IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 6, 2025. At this meeting, the DUR Commission members discussed prior authorization (PA) criteria for Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors; Anti-Diabetic Non-Insulin Agents; Dupilumab (Dupixent); Givinostat (Duvyzat); IL-5 Antagonists; Janus Kinase (JAK) Inhibitors; Lebrikizumab-lbkz (Ebglyss); Nemolizumab-ilto (Nemluvio); Olezarsen (Tryngolza); Omalizumab (Xolair); and Palopegteriparatide (Yorvipath). Additionally, the DUR Commission recommends a ProDUR edit for the concurrent use of a DPP-4 inhibitor containing agent with a GLP-1 receptor agonist containing agent. The following recommendations have been made by the DUR Commission:

Please note: The DUR Commission has revised its process for reviewing new and updated prior authorization (PA) criteria, as well as other changes impacting the outpatient pharmacy program, including ProDUR edits. Beginning with the August 6, 2025 meeting, all items will be reviewed and voted on during a single meeting.

- If no major changes are proposed during discussion, the Commission will proceed with a vote, and the recommendation will be submitted to the Department for consideration.
- If significant revisions are suggested, the item will be deferred to the next meeting for further review and voting before a recommendation is made.

Recommendations from the August 6, 2025 meeting also include items initially discussed at the May 6, 2025 meeting and subsequently re-reviewed.

Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for adenosine triphosphate-citrate lyase (ACL) inhibitors. Payment will be considered under the following conditions:

1. Patient meets the FDA approved age; and

2. Documentation of adherence to prescribed lipid lowering medications (including a maximally tolerated statin), prior to ACL inhibitor therapy, for the previous 90 days is provided (further defined below, by diagnosis); and
3. Documentation is provided that medication will be used in combination with a maximally tolerated statin; and
4. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and
5. Patient will continue to follow an appropriate low-fat diet; and
6. Is prescribed by or in consultation with a lipidologist, cardiologist, or endocrinologist; and
7. If patient is taking in combination with:
    a. Simvastatin, dose does not exceed 20mg per day; or
    b. Pravastatin, dose does not exceed 40mg per day; and
8. Concurrent use with a PCSK9 inhibitor will not be considered; and
9. Goal is defined as a 50% reduction in untreated baseline LDL-C; and
10. Is prescribed for one of the following diagnoses:
    a. Heterozygous Familial Hypercholesterolemia (HeFH):
        i. Documentation is provided verifying diagnosis (attach documentation/results), as evidenced by:
            1. Clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) or:
            2. Confirmation of diagnosis by gene or receptor testing; and
        ii. Documentation of untreated LDL-C ≥ 190 mg-dL; and
        iii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily; or
    b. Clinical Atherosclerotic Cardiovascular Disease (ASCVD):
        i. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; and
        ii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily.

If criteria for coverage are met, requests will be approved for 3 months. Additional authorizations will be considered at yearly intervals under the following conditions:

1. Patient continues therapy with a maximally tolerated statin dose and remains at goal; and
2. Patient continues to follow an appropriate low-fat diet; and
3. Documentation of LDL reduction is provided.

