    b. ~~Pediatric patients 6 to less than 12 years of age - 20 kg to 150 kg; and~~
4. *Patient has a h*~~H~~istory of positive skin or RAST test to a perennial aeroallergen; and
5. 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~~
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 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 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
3. Patient has documentation of a trial and therapy failure with at least one preferred first-generation antihistamine; and
4. Patient has documentation of a trial and therapy failure with at least one preferred potent H1 receptor antagonist (hydroxyzine and/or doxepin); and
5. 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.

IgE Mediated Food Allergy

1. *Medication is being prescribed for the reduction of allergic reactions (Type 1) that may occur with accidental exposure to one or more foods in a patient that has an IgE-mediated food allergy; and*
2. *Diagnosis is confirmed by a skin prick test or in vitro test (attach results); and*
3. *Will be used in conjunction with food allergen avoidance.*

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

Oral Glucocorticoids for Duchenne Muscular Dystrophy (formerly Deflazacort [Emflaza])

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for Emflaza (deflazacort). Payment will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and
2. Patient is within the FDA labeled age; and
3. Patient experienced onset of weakness before 5 years of age; and
4. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and
5. Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (significant weight gain defined as 1 standard deviation above baseline percentile rank weight for height) while on prednisone at a therapeutic dose; and
6. Is dosed based on FDA approved dosing.

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 highlighted/italicized or stricken)
Prior authorization (PA) is required for *oral glucocorticoids for Duchenne muscular dystrophy* ~~Emflaza (deflazacort)~~. *Payment for non-preferred agents will be considered when there is documentation of a previous trial and therapy failure with a preferred agent.* Payment will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and

2. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations* ~~Patient is within the FDA labeled age~~; and
3. ~~Patient experienced onset of weakness before 5 years of age; and~~
4. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and
5. Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (significant weight gain defined as 1 standard deviation above baseline percentile rank weight for height) while on prednisone at a therapeutic dose. ~~; and~~
6. ~~Is dosed based on FDA approved dosing.~~

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

Tralokinumab-ldrm (Adbry)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for tralokinumab-ldrm (Adbry). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of moderate to severe atopic dermatitis; and
3. Is prescribed by or in consultation with a dermatologist; and
4. Patient has failed to respond to good skin care and regular use of emollients; and
5. Patient has documentation of an adequate trial and therapy failure with at least one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
6. Patient has documentation of a previous trial and therapy failure with a preferred topical immunomodulator for a minimum of 4 weeks; and
7. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
8. Patient will continue with skin care regimen and regular use of emollients.

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy and documentation patient will continue with skin care regimen and regular use of emollients.

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 and/or stricken)

Prior authorization (PA) is required for tralokinumab-Idrm (Adbry). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following conditions are met:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of moderate to severe atopic dermatitis; and
3. Is prescribed by or in consultation with a dermatologist; and
4. Patient has failed to respond to good skin care and regular use of emollients; and
5. Patient has documentation of an adequate trial and therapy failure with at least one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
6. Patient has documentation of a previous trial and therapy failure with a preferred topical immunomodulator for a minimum of 4 weeks; and
7. ~~Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and~~
8. Patient will continue with skin care regimen and regular use of emollients.

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy and documentation patient will continue with skin care regimen and regular use of emollients.

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

Zuranolone (Zurzuvae)

Newly Proposed Prior Authorization Criteria

Prior authorization (PA) is required for zuranolone (Zurzuvae). Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a diagnosis of postpartum depression (PPD); and
3. Patient is 12 months or less postpartum on the date of request (state date of delivery); and
4. The onset of the current depressive episode was during the third trimester or within 4 weeks postpartum; and
5. Patient has not received brexanolone for the current PPD episode; and
6. Only one course of treatment (i.e., 14 days) per pregnancy will be considered. Extension of therapy beyond 14 days will not be authorized.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Biologicals for Inflammatory Bowel Disease; Janus Kinase Inhibitors;

Maralixibat (Livmarli); Omalizumab (Xolair); Oral Glucocorticoids for Duchenne Muscular Dystrophy; Tralokinumab (Adbry); and Zuranolone (Zurzuvae).

Sincerely,

Pamela Smith R.Ph.

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

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Gina Kuebler, R.Ph, Iowa Medicaid