IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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November 7, 2025

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Dear Abby:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 5, 2025. At this meeting, Commission members reviewed and discussed prior authorization (PA) criteria for Brensocatib (Brinsupri); Diazoxide Choline (Vykat XR); Incretin Mimetics for Non-Diabetes Indications; Janus Kinase (JAK) Inhibitors; Pegcetacoplan (Empaveli); Sepiapterin (Sephience); and Select Topical Agents. Additionally, the Commission discussed removal of PA criteria for Hepatitis C Treatments, Direct Acting Antivirals (DAAs), along with the implementation of ProDUR edits for preferred DAAs. These edits include quantity limits, treatment duration, and a lookback to identify treatment experienced patients. The following recommendations have been made by the DUR Commission:

Brensocatib (Brinsupri)

Newly Proposed Clinical Prior Authorization Criteria
Prior authorization (PA) is required for brensocatib (Brinsupri). Payment will be considered for an FDA approved or compendia indicated diagnosis 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 non-cystic fibrosis bronchiectasis (NCFB) confirmed by a chest CT scan; and
3. Patient is 18 years of age or older with a history of ≥ 2 pulmonary exacerbations requiring antibiotic treatment in the previous 12 months; or
4. Patient is 12 to 17 years of age with ≥ 1 pulmonary exacerbation requiring antibiotic treatment in the previous 12 months; and
5. Patient has experienced at least 2 of the following symptoms in the previous 12 months: cough, chronic sputum production, and/or chronic respiratory infections; and

6. Patient has been counseled on the importance of abstinence from tobacco and, if a current smoker, been encouraged to enroll in a smoking cessation program; and
7. Is prescribed by or in consultation with a pulmonologist or infectious disease specialist.

Initial requests will be approved for 12 months. Additional authorizations will be considered annually with documentation of a positive clinical response to therapy, demonstrated by at least one of the following:

1. Improvement in or stabilization of symptoms; or
2. Reduction in or stabilization of the frequency, severity, or duration of exacerbations; or
3. Reduction in the decline of FEV_1.

Diazoxide Choline (Vykat XR)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for diazoxide choline (Vykat XR). 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 Prader-Willi syndrome confirmed by genetic testing (attach results); and
3. Patient has hyperphagia with associated symptoms such as food-seeking behaviors (hoarding, foraging, stealing, and attempting to consume inedible items); and
4. Patient's current weight in kg is provided; and
5. Is prescribed by or in consultation with an endocrinologist.

If the criteria for coverage is met, initial requests will be approved for 6 months. Additional approvals will be considered under the following conditions:

1. Documentation showing improvement or stabilized signs and symptoms of disease such as decrease in food related behaviors, lessened food preoccupation that affects daily life, etc., and
2. Patient's current weight in kg is provided.

Hepatitis C Treatments, Direct Acting Antivirals – Removal of Prior Authorization Criteria

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for hepatitis C direct-acting antivirals (DAA). 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. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient has a diagnosis of chronic hepatitis C; and
2. Patient has had testing for hepatitis C virus (HCV) genotype; and
3. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
4. Patient's prior HCV DAA treatment history is provided (treatment naïve or

treatment experienced); and
5. DAAs approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines and patient's weight is provided; and
6. Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
7. If patient is recently eligible for Iowa Medicaid and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.
8. The 72-hour emergency supply rule does not apply to DAAs.

Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions:

1. Patient must meet all criteria for treatment approval above; and
2. The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and
3. HCV retreatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and
4. Patient has not been previously treated with and failed the requested DAA therapy; and
5. Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.

Incretin Mimetics for Non-Diabetes Indications

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for incretin mimetics not otherwise covered by the Anti-Diabetics Non-Insulin Agents PA criteria for covered FDA approved or compendia indications. Payment for excluded medical use(s) (e.g. weight loss), as defined in the Iowa State Plan and Iowa Administrative Code 441 – 78.2(4) will be denied. Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has been screened for and does not have type 1 or type 2 diabetes mellitus (attach current lab results, obtained within 6 months of request, documenting an A1C < 6.5% or a fasting plasma glucose < 126 mg/dL); and
3. The requested drug will be used to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in an adult with established cardiovascular disease (CVD) and either obesity or overweight; and
    a. Patient has established CVD with history of one of the following (attach chart notes documenting diagnosis):
        i. Prior myocardial infarction (MI);
        ii. Prior stroke (ischemic or hemorrhagic);
        iii. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; and