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

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

Prior authorization (PA) is required for adenosine triphosphate-citrate lyase (ACL) inhibitors. Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication(s), including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations* ~~Patient meets the FDA approved age~~; and
2. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to *lipid lowering medication* ~~pharmacologic~~ therapy; and
3. Patient will continue to follow an appropriate low-fat diet; and
4. *Patient has one of the following diagnoses:*
    a. *Heterozygous familial hypercholesterolemia (HeFH); or*
    b. *Primary hyperlipidemia; or*
    c. *Established cardiovascular disease (CVD) (e.g. previous myocardial infarction, history of an acute coronary syndrome, angina, previous stroke or transient ischemic attack, coronary artery disease, peripheral arterial disease, coronary or other arterial revascularization); or*
    d. *At risk for a CVD event but without established CVD (e.g. diabetes mellitus (type 1 or type 2), a Reynolds Risk score > 20% or a SCORE Risk score > 7.5% over 10 years, a coronary artery calcium score > 300 Agatston units); and*
5. *Meets one of the following:*
    ~~a. Documentation of adherence to prescribed lipid lowering medications (including a maximally tolerated statin), prior to ACL inhibitor therapy, for the previous 90 days is provided (further defined below, by diagnosis); and~~
    b. Patient *must be adherent to lipid lowering medication therapy and* is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials, *including atorvastatin and rosuvastatin, at maximally tolerated doses,* used in combination with *ezetimibe for a minimum of 90 consecutive days* ~~other lipid lowering medications~~. ~~Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily~~*; or*
    c. Patient is statin intolerant as documented by an inability to tolerate at least two chemically distinct statins; or
    d. Patient has an FDA labeled contraindication to all statins; and
6. Goal is defined as a 50% reduction in untreated baseline LDL-C.
~~7. Documentation is provided that medication will be used in combination with a maximally tolerated statin; and~~
~~8. Is prescribed by or in consultation with a lipidologist, cardiologist, or endocrinologist; and~~
~~9. If patient is taking in combination with:~~
    ~~a. Simvastatin, dose does not exceed 20mg per day; or~~
    ~~b. Pravastatin, dose does not exceed 40mg per day; and~~
10. Concurrent use with a PCSK9 inhibitor will not be considered.~~; and~~
~~11. Is prescribed for one of the following diagnoses:~~
    ~~a. Heterozygous Familial Hypercholesterolemia (HeFH):~~
        ~~i. Documentation is provided verifying diagnosis (attach documentation/results), as evidenced by:~~
            ~~1. Clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) or:~~

~~2. Confirmation of diagnosis by gene or receptor testing; and~~
~~ii. Documentation of untreated LDL-C ≥ 190 mg-dL; and~~
~~iii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily; or~~
~~b. Clinical Atherosclerotic Cardiovascular Disease (ASCVD):~~
~~i. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; and~~
~~ii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily.~~

If criteria for coverage are met, requests will be approved for 3 months. Additional authorizations will be considered at yearly intervals under the following conditions:

1. Patient continues ~~therapy~~ with *lipid lowering therapy at* a maximally tolerated ~~statin~~ dose ~~and remains at goal~~; *or* ~~and~~
2. *Patient is intolerant to or has a contraindication to statins; and*
3. Patient continues to follow an appropriate low-fat diet; and
4. Documentation of *a positive response to therapy (e.g.,* LDL-*C* reduction*)* ~~is provided~~.

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

Anti-Diabetic Non-Insulin Agents

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for select preferred anti-diabetic, non-insulin agents subject to clinical criteria. 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. For the treatment of Type 2 Diabetes Mellitus, a current A1C is provided; and
3. Requests for non-preferred antidiabetic, non-insulin agents subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class. Additionally, requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with at least 3 preferred agents from 3 different drug classes at maximally tolerated doses.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated. Requests for weight loss are not a covered diagnosis of use and will be denied.

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for select preferred anti-diabetic, non-insulin agents subject to clinical criteria. 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. For the treatment of Type 2 Diabetes Mellitus, a current A1C is provided; and
3. *Requests for combination therapy with a DPP-4 inhibitor containing agent with a GLP-1 receptor agonist containing agent will not be considered; and*
4. Requests for non-preferred antidiabetic, non-insulin agents subject to clinical criteria, will be authorized only for cases in which there is documentation of previous trials and therapy failures with a preferred drug in the same class. Additionally, requests for a non-preferred agent for the treatment of Type 2 Diabetes Mellitus must document previous trials and therapy failures with at least 3 preferred agents from 3 different drug classes at maximally tolerated doses.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated. Requests for weight loss*, which is* ~~are~~ not a covered diagnosis of use*,* ~~and~~ will be denied.

