IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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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 1, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Long-Acting Opioids; Adalimumab (Humira) for Hidradenitis Suppurativa; Rifaximin (Xifaxan); Ivabradine (Corlanor); Deferasirox; and Eluxadoline (Viberzi). The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a April 11, 2016 letter that was sent to them detailing the proposed criteria for Long-Acting Opioids; Adalimumab (Humira) for Hidradenitis Suppurativa; Rifaximin (Xifaxan); Ivabradine (Corlanor); Deferasirox; and Eluxadoline (Viberzi).

Long-Acting Opioids

Proposed Long-Acting Opioids Prior Authorization Criteria (*changes italicized*)
Prior authorization is required for all non-preferred long-acting *opioids*. Payment will be considered under the following conditions:

1. *Patient has a diagnosis of chronic pain severe enough to require daily, around-the-clock, long-term opioid treatment; and*
2. *Patient has tried and failed at least two nonpharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]) and*
3. *Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants)*
4. There is documentation of previous trial and therapy failure with one preferred long-acting *opioid* at *a maximally tolerated* dose, and
5. A signed chronic opioid therapy management plan between the prescriber and patient must be included with the prior authorization, and

6. The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ *and determine if use of a long-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse* prior to requesting prior authorization, *and*
7. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder*) *of opioids*.
8. Requests for long-acting *opioids* will only be considered for FDA approved dosing *intervals*. *As-needed (PRN) dosing will not be considered.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a long-acting opioid is appropriate for this member.*

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

Adalimumab (Humira®) for Hidradenitis Suppurativa

Newly Proposed Prior Authorization Criteria

Prior authorization is required for biologicals FDA approved for the treatment of Hidradenitis Suppurativa (HS). Patients initiating therapy with a biological agent must:

1. Be screened for hepatitis B and C. Patients with active hepatitis B will not be considered for coverage; and
2. Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biologic agent; and
3. Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and
4. Be 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.

Payment will be considered under the following conditions:

1. Patient has a diagnosis of moderate to severe HS with Hurley Stage II or III disease; and
2. Patient is 18 years of age or older; and
3. Patient has at least three (3) abscesses or inflammatory nodules; and
4. Patient has documentation of adequate trials and therapy failures with the following:
    a. Daily treatment with topical clindamycin;
    b. Oral clindamycin plus rifampin;
    c. Maintenance therapy with tetracyclines (doxycycline or minocycline).

If criteria for coverage are met, initial requests will be given for 3 months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count from initiation of therapy.

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

Rifaximin (Xifaxan®)

Newly Proposed Prior Authorization Criteria

Prior authorization is required for rifaximin. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. A diagnosis of travelers' diarrhea:
    a. Patient is 12 years of age or older; and
    b. Patient has a diagnosis of travelers' diarrhea not complicated by fever or blood in the stool or diarrhea due to pathogens other than *Escherichia coli*; and
    c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred generic fluoroquinolone or azithromycin.
    d. A maximum 3 day course of therapy (9 tablets) of the 200mg tablets per 30 days will be allowed.
2. A diagnosis of hepatic encephalopathy:
    a. Patient is 18 years of age or older; and
    b. Patient has a diagnosis of hepatic encephalopathy; and
    c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with lactulose.
3. A diagnosis of irritable bowel syndrome with diarrhea:
    a. Patient is 18 years of age or older; and
    b. Patient has a diagnosis of irritable bowel syndrome with diarrhea; and
    c. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with a preferred antispasmotic agent (dicyclomine, hyoscyamine); and
    d. Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with amitriptyline and loperamide.
    e. If criteria for coverage are met, a single 14-day course will be approved.
    f. Subsequent requests will require documentation of recurrence of IBS-D symptoms. A minimum 10 week treatment-free period between courses is required.
    g. A maximum of 3 treatment courses of rifaximin will be allowed per lifetime.

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

Ivabradine (Corlanor®)

Newly Proposed Prior Authorization Criteria

Prior authorization is required for ivabradine. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of stable, symptomatic heart failure (NYHA Class II, III, or IV); and
3. Patient has documentation of a left ventricular ejection fraction ≤35%; and
4. Patient is in sinus rhythm with a resting heart rate of ≥70 beats per minute; and
5. Patient has documentation of blood pressure ≥90/50 mmHg; and
6. Heart failure symptoms persist with maximally tolerated doses of at least one beta-blocker with proven mortality benefit in a heart failure clinical trial (e.g. carvedilol 50mg daily, metoprolol succinate 200mg daily, or bisoprolol 10mg daily), or patient has a documented intolerance or FDA labeled contraindication to beta-blockers; and
7. Patient has documentation of a trial and continued use with a preferred ACE inhibitor or preferred ARB at a maximally tolerated dose.

