IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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March 4, 2021

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, March 3, 2021. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Elagolix Products; Select Anticonvulsants; and Satralizumab (Enspryng). The following recommendations have been made by the DUR Commission:

Comments were received and reviewed from the medical/pharmacy associations in response to a November 11, 2020 letter that was sent to them detailing the proposed criteria for Elagolix Products; Select Anticonvulsants; and Satralizumab (Enspryng).

Elagolix Products

Current Clinical Prior Authorization Criteria [Elagolix (Orilissa)]
Prior authorization (PA) is required for gonadotropin-releasing hormone (GnRH) antagonists. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
2. Pregnancy has been ruled out; and
3. Patient does not have osteoporosis; and
4. Patient does not have severe hepatic impairment; and
5. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and
6. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and
7. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
8. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose.

Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.

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

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

Prior authorization (PA) is required for *elagolix containing drugs* ~~gonadotropin-releasing hormone (GnRH) antagonists~~. Payment will be considered for patients when the following is met:

1. Pregnancy has been ruled out; and
2. Patient does not have osteoporosis; and
3. Patient does not have severe hepatic impairment; and
4. Patient is not taking a strong organic anion transporting polypeptide (OATP) 1B1 inhibitor (e.g. cyclosporine and gemfibrozil); and
5. *Requests for elagolix (Orilissa) will be considered under the following conditions:*
    a. Patient has a diagnosis of moderate to severe pain associated with endometriosis; and
    b. Patient has documentation of a previous trial and therapy failure with at least one preferred oral NSAID and at least one preferred 3-month course of a continuous hormonal contraceptive taken concurrently; and
    c. Patient has documentation of a previous trial and therapy failure with a preferred GnRH agonist.
    d. Initial requests will be considered for 3 months. Additional requests will be considered upon documentation of improvement of symptoms.
    e. Requests will be considered for a maximum of 24 months for the 150mg dose and six (6) months for the 200mg dose~~.~~*; or*
6. *Requests for elagolix, estradiol, and norethindrone acetate; elagolix (Oriahnn) will be considered under the following conditions:*
    a. *Patient is premenopausal; and*
    b. *Patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids); and*
    c. *Patient has documentation of a previous trial and therapy failure with at least one preferred 3-month course of a continuous hormonal contraceptive; and*
    d. *Patient has documentation of a previous trial and therapy failure with tranexamic acid.*
    e. *Initial requests will be considered for 6 months. Additional requests will be considered upon documentation of improvement of symptoms.*
    f. *Requests will be considered for a maximum of 24 months of treatment.*

Select Anticonvulsants

Current Clinical Prior Authorization Criteria [Cannabidiol (Epidiolex)]

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

1. Patient meets the FDA approved age; and
2. Baseline serum transaminases (ALT and AST) and total bilirubin levels have been obtained prior to initiating therapy (attach results); and

3. A diagnosis of Lennox-Gastaut syndrome with documentation of an adequate trial and inadequate response with at least two concomitant antiepileptic drugs (AEDs) from the following:
    a. Valproic acid,
    b. Lamotrigine,
    c. Topiramate,
    d. Felbamate,
    e. Rufinamide,
    f. Clobazam, or
4. A diagnosis of Dravet syndrome with documentation of an adequate trial and inadequate response with at least two concomitant AEDs from the following:
    a. Clobazam,
    b. Valproic Acid,
    c. Levetiracetam,
    d. Topiramate, and
5. Is prescribed by or in consultation with a neurologist; and
6. The total daily dose does not exceed 20 mg/kg/day.

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

<u>Newly Proposed Clinical Prior Authorization Criteria</u>

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

1. Patient meets the FDA approved age for submitted diagnosis and drug; and
2. Patient has an FDA approved or compendia indicated diagnosis, for requested drug, of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex, with documentation of an adequate trial and inadequate response with at least two preferred concomitant antiepileptic drugs (AEDs), if available; and
3. Is prescribed by or in consultation with a neurologist; and
4. Patient's current weight is provided; and
5. Follows FDA approved dosing for indication and drug. The total daily dose does not exceed the following:
    a. Cannabidiol
        i. Lennox-Gastaut syndrome or Dravet syndrome: 20 mg/kg/day; or
        ii. Tuberous sclerosis complex: 25 mg/kg/day; or
    b. Fenfluramine
        i. With concomitant stiripentol (plus clobazam): 0.4 mg/kg/d with a maximum of 17 mg per day; or
        ii. Without concomitant stiripentol: 0.7 mg/kg/day with a maximum of 26 mg per day; or
    c. Stiripentol
        i. Prescribed concomitantly with clobazam; and
        ii. 50 mg/kg/day with a maximum of 3,000 mg/day.

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

Satralizumab (Enspryng)

Newly Proposed Clinical Prior Authorization Criteria

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

1. Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD); and
2. Patient is anti-aquaporin 4 (AQP4) seropositive (attach documentation); and
3. Patient meets the FDA approved age and dosing; and
4. Patient has a history of at least 1 relapse in the previous 12 months prior to initiation of therapy; and
5. Patient has been tested for tuberculosis prior to the initiation of therapy and does not have active or untreated latent tuberculosis; and
6. Patient has been tested for hepatitis B virus (HBV) prior to the initiation of therapy and confirmed negative for active HBV; and
7. Prescribed by a neurologist.

If criteria for coverage are met, initial requests will be given for 1 year. Additional authorizations will be considered upon documentation of clinical response to therapy (i.e. a reduction in the frequency of relapse).

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Elagolix Products; Select Anticonvulsants; and Satralizumab (Enspryng).

Sincerely,

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

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