Dupilumab (Dupixent)

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for Dupixent (dupilumab). 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 when patient has an FDA approved or compendia indication for the requested drug 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's current weight in kilograms (kg) is provided; and
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Patient has failed to respond to good skin care and regular use of emollients; and
    b. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    c. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    d. Patient will continue with skin care regimen and regular use of emollients; or
4. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) or with oral corticosteroid dependent asthma; and
    a. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted in adults; < 90% predicted in adolescents 12 to 17 years of age; and < 95% predicted in children 6 to 11 years of age; and

b. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long-acting beta $_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and
c. Patient must have one of the following, in addition to the regular maintenance medications defined above:
    i. One (1) or more exacerbations in the previous year or
    ii. Require daily oral corticosteroids for at least 3 days; or

5. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
    a. Documentation dupilumab will be used as an add-on maintenance treatment; and
    b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; or
6. Patient has a diagnosis of eosinophilic esophagitis (EoE); and
    a. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
    b. Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and
    c. Documentation of previous trials and therapy failures with all of the following:
        i. High dose proton pump inhibitor (PPI) for at least 8 weeks; and
        ii. Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension): and
        iii. Dietary therapy; or
7. Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and
    a. Patient has experienced severe to very severe pruritus, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and
    b. Patient has ≥ 20 nodular lesions (attach documentation); and
    c. Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; ~~and~~ *or*
8. Patient has a diagnosis of chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype; and
    a. Patient has moderate to severe airflow limitation, measured within the past 12 months, as evidenced by both of the following:
        i. FEV1/FVC ratio < 0.7, and
        ii. FEV1 % predicted between 30% to 79%; and
    b. Patient has a minimum blood eosinophil count of 300 cells/mcL, measured within the past 12 months; and
    c. Patient has documentation of maximal inhaled therapy for 3 or more months and an inadequate response to:
        i. Triple therapy with all of the following treatments:
            1. Long-acting muscarinic antagonist/anticholinergic (LAMA); and
            2. Long-acting beta agonist (LABA); and
            3. Inhaled corticosteroid (ICS); or

ii. Double therapy with all of the following if ICS is contraindicated
    1. LABA; and
    2. LAMA; and

d. Patient has history of at least 2 moderate or 1 severe exacerbation(s) in the previous 12 months despite receiving maximal triple therapy or double therapy (defined above). Moderate exacerbation is defined as patient required treatment with systemic corticosteroids and/or antibiotics and severe exacerbation is defined as hospitalization or observation for over 24 hours in an emergency department or urgent care facility; and
e. Patient will continue to receive maintenance therapy (as documented above) concomitantly with dupilumab; and

9. Dose does not exceed the FDA approved dosing for indication.

If criteria for coverage are met, initial authorization will be given for 6 months for all the above indications, except for COPD, which will receive an initial authorization of 12 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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 (changed italicized/highlighted and/or stricken)
Prior authorization (PA) is required for Dupixent (dupilumab). 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 when patient has an FDA approved or compendia indication for the requested drug 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's current weight in kilograms (kg) is provided; and
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Patient has failed to respond to good skin care and regular use of emollients; and
    b. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    c. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    d. Patient will continue with skin care regimen and regular use of emollients; or
4. Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) or with oral corticosteroid dependent asthma; and
    a. Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted in adults; < 90% predicted in adolescents 12 to 17 years of age; and < 95% predicted in children 6 to 11 years of age; and
    b. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long-acting beta $_2$ agonist [LABA], *or* leukotriene receptor antagonist [LTRA]~~, oral theophylline~~) for a minimum of 3 consecutive

months. Patient must be compliant with therapy, based on pharmacy claims; and

c. Patient must have one of the following, in addition to the regular maintenance medications defined above:
    i. One (1) or more exacerbations in the previous year or
    ii. Require daily oral corticosteroids for at least 3 days; or

5. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP); and
    a. Documentation dupilumab will be used as an add-on maintenance treatment; and
    b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
        i. Nasal corticosteroid spray; and
        ii. Oral corticosteroid; or
6. Patient has a diagnosis of eosinophilic esophagitis (EoE); and
    a. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) as confirmed by endoscopic esophageal biopsy (attach results); and
    b. Patient has signs and symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, food refusal, abdominal pain, heartburn regurgitation, chest pain and/or, odynophagia); and
    c. Documentation of previous trials and therapy failures with all of the following:
        i. High dose proton pump inhibitor (PPI) for at least 8 weeks; and
        ii. Swallowed topical corticosteroid (e.g., fluticasone propionate, oral budesonide suspension): and
        iii. Dietary therapy; or
7. Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and
    a. Patient has experienced severe to very severe pruritus, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and
    b. Patient has ≥ 20 nodular lesions (attach documentation); and
    c. Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days; ~~and~~ *or*
8. Patient has a diagnosis of chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype; and
    a. Patient has moderate to severe airflow limitation, measured within the past 12 months, as evidenced by both of the following:
        i. FEV1/FVC ratio < 0.7, and
        ii. FEV1 % predicted between 30% to 79%; and
    b. Patient has a minimum blood eosinophil count of 300 cells/mcL, measured within the past 12 months; and
    c. Patient has documentation of maximal inhaled therapy for 3 or more months and an inadequate response to:
        i. Triple therapy with all of the following treatments:
            1. Long-acting muscarinic antagonist/anticholinergic (LAMA); and
            2. Long-acting beta agonist (LABA); and
            3. Inhaled corticosteroid (ICS); or
        ii. Double therapy with both of the following if ICS is contraindicated
            1. LABA; and
            2. LAMA; and
    d. Patient has history of at least 2 moderate or 1 severe exacerbation(s) in the previous 12 months despite receiving maximal triple therapy or double therapy

(defined above). Moderate exacerbation is defined as patient required treatment with systemic corticosteroids and/or antibiotics and severe exacerbation is defined as hospitalization or observation for over 24 hours in an emergency department or urgent care facility; and

e. Patient will continue to receive maintenance therapy (as documented above) concomitantly with dupilumab; ~~and~~ *or*

9. *Patient has a diagnosis of chronic spontaneous urticaria (CSU) with no known cause; and*
    a. *Patient has documentation of an adequate trial and therapy failure with a preferred second generation H1 receptor antihistamine for at least 2 weeks.*
10. ~~Dose does not exceed the FDA approved dosing for indication.~~

If criteria for coverage are met, initial authorization will be given for 6 months for all the above indications, except for COPD *and CSU*, which will receive an initial authorization of 12 months to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy *and continued use of add-on maintenance therapy, where indicated*.

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

Givinostat (Duvyzat)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for givinostat (Duvyzat). 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 Duchene 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; and
3. Is prescribed by or in consultation with a physician who specializes in treatment of DMD; and
4. Patient has documentation of a trial and inadequate response to an oral glucocorticoid for at least 6 months; and
5. Givinostat will be prescribed concurrently with an oral glucocorticoid; and
6. Patient's current body weight in kilograms (kg) is provided.

If criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 12-month intervals when the following criteria are met:

1. Documentation of a positive response to therapy (e.g. improved strength, pulmonary function test, or functional assessments); and
2. Patient continues to receive concomitant glucocorticoid therapy; and
3. Patient's current body weight in kg is provided.

