IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Susan L. Parker, R.Ph, Pharm.D.
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 3, 2022. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Tasimelteon (Hetlioz); Janus Kinase Inhibitors; Tralokinumab-Idrm (Adbry); Crisaborole (Eucrisa); Extended-Release Formulations; Non-Preferred Drug; Biologicals for Hidradenitis Suppurativa; and Ophthalmic Agents for Presbyopia. The DUR Commission members also discussed ProDUR edits for Initial Days' Supply Limit – Benzodiazepines; Benzodiazepine Cumulative Quantity Limit; and quantity limits for select drugs (as detailed below). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a May 9, 2022 letter that was sent to them detailing the proposed criteria for Tasimelteon (Hetlioz); Janus Kinase Inhibitors; Tralokinumab-Idrm (Adbry); Crisaborole (Eucrisa); Extended-Release Formulations; Non-Preferred Drug; Biologicals for Hidradenitis Suppurativa; and Ophthalmic Agents for Presbyopia. Also included were details regarding proposed ProDUR edits for Initial Days' Supply Limit – Benzodiazepines; Benzodiazepine Cumulative Quantity Limit; and quantity limits for select drugs.

Tasimelteon (Hetlioz)

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for tasimelteon (Hetlioz®). Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered under the following conditions:

1. Patient has a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as confirmed by a sleep specialist; and
2. Patient is 18 years of age or older; and

3. Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and
4. Patient has a documented trial and therapy failure with ramelteon (Rozerem®).

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered when the patient has received 3 months of continuous therapy and patient has achieved adequate results with tasimelteon (Hetlioz®), such as entrainment, significant increases in nighttime sleep, and/or significant decreases in daytime sleep.

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted and stricken)
Prior authorization (PA) is required for tasimelteon (Hetlioz®). *Requests will be considered when patient has an FDA approved or compendia indication for the requested drug.* ~~Requests for doses above the manufacturer recommended dose will not be considered.~~
Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a *documented* diagnosis of:
    a. Non-24-Hour Sleep-Wake Disorder (Non-24)~~, as confirmed by a sleep specialist~~; and
        ~~i. Patient is 18 years of age or older; and~~
        ii. Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and
        iii. Patient has a documented trial and therapy failure with ramelteon (Rozerem®)*; or*
    b. *Sleep disturbances in Smith-Magenis Syndrome (SMS); and*
        i. *Documentation of confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is provided (attach results); and*
        ii. *Patient has a documented trial and therapy failure with at least one other medication used for sleep disturbances; and*
3. *Is prescribed by, or in consultation with a physician who specializes in the treatment of sleep disorders; and*
4. *Will not be used concurrently with other sleep medications.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered *under the following conditions:*

1. *Patient's use of tasimelteon (Hetlioz®) has been continuous without gaps in treatment;* ~~when the patient has received 3 months of continuous therapy~~ and
2. *Documentation* patient has *experienced a positive clinical response to therapy* ~~achieved adequate results~~ with tasimelteon (Hetlioz®), such as entrainment, significant increases in nighttime sleep, ~~and/or~~ significant decreases in daytime sleep*, and/or nighttime sleep quality*.

Janus Kinase Inhibitors

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

1. Patient meets the FDA approved age for indication; and
2. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, biologic DMARDs or potent immunosuppressants (azathioprine or cyclosporine); and
3. Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and
4. Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and
5. Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and
6. Patient is not at an increased risk of gastrointestinal perforation; and
7. Patient does not have an active, serious infection, including localized infections; and
8. Medication will not be given concurrently with live vaccines; and
9. Follows FDA approved dosing based on indication; and
10. 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 to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
        iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR
    d. Polyarticular Course Juvenile Idiopathic Arthritis; with
        i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and
        ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        iii. A documented trial and inadequate response with a preferred TNF inhibitor.

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 stricken/italicized and/or highlighted)
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* when the following conditions are met:

~~1. Patient meets the FDA approved age for indication; and~~

2. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, *biological therapies,* ~~biologic DMARDs~~ or potent immunosuppressants (azathioprine or cyclosporine); and
3. *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*

~~4. Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and~~

~~5. Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and~~

~~6. Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and~~

~~7. Patient is not at an increased risk of gastrointestinal perforation; and~~

~~8. Patient does not have an active, serious infection, including localized infections; and~~

