IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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February 4, 2026

Abby Cate, Pharm.D.
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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 4, 2026. At this meeting, Commission members reviewed and discussed prior authorization (PA) criteria for Dupilumab (Dupixent); Finerenone (Kerendia); Janus Kinase Inhibitors; Remibrutinib (Rhapsido); and Tezepelumab-ekko (Tezspire). The following recommendations have been made by the DUR Commission:

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], or leukotriene receptor antagonist [LTRA]) 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-2 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; 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.

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.

Proposed Clinical Prior Authorization Criteria (changes 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]) 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; 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-2 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; 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*; or*
10. *Patient has a diagnosis of bullous pemphigoid (BP); and*
    a. *Is initiated with a tapering course of oral corticosteroids.*

If criteria for coverage are met, initial authorization will be given for 6 months for all the above indications, except for COPD*,* ~~and~~ CSU*, and BP* 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.

Finerenone (Kerendia)

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for finerenone (Kerendia). Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling, including age, dosing, contraindications, warnings and precautions, and drug interactions; and
2. Patient has a diagnosis of chronic kidney disease (CKD) associated with Type 2 Diabetes (T2D); and
3. Patient is currently receiving a maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB); and
4. Patient is currently receiving a maximally tolerated dose of a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease [i.e., dapagliflozin (Farxiga)]; and
5. Patient has the following baseline tests prior to initiation of treatment with finerenone:
   a. Serum potassium is ≤5.0 mEq/L; and
   b. Estimated glomerular filtration rate (eGFR) is ≥ 25 mL/min/1.73m^2; and

c. Urine albumin to creatinine ratio (UACR) is ≥ 30 mg/g.

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

Initial authorizations will be approved for six months. Additional PAs will be considered with the following documentation:

1. Patient's serum potassium is < 5.5 mEq/L; and
2. Patient's eGFR is ≥ 25 mL/min/1.73m2; and
3. Patient remains on a maximally tolerated dose of an ACEi or ARB; and
4. Patient remains on a maximally tolerated dose of an SGLT2 inhibitor.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted, and/or stricken)
Prior authorization (PA) is required for finerenone (Kerendia). Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling, including age, dosing, contraindications, warnings and precautions, and drug interactions; and
2. Patient has a diagnosis of chronic kidney disease (CKD) associated with Type 2 Diabetes (T2D); and
    a. Patient is currently receiving a maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB); and
    b. Patient is currently receiving a maximally tolerated dose of a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease (i.e., dapagliflozin [Farxiga]*, empagliflozin [Jardiance*]); *or* ~~and~~
3. *Patient has a diagnosis of heart failure; and*
    a. *Patient has a left ventricular ejection fraction (LVEF) ≥ 40%; and*
    b. *Patient is currently receiving a maximally tolerated dose of a SGLT2 inhibitor indicated for use in patients with heart failure (i.e., dapagliflozin [Farxiga], empagliflozin [Jardiance]); and*
4. Patient has the following baseline tests prior to initiation of treatment with finerenone:
    a. Serum potassium is ≤ 5.0 mEq/L; and
    b. Estimated glomerular filtration rate (eGFR) is ≥ 25 mL/min/1.73m^2; and
    c. Urine albumin to creatinine ratio (UACR) is ≥ 30 mg/g.

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

Initial authorizations will be approved for *one year* ~~six months~~. Additional PAs will be considered with the following documentation:

1. Patient's eGFR is ≥ 25 mL/min/1.73m2; and
2. *For a diagnosis of CKD associated with T2D:*
    a. Patient's serum potassium is < 5.5 mEq/L; and
    b. Patient remains on a maximally tolerated dose of an ACEi or ARB; and
    c. Patient remains on a maximally tolerated dose of an SGLT2 inhibitor*; or*
3. *For a diagnosis of heart failure:*
    a. *Patient's serum potassium is < 6 mEq/L; and*

b. *Patient remains on a maximally tolerated dose of an SGLT2 inhibitor.*

Janus Kinase (JAK) 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 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; 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 (topical treatments):
        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 chronic hand eczema (topical treatments):
        1. Chronic hand eczema has persisted for more than 3 months or recurred two or more times within a 12-month time frame after the initial occurrence with complete clearances between relapses; and
        2. Patient has been instructed to use no more than 30 grams per 2 weeks or 60 grams per month of topical delgocitinib; or
    vi. For moderate to severe atopic dermatitis (oral treatments):
        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.

<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; *or*
        ii. *If TNF inhibitors are clinically inadvisable, documentation of at least one approved systemic therapy;* OR
    d. Moderately to severely active Crohn's disease; with
        i. A documented trial and inadequate response with a preferred TNF inhibitor; or
        ii. *If TNF inhibitors are clinically inadvisable, documentation of at least one approved systemic therapy;* 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 (topical treatments):
    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 chronic hand eczema (topical treatments):
    1. Chronic hand eczema has persisted for more than 3 months or recurred two or more times within a 12-month time frame after the initial occurrence with complete clearances between relapses; and
    2. Patient has been instructed to use no more than 30 grams per 2 weeks or 60 grams per month of topical delgocitinib; or
vii. For moderate to severe atopic dermatitis (oral treatments):
    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.

Remibrutinib (Rhapsido)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for remibrutinib (Rhapsido). 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 has a diagnosis of chronic spontaneous urticaria (CSU) with no known cause; and
3. Patient has documentation of an adequate trial and therapy failure with a preferred second generation H1 receptor antihistamine for at least 2 weeks.

If criteria for coverage are met, initial authorization will be given for 12 months to assess the response to treatment. Requests 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 the use of these agents would be medically contraindicated.

Tezepelumab-ekko (Tezspire)

Current Clinical Prior Authorization Criteria
Prior authorization (PA) is required for tezepelumab-ekko (Tezspire) prefilled pen. Requests for tezepelumab-ekko (Tezspire) single dose vial or prefilled syringe will not be considered through the pharmacy benefit. 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 severe asthma; and
    a. 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
    b. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months, or
        ii. One or more asthma exacerbations resulting in hospitalization in the previous 12 months; and
    c. This medication will be used as an add-on maintenance treatment; and
    d. Patient/caregiver will administer medication in patient's home; and
    e. Is not prescribed in combination with other biologics indicated for asthma.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Requests 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 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 tezepelumab-ekko (Tezspire) prefilled pen. Requests for tezepelumab-ekko (Tezspire) single dose vial or prefilled syringe will not be considered through the pharmacy benefit. 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 severe asthma; and
    a. 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
    b. Patient must have one of the following, in addition to the regular maintenance medications defined above:
        i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months, or
        ii. One or more asthma exacerbations resulting in hospitalization in the previous 12 months; and
    c. This medication will be used as an add-on maintenance treatment; and
    d. Patient/caregiver will administer medication in patient's home; and
    e. Is not prescribed in combination with other biologics indicated for asthma*; or*

3. Patient has a diagnosis of inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP); and
    a. Documentation that tezepelumab 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.

If criteria for coverage are met, initial authorization will be given for 6 months to assess the response to treatment. Requests 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 the use of these agents would be medically contraindicated.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations regarding Dupilumab (Dupixent); Finerenone (Kerendia); Janus Kinase Inhibitors; Remibrutinib (Rhapsido); and Tezepelumab-ekko (Tezspire).

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