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

IL-5 Antagonists

Current Clinical Prior Authorization Criteria

Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug 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 severe asthma with an eosinophilic phenotype, and
    a. Patient has a pretreatment blood eosinophil count of ≥ 150 cells/mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells/ mcL within 12 months prior to initiation of therapy; and
    b. 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
    c. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and
    d. A pretreatment forced expiratory volume in 1 second (FEV_1) < 80% predicted in adults and < 90% in adolescents; or
3. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and
    a. Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and
    b. One of the following:
        i. Eosinophil count > 1000 cells/mcL; or
        ii. Eosinophil count > 10% of the total leukocyte count; and
4. Patient has a diagnosis of hypereosinophilic syndrome (HES); and
    a. Patient has been diagnosed with HES for ≥ 6 months prior to starting treatment; and
    b. Documentation that non-hematologic secondary causes of HES have been ruled out; and
    c. Documentation patient does not have FIP1L1-PDGFRα kinase-positive HES: and
    d. Documentation of ≥ 2 HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and
    e. Patient has a blood eosinophil count ≥ 1,000 cells/mcL; and
    f. Medication will be used in combination with stable doses of at least one other HES therapy; and
5. Patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP); and
    a. Documentation mepolizumab will be used as an add-on maintenance treatment with a nasal corticosteroid spray; and
    b. Documentation of an adequate trial and therapy failure with at least one

preferred medication from each of the following categories:
    i. Nasal corticosteroid; and
    ii. Oral corticosteroid; and
6. Prescribed by or in consultation with an allergist, hematologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist.

If criteria for coverage are met, an initial authorization will be given for 3 months for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis or 6 months for a diagnosis of hypereosinophilic syndrome or CRSwNP 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:
Severe Asthma with an Eosinophilic Phenotype:
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.

Eosinophilic Granulomatosis with Polyangiitis
1. Patient has demonstrated a positive clinical response to therapy (increase in remission time).

Hypereosinophilic Syndrome:
1. Patient has demonstrated positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and
2. Medication continues to be used in combination with stable doses or at least one other HES therapy.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
1. Patient has demonstrated positive clinical response to therapy (improvement in symptoms); and
2. Continues to receive medication as add-on maintenance therapy with a nasal corticosteroid spray.

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

<u>Proposed Clinical Prior Authorization Criteria</u> (changes highlighted/italicized and/or stricken)
Prior authorization is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered when patient has an FDA approved or compendia indication for the requested drug 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 severe asthma with an eosinophilic phenotype, and

a. Patient has a pretreatment blood eosinophil count of ≥ 150 cells/mcL within the previous 6 weeks or blood eosinophils ≥ 300 cells/ mcL within 12 months prior to initiation of therapy; and
b. 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
c. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and
d. A pretreatment forced expiratory volume in 1 second (FEV_1) < 80% predicted in adults and < 90% in adolescents; or

3. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and
   a. Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and
   b. One of the following:
      i. Eosinophil count > 1000 cells/mcL; or
      ii. Eosinophil count > 10% of the total leukocyte count; ~~and~~ *or*
4. Patient has a diagnosis of hypereosinophilic syndrome (HES); and
   a. Patient has been diagnosed with HES for ≥ 6 months prior to starting treatment; and
   b. Documentation that non-hematologic secondary causes of HES have been ruled out; and
   c. Documentation patient does not have FIP1L1-PDGFRα kinase-positive HES: and
   d. Documentation of ≥ 2 HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and
   e. Patient has a blood eosinophil count ≥ 1,000 cells/mcL; and
   f. Medication will be used in combination with stable doses of at least one other HES therapy; ~~and~~ *or*
5. Patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP); and
   a. Documentation mepolizumab will be used as an add-on maintenance treatment with a nasal corticosteroid spray; and
   b. Documentation of an adequate trial and therapy failure with at least one preferred medication from each of the following categories:
      i. Nasal corticosteroid; and
      ii. Oral corticosteroid; ~~and~~ *or*
6. *Patient has a diagnosis of chronic obstructive pulmonary disease (COPD) with an eosinophilic phenotype; and*
   a. *Patient has moderate to very severe airflow limitation, measured within the past 12 months, as evidenced by both of the following:*
      i. *FEV_1/FVC ratio < 0.7, and*
      ii. *FEV_1% predicted of 20% and 80%; and*
   b. *Patient has a minimum blood eosinophil count of 150 cells/mcL, measured with in the past 12 months; and*
   c. *Patient has documentation of maximal inhaled therapy for 3 or more months and an inadequate response to therapy with:*

