Iowa Department of Human Services

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INFORMATIONAL LETTER NO. 1683-MC

TO: Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse Practitioners, Therapeutically Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics, Skilled Nursing Facilities, Intermediate Care Facilities, Nursing Facilities-Mental ILL, Federally Qualified Health Centers (FQHC), Indian Health Service, Maternal Health Centers, Certified Nurse Midwife, Community Mental Health, Family Planning, Residential Care Facilities, ICF/ID State and Community Based ICF/ID Providers and Managed Care Organizations (MCOs)

FROM: Iowa Department of Human Services, Iowa Medicaid Enterprise

DATE: June 22, 2016

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: August 1, 2016

1. **New Drug Prior Authorization Criteria-** See complete prior authorization criteria posted on the Iowa Medicaid PDL website under the Prior Authorization Criteria[1] tab.

   - **Biologicals for Hidradenitis Suppurativa**
     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 five 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 percent 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.

[1] http://www.iowamedicaidpdl.com/pa_criteria

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 three months. Additional authorizations will be considered upon documentation of clinical response to therapy. Clinical response is defined as at least a 50 percent 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.

- **Eluxadoline (Viberzi™)**

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 three 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 three 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.

- **Ivabradine (Corlanor®)**
  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.

- **Rifaximin (Xifaxan®)**
  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 three 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 three 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.

2. Changes to Existing Prior Authorization Criteria- *Changes are italicized.* See complete prior authorization criteria posted on the Iowa Medicaid PDL website under the Prior Authorization Criteria[2] tab.

- **Long Acting Opioids (formerly Long Acting Narcotics):**
  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[3] *and determine if use of a*

[2] http://www.iowamedicaidpdl.com/pa_criteria
[3] https://pmp.iowa.gov/IAPMPWebCenter/

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 three 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[4] *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.

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

  Transfusional Iron Overload
  Initiation of Therapy
  5. Starting dose does not exceed: *Exjade* - 20mg/kg/day *OR Jadenu - 14mg/kg/day.* Calculate dose to the nearest whole tablet.

  Continuation of Therapy
  3. Dose does not exceed: *Exjade* - 40mg/kg/day *OR Jadenu - 28mg/kg/day*.

  Non-Transfusional Iron Overload
  Initiation of Therapy
  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).*

  Continuation of Therapy
  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).*

[4] https://pmp.iowa.gov/IAPMPWebCenter/

3. **Preferred Brand Name Drugs on the PDL-Pharmacy Clarification**
When a status change occurs for a previously preferred brand name drug to non-preferred status, up to a *minimum* of 30 days transition period is given to pharmacies to help utilize existing brand name product in stock in an effort to decrease a pharmacy's remaining brand name drug inventory (see PDL comment section regarding transition periods exceeding 30 days). If additional stock remains beyond this time period, pharmacies may call the POS Helpdesk at 877-463-7671 or 515-256-4608 (local) to request an override for the non-preferred brand name drug with a recent status change.

4. **DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website under the Newsletters[5] link.

We encourage providers to go to the Iowa Medicaid Preferred Drug List (PDL) website[6] to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or email info@iowamedicaidpdl.com.

[5] http://www.iadur.org/newsletters
[6] www.iowamedicaidpdl.com