~~9. Medication will not be given concurrently with live vaccines; and~~

~~10. Follows FDA approved dosing based on indication; and~~

11. Patient has a diagnosis of:
    a. Moderate to severe rheumatoid arthritis *(baricitinib, tofacitinib, upadacitinib)*; with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate; and
        ii. A documented trial and inadequate response to one preferred TNF inhibitor; OR
    b. Psoriatic arthritis *(tofacitinib, upadacitinib)*; with
        i. A documented trial and inadequate response, at a maximally tolerated dose, with methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. Documented trial and therapy failure with one preferred TNF inhibitor used for psoriatic arthritis; OR
    c. Moderately to severely active ulcerative colitis *(tofacitinib, upadacitinib)*; with
        i. A documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and
        ii. A documented trial and inadequate response with a preferred TNF inhibitor; and
        iii. If requested dose is for tofacitinib 10mg twice daily, an initial 16 weeks of therapy will be allowed. Continued requests at this dose will need to document an adequate therapeutic benefit; OR
    d. Polyarticular Course Juvenile Idiopathic Arthritis *(tofacitinib)*; with
        i. A documented trial and inadequate response to intraarticular glucocorticoid injections; and
        ii. A documented trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        iii. A documented trial and inadequate response with a preferred TNF inhibitor*; OR*
    e. Ankylosing spondylitis (tofacitinib, upadacitinib); with

i. A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and

ii. A documented trial and inadequate response with at least one preferred TNF inhibitor; OR

f. Atopic dermatitis; with

i. Documentation patient has failed to respond to good skin care and regular use of emollients; and

ii. A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and

iii. A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and

iv. For mild to moderate atopic dermatitis (ruxolitinib)

a. A documented trial and therapy failure with crisaborole; and

b. Affected area is less than 20% of body surface area (BSA); and

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

v. For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):

a. A documented trial and therapy failure with cyclosporine or azathioprine; and

b. Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.

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

Tralokinumab (Adbry)

Newly Proposed Clinical Prior Authorization Criteria

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

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

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

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

Crisaborole (Eucrisa)

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

1. Patient has a diagnosis of mild to moderate atopic dermatitis; and
2. Patient is within the FDA labeled age; and
3. Patient has failed to respond to good skin care and regular use of emollients; and
4. Patient has documentation of an adequate trial and therapy failure with two preferred medium to high potency topical corticosteroids for a minimum of 2 consecutive weeks; and
5. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
6. Patient will continue with skin care regimen and regular use of emollients.
7. Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.

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

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization (PA) is required for Eucrisa (crisaborole). Payment will be considered ~~for patients~~ when *patient has an FDA approved or compendia indication 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 mild to moderate atopic dermatitis; and
3. ~~Patient is within the FDA labeled age; and~~
4. Patient has failed to respond to good skin care and regular use of emollients; and
5. Patient has documentation of an adequate trial and therapy failure with *one* ~~two~~ preferred medium to high potency topical corticosteroid~~s~~ for a minimum of 2 consecutive weeks; and
6. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
7. Patient will continue with skin care regimen and regular use of emollients.
8. Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.

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

Extended Release Formulations

Current Prior Authorization Criteria
Payment for a non-preferred extended release formulation will be considered when the following criteria are met:

1. Previous trial and therapy failure with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance and
2. Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis.

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

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)
Payment for a non-preferred extended release formulation 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. Previous trial and therapy failure with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and
3. Previous trial and therapy failure at a therapeutic dose with a preferred drug of a different chemical entity indicated to treat the submitted diagnosis.

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

Non-Preferred Drug

Current Prior Authorization Criteria
Prior authorization (PA) is required for non-preferred drugs as specified on the Iowa Medicaid Preferred Drug List. Payment for a non-preferred medication will be authorized only for cases in which there is documentation of previous trial and therapy failure with the preferred agent, unless evidence is provided that use of these agents would be medically contraindicated.

Proposed Prior Authorization Criteria (changes italicized/highlighted/stricken)
Prior authorization (PA) is required for non-preferred drugs as specified on the Iowa Medicaid Preferred Drug List. Payment for a non-preferred medication will be *considered for an FDA approved or compendia indicated diagnosis* ~~authorized~~ only for cases in which there is documentation of previous trial and therapy failure with the preferred agent*(s)*, unless evidence is provided that use of these agents would be medically contraindicated. *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.*

Biologicals for Hidradenitis Suppurativa

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for biologicals FDA approved for the treatment of Hidradenitis Suppurativa (HS). Patients initiating therapy with a biological agent must:

1. Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and
2. Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and
3. Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and
4. Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.