i. *Triple therapy with all of the following treatments:*
    1. *Long-acting muscarinic antagonist/anticholinergic (LAMA); and*
    2. *Long-acting beta2-agonist (LABA); and*
    3. *Inhaled corticosteroid (ICS); or*

ii. *Double therapy with both of the following if ICS is contraindicated:*
    1. *LABA; and*
    2. *LAMA; and*

d. *Patient has a history of at least 2 moderate or 1 severe exacerbation(s) in the previous 12 months despite receiving maximal triple therapy or double therapy (defined above). Moderate exacerbation is defined as patient required treatment with systemic corticosteroids and/or antibiotics and severe exacerbation is defined as hospitalization or observation for over 24 hours in an emergency department or urgent care facility; and*

e. *Documentation mepolizumab will be used as an add-on maintenance treatment with triple or double therapy (as defined above); and*

7. *Medication will be administered in the patient's home; and*
8. Prescribed by or in consultation with an allergist, hematologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist.

If criteria for coverage are met, an initial authorization will be given for 3 months for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis*,* ~~or~~ 6 months for a diagnosis of hypereosinophilic syndrome or CRSwNP*, or 12 months for a diagnosis of COPD* 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:
Severe Asthma with an Eosinophilic Phenotype:

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.

Eosinophilic Granulomatosis with Polyangiitis

1. Patient has demonstrated a positive clinical response to therapy (increase in remission time).

Hypereosinophilic Syndrome:

1. Patient has demonstrated positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and
2. Medication continues to be used in combination with stable doses or at least one other HES therapy.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

1. Patient has demonstrated positive clinical response to therapy (improvement in symptoms); and
2. Continues to receive medication as add-on maintenance therapy with a nasal corticosteroid spray.

Chronic Obstructive Pulmonary Disease (COPD)

1. *Patient has demonstrated positive clinical response to therapy; and*
2. *Continues to receive add-on maintenance therapy with triple or double therapy (as*

defined above).

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

Janus Kinase (JAK) Inhibitors

Current Clinical Prior Authorization

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 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; 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; 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; with
        i. A documented trial and inadequate response with a preferred TNF inhibitor; and
        ii. 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; with
        i. A documented trial and inadequate response with a preferred TNF inhibitor; OR
    e. Polyarticular Course Juvenile Idiopathic Arthritis; with
        i. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; OR
    f. Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or

nonradiographic axial spondyloarthritis); 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
    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:
        a. Affected area is less than 20% of body surface area (BSA); and
        b. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or
    v. For moderate to severe atopic dermatitis
        a. A documented trial and therapy failure with a systemic drug product for the treatment of moderate to severe atopic dermatitis, including biologics; 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; 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.

<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 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; 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; 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; with
        ~~i.~~ A documented trial and inadequate response with a preferred TNF inhibitor; ~~and~~
        ii. ~~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; with
        i. A documented trial and inadequate response with a preferred TNF inhibitor; OR
    e. Polyarticular Course Juvenile Idiopathic Arthritis; with
        i. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; OR
    f. Axial spondyloarthritis conditions (e.g., ankylosing spondylitis or nonradiographic axial spondyloarthritis); 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
        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:
            1. Affected area is less than 20% of body surface area (BSA); and
            2. Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or

v. For moderate to severe atopic dermatitis:
    1. A documented trial and therapy failure with a systemic drug product for the treatment of moderate to severe atopic dermatitis, including biologics; and
    2. 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; 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*; or*

i. Giant Cell Arteritis; with
    i. Documentation patient is currently taking a glucocorticoid, with a tapering dose, or has discontinued use of glucocorticoids.