    b. Patient has a baseline body mass index (BMI) ≥ 27 kg/m^2 (attach documentation), obtained within 6 months of request; and
    c. Patient has been evaluated for cardiovascular standard of care treatment; and
    d. For Wegovy:
        i. Patient is ≥ 45 years of age; and
        ii. Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and
        iii. Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment; or
4. Patient has a diagnosis of moderate to severe obstructive sleep apnea (OSA); and
    a. Patient has a baseline BMI ≥ 30 kg/m^2; and
    b. Prescriber attests patient has a recent (within prior three years) apnea/hypopnea index (AHI) ≥ 15 events per hour, as documented by a polysomnography (PSG) or at-home sleep study (document AHI); and
    c. For Zepbound:
        i. Patient meets the FDA approved age for OSA; and
        ii. Initiation and escalation dosages will be permitted up to a maximum of 20 weeks prior to reaching the recommended maintenance dosage of 10 mg to 15 mg once weekly; and
        iii. Maintenance dosages other than 10 mg to 15 mg once weekly will not be approved for maintenance treatment; and
5. Patient will use medication in combination with a reduced calorie diet and increased physical activity; and
6. The requested agent will not be used in combination with other incretin mimetics.

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

Requests will be considered for initiation and appropriate dosage escalation. Requests for continuation of therapy, once at an established maintenance dose, will be considered at 12-month intervals when:

1. The requested drug will be used to reduce the risk of MACE; and
    a. Patient has been evaluated for cardiovascular standard of care treatment; and
    b. For Wegovy, a maintenance dose of 1.7 mg or 2.4 mg once weekly is requested; ~~and~~ *or*
2. The requested drug will be used to treat moderate to severe OSA; and
    a. Documentation of a positive response to therapy is provided; and
    b. The maintenance dose is requested and maintained (Zepbound 10 mg to 15 mg once weekly); and
3. Patient does not have type 1 or type 2 diabetes; and
4. Patient continues to use medication in combination with a reduced calorie diet and increased physical activity; and
5. The requested agent will not be used in combination with other incretin mimetics.

<u>Proposed Clinical Prior Authorization Criteria</u> (changes highlighted/italicized and/or stricken)
Prior authorization (PA) is required for incretin mimetics not otherwise covered by the Anti-Diabetics Non-Insulin Agents PA criteria for covered FDA approved or compendia indications. Payment for excluded medical use(s) (e.g. weight loss), as defined in the Iowa State Plan and Iowa Administrative Code 441 – 78.2(4) will be denied. Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has been screened for and does not have type 1 or type 2 diabetes mellitus ~~(attach current lab results, obtained within 6 months of request, documenting an A1C < 6.5% or a fasting plasma glucose < 126 mg/dL)~~; and
3. The requested drug will be used to reduce the risk of major adverse cardiovascular events (MACE) (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in an adult with established cardiovascular disease (CVD) and either obesity or overweight; and
    a. Patient has established CVD*, i.e. coronary artery disease (angina, MI), cerebrovascular disease (stroke, transient ischemic attack), peripheral arterial disease, heart failure, atrial fibrillation and other arrhythmias, valvular heart disease, congenital heart disease, cardiomyopathies, aortic disease (aneurysm, dissection), DVT or PE, and* ~~with history of one of the following (attach chart notes documenting diagnosis):~~
        ~~i. Prior myocardial infarction (MI);~~
        ~~ii. Prior stroke (ischemic or hemorrhagic);~~
        ~~iii. Symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index (ABI) less than 0.85 (at rest), peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; and~~
    b. Patient has a baseline body mass index (BMI) ≥ 27 kg/m^2 (attach documentation), obtained within 6 months of request; and
    c. Patient has been evaluated for cardiovascular standard of care treatment; and
    d. For Wegovy:
        i. Patient is ≥ *18* ~~45~~ years of age; and
        ii. Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and
        iii. Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment; or
4. Patient has a diagnosis of moderate to severe obstructive sleep apnea (OSA); and
    a. Patient has a baseline BMI ≥ 30 kg/m^2; and
    b. Prescriber attests patient has a recent (within prior three years) apnea/hypopnea index (AHI) ≥ 15 events per hour, as documented by a polysomnography (PSG) or at-home sleep study (document AHI); and
    c. For Zepbound:
        i. Patient meets the FDA approved age for OSA; and
        ii. Initiation and escalation dosages will be permitted up to a maximum of 20 weeks prior to reaching the recommended maintenance dosage of 10 mg to 15 mg once weekly; and
        ~~iii.~~ Maintenance dosages other than 10 mg to 15 mg once weekly will not be approved for maintenance treatment; *or* ~~and~~
5. *Patient has a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH); and*
    a. *Patient has moderate to advanced liver fibrosis (stages F2 to F3 fibrosis) as confirmed by one of the following (attach results from testing documenting fibrosis stage);*

