IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
1305 East Walnut – Des Moines, IA 50309 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
Melissa Klotz, Pharm.D.
Jason Kruse, D.O
Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Jason Wilbur, M. D.
Charles Wadle, D.O.
John Ellis, Pharm.D.
Lisa Todd, R.Ph.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

February 2, 2022

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
1305 East Walnut
Des Moines, Iowa 50309

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 2, 2022. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Select Preventative Migraine Treatments; Hepatitis C Treatments, Direct Acting Antivirals; Janus Kinase Inhibitors; Apremilast (Otezla); Biologicals for Arthritis; Triheptanoin (Dojolvi); and Baclofen Oral Solution (Ozobax). The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to November 8, 2021 letter that was sent to them detailing the proposed criteria for Select Preventative Migraine Treatments; Hepatitis C Treatments, Direct Acting Antivirals; Janus Kinase Inhibitors; Apremilast (Otezla); Biologicals for Arthritis; Triheptanoin (Dojolvi); and Baclofen Oral Solution (Ozobax).

Select Preventative Migraine Treatments (formerly CGRP Inhibitors)

Current Clinical Prior Authorization Criteria (CGRP Inhibitors)
Prior authorization (PA) is required for CGRP Inhibitors. Payment will be considered for a FDA approved or compendia indicated diagnosis under the following conditions:

1. Patient has one of the following diagnoses:
    a. Chronic Migraine, defined as:
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or
    b. Episodic Migraine, defined as:
        i. 4 to 14 migraine days per month for a minimum of 3 months; or
    c. Episodic Cluster Headache, defined as:

        i. Occurring with a frequency between one attack every other day and 8 attacks per day; and
        ii. With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and
        iii. Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and
2. Patient meets the FDA approved age; and
3. Patient has been evaluated for and does not have medication overuse headache; and
4. For Episodic and Chronic Migraine, patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e., anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or
5. For Episodic Cluster Headache, patient has documentation of
    a. A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and
    b. A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.
6. The requested dose does not exceed the maximum FDA labeled dose for the submitted diagnosis; and
7. Lost, stolen, or destroyed medication replacement requests will not be authorized.

Initial requests will be approved for 3 months. Additional PAs will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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

<u>Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted and/or stricken)</u>
Prior authorization (PA) is required for *select preventative migraine agents* ~~CGRP Inhibitors~~. *Payment for non-preferred select preventative migraine agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred, select preventative migraine agent.* Payment will be considered ~~for a FDA approved or compendia indicated diagnosis~~ under the following conditions:

1. Patient has one of the following diagnoses:
    a. Chronic Migraine, defined as:

i. ≥ 15 headache days per month for a minimum of 3 months; and
ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or

b. Episodic Migraine, defined as:
i. 4 to 14 migraine days per month for a minimum of 3 months; or

c. Episodic Cluster Headache, defined as:
i. Occurring with a frequency between one attack every other day and 8 attacks per day; and
ii. With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods ≥3 months; and
iii. Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and

2. *Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings and precautions* ~~Patient meets the FDA approved age~~; and
3. *The requested agent will not be used in combination with another CGRP inhibitor for the preventative treatment of migraine; and*
4. Patient has been evaluated for and does not have medication overuse headache; and
5. For Episodic and Chronic Migraine, patient has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e., anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); or
6. For Episodic Cluster Headache, patient has documentation of
   a. A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and
   b. A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480mg to 960mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.
7. ~~The requested dose does not exceed the maximum FDA labeled dose for the submitted diagnosis; and~~
8. Lost, stolen, or destroyed medication replacement requests will not be authorized.

Initial requests will be approved for 3 months. Additional PAs will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days, reduced weekly cluster headache attack frequency).

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

Hepatitis C Treatments, Direct Acting Antivirals

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for hepatitis C treatments. 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's age and/or weight is within the FDA labeled age and/or weight; and
3. Patient has had testing for hepatitis C virus (HCV) genotype; and
4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
5. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and
6. Patient's prior treatment history is provided (treatment naïve or treatment experienced); and
7. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
8. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
9. HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and
10. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
    a. Patient is not a pregnant female or male with a pregnant female partner; and
    b. Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
    c. Monthly pregnancy tests will be performed during treatment; and
11. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
12. Documentation is provided for patients who are ineligible to receive ribavirin.
13. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.
14. Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
15. 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.
16. Lost or stolen medication replacement requests will not be authorized.
17. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Only one treatment attempt will be allowed per calendar year, regardless of compliance.

