IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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November 7, 2019

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
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611 5th Avenue
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, November 6, 2019. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Multiple Sclerosis Agents, Oral; Ospemifene (Osphena); Abilify MyCite; and CGRP Inhibitors. The DUR Commission members also discussed a proposed ProDUR quantity limit and maximum milligram per day edit for gabapentinoid agents. 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 19, 2019 letter that was sent to them detailing the proposed criteria for Multiple Sclerosis Agents, Oral; Ospemifene (Osphena); Abilify MyCite; and CGRP Inhibitors in addition to the proposed ProDUR quantity limit for gabapentinoid agents.

Multiple Sclerosis Agents – Oral

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized or stricken)
For patients initiating therapy with a preferred oral medication, 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:

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

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

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*; and*~~.~~
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*; and*~~.~~
3. Patient does not have a baseline QTc interval ≥ 500ms*; and*~~.~~
4. Patient is not being treated with Class la or Class lll anti-arrhythmic drugs.

For patients initiating therapy with teriflunomide (Aubagio):

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

For patients initiating therapy with dimethyl fumarate (Tecfidera):

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

For patients initiating therapy with cladribine (Mavenclad):

1. *Patient's current weight is provided; and*
2. *Patient does not have a current malignancy and patient is up to date on all age appropriate malignancy screening; and*
3. *Pregnancy has been excluded in females of reproductive potential; and*
4. *Women and men of reproductive potential must use effective contraception during treatment and for 6 months after the last dose in each treatment course; and*
5. *Women must not intend to breastfeed while being treated and for 10 days after the last dose; and*
6. *Patient does not have HIV infection; and*
7. *Patient does not have active chronic infection (e.g. hepatitis or tuberculosis); and*
8. *No more than two yearly treatment courses (i.e. two treatment courses consisting of two treatment cycles) will be considered.*

For patients initiating therapy on siponimod (Mayzent):

1. *Patient does not have a CYP2C9*3/*3 genotype; and*
2. *Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; and*
3. *Patient does not have a presence of Mobitz Type II 2nd degree, 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker.*

Ospemifene (Osphena)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for ospemifene (Osphena). Requests for a diagnosis of moderate to severe dyspareunia are considered not medically necessary and will be denied. Payment will be considered under the following conditions:

1. Patient is a post-menopausal woman with a diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy; and
2. Patient has documentation of an adequate trial and therapy failure with a preferred vaginal estrogen agent; and
3. Patient does not have any contraindications to ospemifene as listed in the FDA approved label; and
4. Will not be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; and
5. Patient does not have severe hepatic impairment (Child-Pugh Class C); and
6. Patient will be evaluated periodically as clinically appropriate to determine if treatment is still necessary as ospemifene should be used for the shortest duration consistent with treatment goals and risks for the individual woman; and
7. Dose does not exceed the FDA approved dose.

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

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy.

Aripiprazole Tablets with Sensor (Abilify MyCite)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for aripiprazole tablets with sensor (Abilify MyCite). Payment will be considered under the following conditions:

1. Patient has a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder; and
2. Patient meets the FDA approved age for use of the Abilify MyCite device; and
3. Dosing follows the FDA approved dose for the submitted diagnosis; and
4. Documentation of patient adherence to generic aripiprazole tablets is less than 80% within the past 6 months (prescriber must provide documentation of the previous 6 months' worth of pharmacy claims for aripiprazole documenting non-adherence); and
5. Documentation all the following strategies to improve patient adherence have been tried without success:
    a. Utilization of a pill box
    b. Utilization of a reminder device (e.g. alarm, application, or text reminder)
    c. Involving family members or friends to assist
    d. Coordinating timing of dose with dosing of another daily medication; and
6. Documentation of a trial and intolerance to a preferred long-acting aripiprazole injectable agent; and
7. Prescriber agrees to track and document adherence of Abilify MyCite through the web-based portal for health care providers and transition member to generic

aripiprazole tablets after a maximum of 4 months use of Abilify MyCite. Initial approvals will be given for one month. Prescriber must review member adherence in the web-based portal and document adherence for additional consideration. If non-adherence continues, prescriber must document a plan to improve adherence. If adherence is improved, consideration to switch member to generic aripiprazole tablets must be considered. Note, the ability of the Abilify MyCite to improve patient compliance has not been established.

8. Requests will not be considered for patients in long-term care facilities.
9. A once per lifetime approval will be allowed.

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

CGRP Inhibitors

Proposed Clinical Prior Authorization Criteria *(changes highlighted/italicized or stricken)*
Prior authorization is required for CGRP Inhibitors. Payment will be considered for *a FDA approved or compendia indicated diagnosis under the following conditions* ~~patients when the following is met~~:

1. Patient has *one of the following* ~~a~~ *diagnose~~i~~s* ~~of migraine as defined by one of the following~~:
    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; ~~and~~ *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 of ≥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 *for submitted diagnosis*; and
3. Patient has been evaluated for and does not have medication overuse headache; and
4. *For Episodic and Chronic Migraine, ~~P~~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]); ~~and~~ *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 480 mg to 960 mg). 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 prior authorizations 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.

ProDUR Edit Recommendations

The DUR Commission recommended implementing a ProDUR quantity limit on gabapentin (see table below). Additionally, the DUR Commission recommended implementing a maximum milligram per day edit on gabapentin (3600 mg) and pregabalin immediate release (600 mg), limiting each medication to the maximum milligram per day across all strengths.

Recommended Quantity Limits for Gabapentin

Strength	Daily Quantity Limit	Monthly Quantity Limit
100 mg	6 capsules	180 capsules
300 mg	9 capsules	270 capsules
400 mg	9 capsules/tablets	270 capsules/tablets
600 mg	6 tablets	180 capsules
800 mg	4.5 tablets	135 tablets
50 mg/mL	72 mL	2160 mL

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; Ospemifene (Osphena); Abilify MyCite; and CGRP Inhibitors in addition to the proposed ProDUR quantity limit and maximum milligram per day edit for gabapentinoid agents.

Sincerely,

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Cc: Erin Halverson, R.Ph, IME
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