i. *Liver stiffness measurement (LSM) by vibration-controlled transient elastography (VCTE) (e.g. FibroScan), with a LSM of 8 kPa to 15 kPa; or*
ii. *LSM by magnetic resonance elastography (MRE) with a LSM of 3.1 kPa to 4.4 kPa; or*
iii. *Liver biopsy with a non-alcoholic fatty liver disease (NAFLD) Activity Score (NAS) ≥4 with a score of 1 or more in steatosis, lobular inflammation, and hepatocyte ballooning; and*

b. Patient has been evaluated for cardiometabolic standard of care treatment; and
c. Concurrent use of an incretin mimetic with resmetirom (Rezdiffra) for the treatment of MASH will only be considered after documented trials of each agent individually at therapeutic doses, with evidence of inadequate response; and
d. Patient has not had significant alcohol consumption within the past year (> 20 g per day in women or > 30 g per day in men); and
e. *For Wegovy:*
i. Initiation and escalation dosages will be permitted for a maximum of 8 weeks for each dosage; and
ii. Maintenance dosages other than 1.7 mg or 2.4 mg once weekly will not be approved for maintenance treatment (see requests for continuation of therapy below for maintenance dose requirement); and

6. Patient will use medication in combination with a reduced calorie diet and increased physical activity; and
7. The requested agent will not be used in combination with other incretin mimetics.

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

Requests will be considered for initiation and appropriate dosage escalation. Requests for continuation of therapy, once at an established maintenance dose will be considered at 12-month intervals when:

1. The requested drug will be used to reduce the risk of MACE; and
    a. Patient has been evaluated for cardiovascular standard of care treatment; and
    b. For Wegovy, a maintenance dose of 1.7 mg or 2.4 mg once weekly is requested; or
2. The requested drug will be used to treat moderate to severe OSA; and
    a. Documentation of a positive response to therapy is provided; and
    b. The maintenance dose is requested and maintained (Zepbound 10 mg to 15 mg once weekly); *or* ~~and~~
3. *The requested drug will be used for noncirrhotic MASH; and*
    a. Documentation of a positive response to therapy (e.g., improvement in or stabilization of fibrosis, improvement in liver function such as reduction in alanine aminotransferase [ALT], improvement in LSM by VCTE, MRE, or biopsy); and
    b. Patient has not progressed to cirrhosis; and
    c. *For Wegovy, a maintenance dose of 2.4 mg once weekly is requested, or 1.7 mg weekly with documentation of an adequate trial and intolerance to the maintenance dose of 2.4 mg once weekly. Patient must have a retrial of the recommended maintenance dose of 2.4 mg once weekly at least annually before a maintenance dose of 1.7 mg will be reauthorized; and*

4. Patient does not have type 1 or type 2 diabetes; and
5. Patient continues to use medication in combination with a reduced calorie diet and increased physical activity; and
6. The requested agent will not be used in combination with other incretin mimetics.

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; 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.

<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
    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.

Pegcetacoplan (Empaveli)

Current Clinical Prior Authorization Criteria

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

1. Request adheres to all FDA approved labeling including age, dosing, contraindications, and warnings and precautions; and
2. Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and
3. Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or ≥ 10% PNH cells; and
4. History of at least one red blood cell transfusion in the previous 12 months; and
5. Documentation of hemoglobin < 10.5 g/dL; and
6. Is not prescribed concurrently with eculizumab (Soliris) or ravulizumab (Ultomiris), unless the patient is in a 4 week period of cross-titration between eculizumab (Soliris) and pegcetacoplan (Empaveli); and
7. Is prescribed by or in consultation with a hematologist; and
8. Medication will be administered in the member's home; and
9. Member or member's care giver has been properly trained in subcutaneous infusion and prescriber has determined home administration is appropriate.