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

Lebrikizumab-lbkz (Ebglyss)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Ebglyss (lebrikizumab-lbkz). 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 when patient has an FDA approved or compendia indication for the requested drug 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's current weight in kilograms (kg) is provided; and
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Patient has failed to respond to good skin care and regular use of emollients; and
    b. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    c. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    d. 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 allow for initial dosing. Requests for continuation of therapy will be considered at 12-month intervals with documentation of an adequate response to therapy and a dose reduction to maintenance dosing.

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

Nemolizumab-ilto (Nemluvio)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Nemluvio (nemolizumab-ilto). 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 when patient has an FDA approved or compendia indication for the requested drug 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's current weight in kilograms (kg) is provided; and
3. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Patient has failed to respond to good skin care and regular use of emollients; and
    b. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    c. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    d. For initial therapy, will be used in combination with a topical corticosteroid and/or a topical immunomodulator; and
    e. Patient will continue with skin care regimen and regular use of emollients; or
4. Patient has a diagnosis of moderate to severe prurigo nodularis (PN); and
    a. Patient has experienced severe to very severe pruritus, as demonstrated by a current Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7; and
    b. Patient has ≥ 20 nodular lesions (attach documentation); and
    c. Documentation of a previous trial and therapy failure with a high or super high potency topical corticosteroid for at least 14 consecutive days.

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess response to therapy. Requests for continuation of therapy will be considered at 12-month intervals with documentation of an adequate response to therapy and a dose reduction to maintenance dosing, where appropriate.

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

Olezarsen (Tryngolza)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for olezarsen (Tryngolza). 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 familial chylomicronemia syndrome (FCS) confirmed by genetic testing, (e.g., biallelic pathogenic variants in FCS-causing genes [*LPL, GPIHBP1, APOA5, APOC2, or LMF1*]) (attach genetic testing results); and
3. The patient has a current fasting triglyceride level of 880 mg/dL or greater (attach current lipid panel obtained within the past 30 days); and
4. The patient will use medication in combination with a low-fat diet (≤ 20 grams of total fat per day); and
5. Is prescribed by or in consultation with a cardiologist, an endocrinologist, or a provider who specializes in lipid management.

If the criteria for coverage are met, initial requests will be given for 6 months. Requests for continuation of therapy will be considered at 12-month intervals under the following conditions:

1. Documentation of a decrease in fasting triglyceride level from baseline (attach current lipid panel obtained within the past 30 days); and
2. Patient continues to use medication in combination with a low-fat diet (≤ 20 grams of total fat per day); and
3. Is prescribed by or in consultation with a cardiologist, an endocrinologist, or a provider who specializes in lipid management.

Omalizumab (Xolair)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for omalizumab (Xolair) prefilled syringe and autoinjector. 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 and precautions, drug interactions, and use in specific populations. Payment for omalizumab (Xolair) prefilled syringe and autoinjector will be considered under the following conditions:

1. 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
2. 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
3. Prescriber is an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist; and
4. 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 IgE levels and body weight. PA requests will be denied in these instances; and
5. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and
6. 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 has a history of positive skin or RAST test to a perennial aeroallergen; and
3. 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.

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. Patient has documentation of an adequate trial and inadequate response with at least two nasal corticosteroids at a maximally tolerated dose; and
3. Will be used concurrently with a nasal corticosteroid.

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.

Proposed Clinical Prior Authorization Criteria (changed italicized/highlighted and/or stricken)
Prior authorization (PA) is required for omalizumab (Xolair) prefilled syringe and autoinjector. 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 and precautions, drug interactions, and use in specific populations. Payment for omalizumab (Xolair) prefilled syringe and autoinjector will be considered *when patient has an FDA approved or compendia indication* under the following conditions:

1. 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
2. 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
3. Prescriber is an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist; and
4. 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 IgE levels and body weight. PA requests will be denied in these instances; and
5. Patient has access to an epinephrine injection to treat allergic reactions that may occur after administration of omalizumab (Xolair); and
6. 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 has a history of positive skin or RAST test to a perennial aeroallergen; and
3. *Symptoms are inadequately controlled with documentation of current treatment with* ~~Patient is currently using~~ a high-dose inhaled corticosteroid