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

Prior authorization (PA) is required for hepatitis C *direct-acting antivirals (DAA)* ~~treatments~~. 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's age and/or weight is within the FDA labeled age and/or weight; and
3. Patient has had testing for hepatitis C virus (HCV) genotype; and
4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
5. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and
6. Patient's prior *HCV DAA* treatment history is provided (treatment naïve or treatment experienced); and
7. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
8. Patient has *been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as the SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools and the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C); and*
9. *Patient has been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission. If patient is currently using IV drugs and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling* ~~abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test~~; and
10. HCV treatment is prescribed by or in consultation with a digestive disease, liver disease, or infectious disease provider practice; and
11. *FDA approved pediatric formulations of HCV DAAs and DAA approved for pediatric use will be considered for those under the age of 18 when used in accordance with current AASLD guidelines including for indication and age; and*
12. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
    a. Patient is not a pregnant female or male with a pregnant female partner; and
    b. Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
    c. Monthly pregnancy tests will be performed during treatment; and
13. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the *DAA* ~~HCV medication~~*; and*~~.~~
14. Documentation is provided for patients who are ineligible to receive ribavirin*; and*~~.~~
15. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved*; and*~~.~~
16. Patient does not have limited life expectancy (less than 12 months) due to non-liver related comorbid conditions.
17. 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.
18. Lost or stolen medication replacement requests will not be authorized.
19. The 72-hour emergency supply rule does not apply to *DAAs* ~~oral hepatitis C antiviral agents~~.

~~Only one treatment attempt will be allowed per calendar year, regardless of compliance.~~

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. *Patients who previously achieved SVR that have HCV recurrence due to IV drug use must have documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment, and can be managed as an initial infection; and*
3. *The requested therapy is FDA approved as therapy for treatment-experienced patients and follows current AASLD guidelines; 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.*

Janus Kinase Inhibitors

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for Janus kinase (JAK) inhibitors. Payment will be considered for a FDA approved or compendia indicated diagnosis when the following conditions are met:

1. Patient meets the FDA approved age; 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.
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 to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, or leflunomide); and
        ii. A documented trial and inadequate response to two preferred biological DMARDs; OR
    b. Psoriatic arthritis; with
        i. A documented trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. Documented trial and therapy failure with two preferred biological agents used for psoriatic arthritis.
    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 biological DMARD; 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.

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

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted and/or stricken)
Prior authorization (PA) is required for 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 a*n* 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* ~~to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, or leflunomide)~~; and
        ii. A documented trial and inadequate response to *one* ~~two~~ preferred *TNF inhibitor* ~~biological DMARDs~~; OR
    b. Psoriatic arthritis; with
        i. A documented trial and inadequate response*, at a maximally tolerated dose,* ~~to therapy with the preferred oral DMARD,~~ *with* methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
        ii. Documented trial and therapy failure with *one* ~~two~~ preferred *TNF inhibitor* ~~biological agents~~ 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* ~~biological DMARD~~; 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.

Apremilast (Otezla)

Current Clinical Prior Authorization Criteria

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

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); or
3. Patient has a diagnosis of moderate to severe plaque psoriasis; and
4. Patient does not have severe renal impairment (CrCl < 30 mL/min).

Psoriatic Arthritis

1. Patient has documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
2. Patient has documentation of trials and therapy failures with two preferred biological agents indicated for psoriatic arthritis.

Plaque Psoriasis

1. Patient has documentation of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine; and
2. Patient has documentation of trials and therapy failures with two preferred biological agents indicated for plaque psoriasis.

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

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

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

1. *Request adheres to all FDA approved labeling for indication, including age, dosing, and contraindications* ~~Patient is 18 years of age or older~~; and
~~2. Patient does not have severe renal impairment (CrCl < 30 mL/min)*; and*~~
3. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); *with*
    a. ~~Patient has~~ ~~d~~*D*ocumentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated)*.*~~; and~~

b. ~~Patient has documentation of trials and therapy failures with two preferred biological agents indicated for psoriatic arthritis.~~*;* or

4. Patient has a diagnosis of ~~moderate to severe~~ plaque psoriasis; *with* ~~and~~
   a. ~~Patient has d~~*Documentation* of a trial and inadequate response to phototherapy, systemic retinoids, methotrexate, or cyclosporine~~.~~*.*; ~~and~~
   b. ~~Patient has documentation of trials and therapy failures with two preferred biological agents indicated for plaque psoriasis.~~
5. *Patient has a diagnosis of Behçet disease; with*
   a. Documentation of active oral ulcers associated with Behçet disease; and
   b. Documentation of a previous trial and inadequate response, at a therapeutic dose, to colchicine.

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

Biologicals for Arthritis

Current Clinical Prior Authorization Criteria

Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

1. Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and
2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and
3. Patient has a diagnosis of rheumatoid arthritis (RA):
   A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxycholoroquine, sulfasalazine, or leflunomide).

Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions; or

1. Patient has a diagnosis of moderate to severe psoriatic arthritis:
   A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
2. Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis:
   A trial and inadequate response to intraarticular glucocorticoid injections and the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

In addition to the above:

Requests for TNF Inhibitors:

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

Requests for Interleukins:

1. Medication will not be given concurrently with live vaccines.

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

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted and/or stricken)
Prior authorization (PA) is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling*, including age, indication, dosing, and contraindications*. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

1. Patient has been screened for hepatitis B and C. Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and
2. Patient has been screened for latent TB infection, patients with latent TB will only be considered after one month of TB treatment and patients with active TB will only be considered upon completion of TB treatment; and
3. Patient has a diagnosis of rheumatoid arthritis (RA)~~:~~*; with*
    a. *Documentation of a* ~~A~~ trial and inadequate response*, at a maximally tolerated dose, with methotrexate* ~~to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD~~ (hydroxycholoroquine, sulfasalazine, or leflunomide *may be used if methotrexate is contraindicated*)~~.~~

~~Upon an unsuccessful methotrexate trial in patients with established RA, the combination trial with a second DMARD may be overridden if there is evidence of severe disease documented by radiographic erosions~~; or

4. Patient has a diagnosis of moderate to severe psoriatic arthritis~~:~~*; with*
    a. *Documentation of a* trial and inadequate response, *at a maximally tolerated dose* ~~to the preferred oral DMARD~~, *with* methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
5. Patient has a diagnosis of moderate to severe juvenile idiopathic arthritis*; with*
    a. *Documentation of a* ~~A~~ trial and inadequate response to intraarticular glucocorticoid injections and ~~the preferred oral DMARD,~~ methotrexate *at a maximally tolerated dose* (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and

In addition to the above:
Requests for TNF Inhibitors:

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

Requests for Interleukins:

1. Medication will not be given concurrently with live vaccines.

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

Triheptanoin (Dojolvi)

Newly Proposed Clinical Prior Authorization Criteria

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

1. Request adheres to all FDA approved labeling for indication, including age, dosing, contraindications, warnings and precautions; and
2. Patient has a diagnosis of long-chain fatty acid oxidation disorder (LC-FAOD), with supporting documentation of gene mutation(s) associated with LC-FAOD (LC-FAODs include: CPT I, CACT, CPT II, VLCAD, TFP, LCHAD); and
3. Patient will not be using another medium chain triglyceride (MCT) product; and
4. Documentation of patient's daily caloric intake (DCI) is provided; and
5. Patient's target daily dosage is provided as a percentage of the patient's total daily prescribed DCI, not to exceed 35%; and
6. Is prescribed by or in consultation with an endocrinologist, geneticist, or metabolic disease specialist.

If the criteria for coverage are met, initial requests will be approved for four months. Additional authorizations will be considered upon documentation of a positive clinical response to therapy.

Baclofen Oral Solution (Ozobax)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization (PA) is required for baclofen oral solution (Ozobax). Payment for a non-preferred agent will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:

1. Patient has a diagnosis of spasticity resulting from multiple sclerosis (relief of flexor spasms and concomitant pain, clonus, and muscular rigidity) or spinal cord injuries/diseases; and
2. Patient meets the FDA approved age; and
3. Documentation of a patient-specific, clinically significant reason (beyond convenience) why the member cannot use baclofen oral tablets, even when tablets are crushed and sprinkled on soft food or liquid. Presence of a nasogastric (NG) tube/J-tube alone are not reasons for approval; and
4. Request does not exceed the maximum dosage of 80mg daily.

Based on current guidelines from the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA), the DUR Commission reviewed prior authorization criteria for the direct acting antivirals (DAAs) used in the treatment of chronic hepatitis C virus (HCV) and discussed changes to the abstinence requirement. Currently, the AASLD/IDSA HCV guidance recommends treatment for all patients with acute or chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy. Additionally, the DUR Commission reviewed other state Medicaid program HCV criteria regarding abstinence from illicit drug use and/or alcohol use. While some states continue to require abstinence, the trend has been for states to remove abstinence criteria or completely remove prior authorization criteria for the initial treatment of HCV. The DUR Commission voted in favor of removing the abstinence requirement, allowing treatment of all members with HCV, regardless of use of illicit drugs or alcohol, aligning the PA criteria with current guidelines. The DUR Commission felt it was important to add requirements to screen members for readiness of HCV treatment, confirming

they have received education on the importance of abstinence from IV drug use and alcohol use, compliance, and how to prevent HCV transmission.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Select Preventative Migraine Treatments; Hepatitis C Treatments, Direct Acting Antivirals; Janus Kinase Inhibitors; Apremilast (Otezla); Biologicals for Arthritis; Triheptanoin (Dojolvi); and Baclofen Oral Solution (Ozobax).

Sincerely,

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

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