Initial authorizations will be approved for 4 weeks if within cross-titration period with eculizumab (Soliris) to verify eculizumab has been discontinued, or for 6 months otherwise.

Additional authorizations will be considered when the following criteria are met:

1. Documentation of a positive clinical response to therapy (e.g., increased or stabilization or hemoglobin levels or reduction in transfusions); and
2. Is not prescribed concurrently with eculizumab (Soliris) or ravulizumab

(Ultomiris).

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

1. Request adheres to all FDA approved labeling including age, dosing, contraindications, and warnings and precautions; and
2. Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and
    a. Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or ≥ 10% PNH cells; and
    b. History of at least one red blood cell transfusion in the previous 12 months; and
    ~~c.~~ Documentation of hemoglobin < 10.5 g/dL; *or* ~~and~~
    ~~d. Is not prescribed concurrently with eculizumab (Soliris) or ravulizumab (Ultomiris), unless the patient is in a 4 week period of cross- titration between eculizumab (Soliris) and pegcetacoplan (Empaveli); and~~
3. *Patient has a diagnosis of complement 3 glomerulopathy (C3G) or immune-complex membranoproliferative glomerulonephritis (IC-MPGN); and*
    a. Diagnosis is confirmed on renal biopsy; and
    b. Patient is on a maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEI), angiotensin receptor blocker (ARB), and/or sodium glucose cotransporter-2 (SGLT2) inhibitor for at least 3 months prior to starting pegcetacoplan; and
    c. Patient has a history of a trial and therapy failure with systemic oral glucocorticoids or mycophenolate mofetil; and
    d. Documentation of a baseline urine protein-to-creatinine ratio (UPCR) ≥ 1g/g; and
    e. Patient has an eGFR ≥ 30 mL/min/1.73 m_2; and
4. *For patients under 18 years of age, current weight in kg is provided; and*
5. Is prescribed by or in consultation with a hematologist *or nephrologist*; and
6. Medication will be administered in the member's home; and
7. Member or member's care giver has been properly trained in subcutaneous infusion *or subcutaneous injection* and prescriber has determined home administration is appropriate*; and*
8. *Will not be used with another complement inhibitor or will only be considered for patients switching from one complement inhibitor to pegcetacoplan based on FDA approved labeling*.

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 *the FDA approved recommended time period when switching from a different complement inhibitor* ~~4 weeks if within cross-titration period with eculizumab (Soliris)~~ to verify *treatment* ~~eculizumab~~ has been discontinued, or for 6 months otherwise.

Additional authorizations will be considered when the following criteria are met:

1. Documentation of a positive clinical response to therapy:
    a. *PNH:* e.g., increased or stabilization or hemoglobin levels or reduction in transfusions; *or*
    b. *C3G or IC-MPGN: e.g., reduction in UPCR from baseline and*

eGFR ≥ 30 mL/min/1.73 m$_2$; and

~~2.~~ Is not prescribed concurrently with *other complement inhibitors* ~~eculizumab (Soliris) or ravulizumab (Ultomiris)~~.

Sepiapterin (Sephience)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for sepiapterin (Sephience). 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 hyperphenylalaninemia (HPA) with sepiapterin-responsive phenylketonuria (PK); and
3. Patient is on a phenylalanine (Phe) restricted diet prior to therapy and will continue throughout therapy; and
4. Patient has a baseline blood Phe level ≥ 360 µmol/L while following a Phe restricted diet, obtained within 2 weeks of initiation of sepiapterin therapy (attach lab results); and
5. Patient's current weight in kg is provided; and
6. Blood Phe levels will be measured after 2 weeks of therapy and at least one more time before initial renewal; and
7. Is not prescribed concurrently with sapropterin (Kuvan) or pegvaliase-pqpz (Palynziq).

Initial requests will be considered for 2 months to assess response to therapy.

