IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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November 9, 2018

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 7, 2018. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Multiple Sclerosis Agents – Oral; Janus Kinase Inhibitors; and Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to an August 3, 2018 letter that was sent to them detailing the proposed criteria for Multiple Sclerosis Agents – Oral; Janus Kinase Inhibitors; and Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors.

Multiple Sclerosis Agents

Proposed Clinical Prior Authorization Criteria *(changes highlighted/stricken/italicized)*
For patients initiating therapy with *a preferred oral agent* ~~fingolimod (Gilenya™)~~, a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:
~~Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions:~~

1. A diagnosis of relapsing forms of multiple sclerosis; and
2. *Patient meets the FDA approved age; and*
3. A previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.
4. Requests for a non-preferred oral multiple sclerosis agent must document a previous

trial and therapy failure with a preferred oral multiple sclerosis agent.

For patients initiating therapy with fingolimod (Gilenya™):

1. Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization or Class lll/lV heart failure.
2. Patient does not have a history or presence of Mobitz Type ll 2nd degree or 3rd degree AV block or sick sinus syndrome, unless the patient has a pacemaker.
3. Patient does not have a baseline QTc interval ≥ 500ms.
4. Patient is not being treated with Class la or Class lll anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio®)~~, documentation of the following must be provided~~:

1. Patient does not have severe hepatic impairment.
2. A negative pregnancy test for females of childbearing age.
3. Use of a reliable form of contraception for females of childbearing age.
4. Patient is not taking leflunomide.

For patients initiating therapy with dimethyl fumarate (Tecfidera™)~~, documentation of the following must be provided~~:

1. Patient does not have a low lymphocyte count as documented by a recent (within 6 months) CBC prior to initiating therapy.
2. Upon renewal, documentation of an updated CBC.

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

Janus Kinase Inhibitors

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization is required for Janus kinase (JAK) inhibitors. 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: and
2. Patient is not using or planning to use ~~tofacitinib~~ *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 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*; OR*.

c. Patient has a diagnosis of moderately to severely active ulcerative colitis, and

i. Has a documented trial and inadequate response to two preferred conventional therapies including amino salicylates and azathioprine/6-mercaptopurine; and

ii. Has a documented trial and inadequate response with a preferred biological DMARD; and

iii. If requested dose is for 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

CGRP Inhibitors

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for CGRP Inhibitors. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of migraine as defined by one of the following:
    a. Chronic Migraine
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headache days per month for a minimum of 3 months; or
    b. Episodic Migraine
        i. 4 to 14 migraine days per month for a minimum of 3 months; and
2. Patient meets the FDA approved age; and
3. Patient has been evaluated for and does not have medication overuse headache; and
4. 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, nadalol, propranolol, timolol], antidepressants, [amitriptyline, venlafaxine]); and
5. The requested dose does not exceed the maximum FDA labeled dose; and
6. Lost, stolen, or destroyed medication replacement requests will not be authorized.

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

The required trials may be overridden when documented evidence is provided that 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 Multiple Sclerosis Agents – Oral; Janus Kinase Inhibitors; and Calcitonin Gene-Related Peptide (CGRP) Receptor Inhibitors

Sincerely,

Pamela Smith R.Ph.

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Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph, IME
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