(ICS)~~,~~ *given in combination with a controller medication (e.g.* long-acting beta~~2~~-agonist [LABA], ~~AND~~ *or* a leukotriene receptor antagonist *[LTRA])*, ~~and is compliant with therapy and asthma symptoms are not adequately controlled after at least~~ *for a minimum of* three (3) *consecutive* months of therapy. *Patient must be compliant with therapy, based on pharmacy claims.*

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 *and controller medication (as defined above)*~~, long-acting beta-agonist, and leukotriene receptor antagonist~~.

Chronic *Spontaneous* ~~Idiopathic~~ Urticaria

1. Patient has a diagnosis of moderate to severe chronic *spontaneous* ~~idiopathic~~ urticaria; and
2. ~~2.~~ Patient has documentation of a*n adequate* trial and therapy failure with ~~at least one~~ *a* preferred second generation *H1 receptor* antihistamine *for at least two weeks.* ~~, 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.

Chronic Rhinosinusitis with Nasal Polyps *(CRSwNP)*

1. Patient has a diagnosis of *chronic rhinosinusitis with* nasal polyps; and
2. Patient has documentation of an adequate trial and *therapy failure* ~~inadequate response~~ with at least *one* ~~two~~ *preferred medication from each of the following categories:*
    a. Nasal corticosteroid~~s~~ *spray* ~~at a maximally tolerated dose~~; and
    b. Oral corticosteroid; and
3. Will be used *as an add on maintenance treatment* ~~concurrently with a nasal corticosteroid~~.

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.

Palopegteriparatide (Yorvipath)

Newly Proposed Clinical Prior Authorization Criteria
Prior authorization (PA) is required for palopegteriparatide (Yorvipath). Payment will be considered when patient has an FDA approved or compendia indication 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 chronic hypoparathyroidism; and
3. Patient has had an inadequate response to maximally tolerated oral calcium and vitamin D analog (e.g., calcitriol) therapy; and
4. Documentation of baseline lab results (attach results obtained within 2 weeks prior to starting therapy) for:
    a. Serum 25 hydroxyvitamin D (25(OH)D) level within the normal range (20 to 80 ng/mL); and
    b. Albumin-corrected serum calcium level ≥ 7.8 g/dL; and
5. Is prescribed by or in consultation with an endocrinologist or nephrologist.

If criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 12-month intervals with:

1. Documentation of a positive response to therapy, as evidenced by normalized albumin-corrected serum calcium level of 8.3 to 10.6 g/dL (attach lab results).

ProDUR Edit
The DUR Commission recommends implementing a ProDUR edit to prevent concurrent use of GLP-1 receptor agonists (GLP-1 RA), including dual GIP/GLP-1 RA agents (e.g., tirzepatide), and DPP-4 inhibitors (DPP-4i).

- A 90-day lookback will be used to identify claims for a GLP-1 RA, including dual GIP/GLP-1 RA, or DPP-4i.
- If concurrent use is detected, the claim will be rejected at the pharmacy point-of-sale (POS).
- Prior authorization will be required if a member is switching from one agent to the other.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors; Anti-Diabetic Non-Insulin Agents; Dupilumab (Dupixent); Givinostat (Duvyzat); IL-5 Antagonists; Janus Kinase (JAK) Inhibitors; Lebrikizumab-lbkz (Ebglyss); Nemolizumab-ilto (Nemluvio); Olezarsen (Tryngolza); Omalizumab (Xolair); and Palopegteriparatide (Yorvipath); and the ProDUR edit for

the concurrent use of a DPP-4 inhibitor containing agent with a GLP-1 receptor agonist containing agent.

Sincerely,

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

Cc: Erin Halverson, R.Ph, Iowa Medicaid
Gina Kuebler, R.Ph, Iowa Medicaid