Payment will be considered under the following conditions:

1. Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and
2. Patient is 18 years of age or older; and
3. Patient has at least three (3) abscesses or inflammatory nodules; and
4. Patient has documentation of adequate trials and therapy failures with the following:
    a. Daily treatment with topical clindamycin;
    b. Oral clindamycin plus rifampin;
    c. Maintenance therapy with tetracyclines (doxycycline or minocycline).

If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of 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/stricken)

Prior authorization (PA) is required for biologicals FDA approved *or compendia indicated* for the treatment of Hidradenitis Suppurativa (HS). *Payment for non-preferred biologic agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred biologic agent.* Patients initiating therapy with a biological agent must:

1. Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and
2. Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and
3. Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and

4. Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment.

Payment will be considered under the following conditions:

1. *Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
2. Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and
3. ~~Patient is 18 years of age or older; and~~
4. Patient has at least three (3) abscesses or inflammatory nodules; and
5. Patient has documentation of adequate trials and therapy failures with the following:
    a. Daily treatment with topical clindamycin;
    b. Oral clindamycin plus rifampin;
    c. Maintenance therapy with *a preferred* tetracycline~~s (doxycycline or minocycline)~~.

If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

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

Ophthalmic Agents for Presbyopia

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for ophthalmic agents indicated for presbyopia. Requests will be considered when patient has an FDA approved or compendia indication for the requested drug. Payment for a non-preferred agent will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a documented diagnosis of presbyopia; and
3. Patient is aged 40 to 55 years old at start of therapy; and
4. Is prescribed by or in consultation with an ophthalmologist or optometrist; and
5. Patient has documentation of a therapeutic failure with corrective lenses (eyeglasses or contact lenses), unless contraindicated or clinically significant intolerance.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered under the following conditions:

1. Patient has a documented improvement in presbyopia defined as the patient gained 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA); and

2. Patient is not experiencing adverse effects from the drug.

Proposed ProDUR Quantity Limits

Drug	**Proposed Quantity Limit per 30 Days** (unless otherwise stated)
Cibinqo (abrocitinib) 50 mg, 100 mg, 200 mg	30
Olumiant (baricitinib) 1 mg, 2 mg	30
Opzelura (ruxolitinib) 1.5% cream	240 g (4 tubes)
Rinvoq (upadacitinib)15 mg, 30 mg	30
Rinvoq (upadacitinib) 45 mg	28 per 28 days
Xeljanz (tofacitinib) 5 mg, 10 mg	60
Xeljanz (tofacitinib) XR 11 mg, 22 mg	30
ProAir HFA 8.5 g (albuterol)	2 inhalers (17 grams)
ProAir Digihaler (albuterol)	2 inhalers
ProAir Respiclick (albuterol)	2 inhalers
Proventil HFA 6.7 g (albuterol)	2 inhalers (13.4 grams)
Ventolin HFA 18 g (albuterol)	2 inhalers (36 grams)
Xopenex HFA 15 g (levalbuterol)	2 inhalers (30 grams)
Halcion 0.125 mg (triazolam)	30
Halcion 0.25 mg (triazolam)	60
Vuity (Pilocarpine) 1.25% opth. soln.	2.5 mL

Proposed ProDUR Initial Days Supply Limit for Benzodiazepines

The DUR Commission made a recommendation to implement a 7-day initial limit on all benzodiazepines for new users. The ProDUR point-of-sale (POS) edit would limit to an initial 7 days' supply for a benzodiazepine if the requested benzodiazepine is not found in pharmacy claims in the preceding 90 days. Exceptions to this edit include nasal and rectal diazepam, nasal midazolam and clobazam. Prior authorization would be required for use beyond the 7-day allowance. The Commission will develop PA criteria for requests exceeding the initial limit at a future meeting and will be shared with interested parties for comment prior to implementation.

Proposed ProDUR Cumulative Quantity Limit for Oral Benzodiazepines

The DUR Commission made a recommendation to implement a cumulative quantity limit of 4 units per day across the benzodiazepine class for solid oral dosage forms. The quantity limit chart would include the following statement: Benzodiazepines are subject to a cumulative quantity limit of 4 units per day, unless otherwise indicated on the chart.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for Tasimelteon (Hetlioz); Janus Kinase Inhibitors; Tralokinumab-Idrm (Adbry); Crisaborole (Eucrisa); Extended-Release Formulations; Non-Preferred Drug; Biologicals for Hidradenitis Suppurativa; and Ophthalmic Agents for Presbyopia; and the Proposed ProDUR initiatives detailed above.

Sincerely,

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

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