Continuation of therapy will be considered when the following criteria are met:

1. Patient's current weight in kg is provided; and
2. Patient continues a Phe restricted diet; and
3. After an initial 2-month treatment, an updated blood Phe level must be provided documenting response to therapy, defined as at least a 30% reduction in blood Phe level. If blood Phe level does not decrease at maximum dose, the patient is considered a non-responder and no further requests will be approved; and
4. Patient continues to respond to therapy as demonstrated by a reduction in Phe blood levels since initiation of therapy; and
5. Is not prescribed concurrently with sapropterin (Kuvan) or pegvaliase-pqpz (Palynziq).

Select Topical Agents

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for select topical agents. Payment for a non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria 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 plaque psoriasis with involvement estimated to affect ≤ 20% of the body surface area; and
    a. Request is for roflumilast 0.3% cream or tapinarof 1% cream; and
    b. Patient has documentation of an adequate trial and therapy failure of

combination therapy with a preferred medium to high potency topical corticosteroid and a preferred topical vitamin D analog for a minimum of 4 consecutive weeks; or

3. Patient has a diagnosis of seborrheic dermatitis; and
    a. Request is for roflumilast 0.3% foam; and
    b. Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred topical corticosteroid (scalp- medium to high potency or nonscalp- low potency) and a preferred topical antifungal for a minimum of 4 consecutive weeks; or
4. Patient has a diagnosis of mild to moderate atopic dermatitis; and
    a. Request is for roflumilast 0.15% cream or tapinarof 1% cream; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. 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; or
    d. Patient has documentation of an adequate trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks.

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 select topical agents. Payment for a non-preferred agent will be considered for an FDA approved or compendia indicated diagnosis for the requested drug when the following criteria 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 *(note, only FDA-approved indications for each drug and specific dosage form will be considered);* and
2. Patient has a diagnosis of plaque psoriasis with *total overall* involvement *on scalp and non-scalp areas* ~~estimated to affect~~ ≤ *25* ~~20~~% of the body surface area *(BSA) at baseline. Total non-scalp BSA should not exceed 20%*; and
    ~~a. Request is for roflumilast 0.3% cream or tapinarof 1% cream; and~~
    b. Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred medium to high potency topical corticosteroid and a preferred topical vitamin D analog for a minimum of 4 consecutive weeks; or
3. Patient has a diagnosis of seborrheic dermatitis; and
    ~~a. Request is for roflumilast 0.3% foam; and~~
    b. Patient has documentation of an adequate trial and therapy failure of combination therapy with a preferred topical corticosteroid (scalp- medium to high potency or nonscalp- low potency) and a preferred topical antifungal for a minimum of 4 consecutive weeks; or
4. Patient has a diagnosis of mild to moderate atopic dermatitis; and
    ~~a. Request is for roflumilast 0.15% cream or tapinarof 1% cream; and~~
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. 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; or

d. Patient has documentation of an adequate trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks.

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

ProDUR Edit
The DUR Commission recommends implementing the following ProDUR edits for preferred agents with the removal of PA criteria for Hepatitis C Treatment, Direct Acting Antivirals.

- Quantity limit

Drug Product	Quantity	Days' Supply
Mavyret tablets	84	28
Mavyret pellets	140 packets (5 cartons)	28
Sofosbuvir 400 mg/velpatasvir 100 mg tablets	28	28
Sofosbuvir 200 mg/velpatasvir 50 mg tablets	56	28
Sofosbuvir 200 mg/velpatasvir 50mg pellets	56	28
Sofosbuvir 150 mg/velpatasvir 37.5mg pellets	28	28

- Treatment duration
  - Mavyret: 16 weeks
  - Sofosbuvir/velpatasvir: 12 weeks
- Lookback for treatment (identify treatment experienced):
  - 365 days

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations regarding Brensocatib (Brinsupri); Diazoxide Choline (Vykat XR); Incretin Mimetics for Non-Diabetes Indications; Janus Kinase (JAK) Inhibitors; Pegcetacoplan (Empaveli); Sepiapterin (Sephience); Select Topical Agents; and the removal of PA criteria for Hepatitis C Treatments, Direct Acting Antivirals (DAAs), along with the implementation of ProDUR edits for preferred DAAs, including quantity limits, treatment duration, and a lookback to identify treatment experienced patients.

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