IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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June 7, 2018

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, June 6, 2018. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; Hepatitis C Treatments; Janus Kinase Inhibitors; Biologicals for Arthritis; Apremilast (Otezla): and Methotrexate Injection. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to an April 9, 2018 letter that was sent to them detailing the proposed criteria for Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; Hepatitis C Treatments; Janus Kinase Inhibitors; Biologicals for Arthritis; Apremilast (Otezla): and Methotrexate Injection.

Vesicular Monoamine Transporter (VMAT) 2 Inhibitors

Newly Proposed Clinical Prior Authorization
Prior authorization is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions:

Tardive Dyskinesia (Ingrezza or Austedo)

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:
    a. Involuntary athetoid or choreiform movements
    b. Documentation or claims history of current or prior chronic use (≥ 3 months or 1 month in patients ≥ 60 years old) of a dopamine receptor blocking agent

(e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)
   c. Symptoms lasting longer than 4-8 weeks; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and
5. Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and
6. For Ingrezza:
   a. Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranylcypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and
   b. Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and
   c. Is prescribed within the FDA approved dosing; or
7. For Austedo:
   a. Patient is not suicidal, or does not have untreated/inadequately treated depression;
   b. Patient does not have hepatic impairment;
   c. Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
   d. Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and
   e. Is prescribed within the FDA approved dosing.

If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met:
1. Patient continues to meet the criteria for initial approval; and
2. Documentation of improvement in TD symptoms as evidenced by a reduction of AIMS score from baseline (attach current AIMS).

<u>Chorea associated with Huntington's disease</u> (Austedo or tetrabenazine)
1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of Huntington's disease with chorea symptoms; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Is prescribed within the FDA approved dosing; and
5. Patient is not suicidal, or does not have untreated or inadequately treated depression; and
6. Patient does not have hepatic impairment; and
7. Patient does not have concurrent therapy with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
8. For tetrabenazine, patients requiring doses above 50mg per day have been tested and genotyped for the drug metabolizing enzyme CYP2D6 to determine if they are a poor metabolizer or extensive metabolizer; and

9. In patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed the following:
    a. Austedo - 36mg per day (18mg single dose) or
    b. Tetrabenazine – 50mg per day (25mg single dose)

If criteria for coverage are met, initial requests will be given for 3 months. Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to meet the criteria for initial approval; and
2. Documentation of improvement in chorea symptoms is provided.

Hepatitis C Agents

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized/stricken)
Prior authorization 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. Viral load will be submitted by prescriber 12 weeks after completion of therapy; and
7. ~~Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:~~
    - ~~Liver biopsy confirming Metavir score ≥ F3; or~~
    - ~~Transient elastography (FibroScan) score ≥ 9.5kPa; or~~
    - ~~FibroSURE (FibroTest) score ≥ 0.58; or~~
    - ~~APRI score > 1.5; or~~
    - ~~Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or~~
    - ~~Physical findings or clinical evidence consistent with cirrhosis; or~~
    - ~~Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis.~~
8. Patient's prior treatment history is provided (treatment naïve or treatment experienced); and
9. 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
10. 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
11. For regimens containing sofosbuvir, patient does not have severe renal impairment

(creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and

12. HCV treatment is prescribed by *or in consultation with* a digestive disease, liver disease, or infectious disease provider practice; and
13. 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
14. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
15. Documentation is provided for patients who are ineligible to receive ribavirin.
16. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.
17. Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.
18. 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.
19. Lost or stolen medication replacement requests will not be authorized.
20. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Janus Kinase Inhibitors

Proposed Clinical Prior Authorization Criteria (changes highlighted/stricken/italicized)
Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met:

1. ~~The~~ Patient *meets the FDA approved age* ~~is 18 years of age or older~~: and
2. ~~The~~ Patient is not using or planning to use tofacitinib in combination with 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~~; and~~ *with*
        i. ~~Has~~ 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~~, or minocycline~~); and

ii. ~~Has~~ A documented trial and inadequate response to two preferred biological DMARDs; ~~and~~ *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.

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

Biologicals for Arthritis

Proposed Clinical Prior Authorization Criteria (changes highlighted/stricken/italicized)
Prior authorization 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 ~~a~~ 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.~~,~~ ~~p~~*P*atients 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* ~~will not be considered for coverage~~; 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~~,or minocycline~~).
   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:
   A trial and inadequate response to the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); or
5. 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.

Apremilast (Otezla)

Proposed Clinical Prior Authorization Criteria (changes highlighted/stricken/italicized)
Prior authorization 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. ~~Prescribed by a rheumatologist or a dermatologist; and~~
5. 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 ~~used~~ *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*.

Methotrexate Injection

Proposed Clinical Prior Authorization Criteria (changes highlighted/stricken/italicized)
Prior authorization is required for non-preferred methotrexate injection. Payment will be considered under the following conditions:

1. Diagnosis of severe, active rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (pJIA) and ALL of the following:
    a. Prescribed by a rheumatologist; and
    b. Patient has a documented trial and intolerance with oral methotrexate; and
    c. Patient has a documented trial and therapy failure or intolerance with at least one other non-biologic DMARD (hydroxychloroquine, leflunomide, ~~minocycline~~ or sulfasalazine); and
    d. Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and
    e. Patient does not reside in a long-term care facility.
2. Diagnosis of severe, recalcitrant, disabling psoriasis and ALL of the following:
    a. Patient is 18 years of age or older; and
    b. Prescribed by a dermatologist; and
    c. Patient has documentation of an inadequate response to all other standard

therapies (oral methotrexate, topical corticosteroids, vitamin D analogues, cyclosporine, systemic retinoids, tazarotene, and phototherapy).

d. Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and
e. Patient does not reside in a long-term care facility.

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

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Vesicular Monoamine Transporter (VMAT) 2 Inhibitors; Hepatitis C Treatments; Janus Kinase Inhibitors; Biologicals for Arthritis; Apremilast (Otezla): and Methotrexate Injection.

Sincerely,

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Cc: Erin Halverson, R.Ph, IME
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