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

Deferasirox

Proposed Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for deferasirox. *Requests will only be considered for FDA approved dosing*. Payment will be considered under the following conditions:

1. Patient does not have a serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance < 40mL/min; and
2. Patient does not have a poor performance status; and
3. Patient does not have a high-risk myelodysplastic syndrome; and
4. Patient does not have advanced malignancies; and
5. Patient does not have a platelet count < 50 x 10^9/L.

Transfusional Iron Overload

Initiation of Therapy

1. Patient is 2 years of age or older; and
2. Patient has documentation of iron overload related to anemia (attach documentation); and
3. Patient has documentation of a recent history of frequent blood transfusions that has resulted in chronic iron overload; and
4. Serum ferritin is consistently > 1000mcg/L (attach lab results dates within the past month).; and
5. Starting dose does not exceed: *Exjade* - 20mg/kg/day *OR Jadenu - 14mg/kg/day.* Calculate dose to the nearest whole tablet.
6. Initial requests will be considered for up to 3 months.

Continuation of Therapy

1. Serum ferritin has been measured within 30 days of continuation of therapy request (attach documentation); and

2. Ferritin levels are > 500mcg/L; and
3. Dose does not exceed: *Exjade* - 40mg/kg/day *OR Jadenu - 28mg/kg/day*.

Non-Transfusional Iron Overload
Initiation of Therapy
1. Patient is 10 years of age or older; and
2. Patient has documentation of iron overload related to anemia (attach documentation); and
3. Serum ferritin and liver iron concentration (LIC) has been measured within 30 days of initiation (attach lab results); and
4. Serum ferritin levels are > 300mcg/L; and
5. LIC are > 5mg Fe/g dw; and
6. Dose does not exceed: *Exjade* - 10mg/kg/day (if LIC is ≤ 15mg Fe/g dw), or 20mg/kg/day (if LIC is > 15mg Fe/g dw); *OR Jadenu - 7mg/kg/day (if LIC is ≤ 15mg Fe/g dw), or 14mg/kg/day (if LIC is > 15mg Fe/g dw).*
7. Initial authorization will be considered for up to 6 months.

Continuation of Therapy
1. Serum ferritin and LIC have been measured within 30 days of continuation of therapy request; and
2. Serum ferritin levels are ~~>~~ ≥ 300mcg/L; and
3. LIC is ≥ 3mg Fe/g dw.
4. Dose does not exceed: *Exjade* - 10mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 20mg/kg/day (if LIC is > 7mg Fe/g dw); *OR Jadenu - 7mg/kg/day (if LIC is 3 to 7 mg Fe/g dw) or 14mg/kg/day (if LIC is > 7mg Fe/g dw).*

Eluxadoline (Viberzi™)

Newly Proposed Prior Authorization Criteria
Prior authorization is required for eluxadoline. Only FDA approved dosing will be considered. Payment will be considered under the following conditions:
1. Patient is 18 years of age or older.
2. Patient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D).
3. Patient does not have any of the following contraindications to therapy:
    a. Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction.
    b. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day.
    c. A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction).
    d. Severe hepatic impairment (Child-Pugh Class C).
    e. Severe constipation or sequelae from constipation.
    f. Known or suspected mechanical gastrointestinal obstruction.
4. Patient has documentation of a previous trial and therapy failure at a therapeutic dose with both of the following:
    a. A preferred antispasmodic agent (dicyclomine or hyoscyamine).
    b. A preferred antidiarrheal agent (loperamide).

If criteria for coverage are met, initial authorization will be given for 3 months to assess the response to treatment. Requests for continuation of therapy will require the following:

1. Patient has not developed any contraindications to therapy (defined above).
2. Patient has experienced a positive clinical response to therapy as demonstrated by at least one of the following:
    a. Improvement in abdominal cramping or pain.
    b. Improvement in stool frequency and consistency.

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 Long-Acting Opioids; Adalimumab (Humira) for Hidradenitis Suppurativa; Rifaximin (Xifaxan); Ivabradine (Corlanor); Deferasirox; and Eluxadoline (Viberzi).

Sincerely,

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Cc: Erin Halverson, R.Ph, IME
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