IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 2, 2017. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for High Dose Opioids; Deflazacort (Emflaza); Hepatitis C Treatments; Crisaborole (Eucrisa); Eluxadoline (Viberzi); and New to Market Drugs. The DUR Commission members also discussed coverage of Omalizumab (Xolair) through the outpatient pharmacy program. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments that were received from the medical/pharmacy associations in response to a June 12, 2017 letter that was sent to them detailing the proposed criteria for High Dose Opioids; Deflazacort (Emflaza); Hepatitis C Treatments; Crisaborole (Eucrisa); Eluxadoline (Viberzi); and New to Market Drugs as well as the recommendation to remove PA criteria and coverage of Omalizumab (Xolair) from the outpatient pharmacy benefit.

High Dose Opioids

Newly Proposed Clinical Prior Authorization Criteria (Recommendation is to apply criteria to new and established patients. Plan to gradually decrease MME per day over time to 90 MME per day.)

Prior authorization is required for use of high-dose opioids ≥ 200 morphine milligram equivalents (MME) per day (See CDC Guideline for Prescribing Opioids for Chronic Pain at https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Patients undergoing active cancer treatment or end-of-life care will not be subject to the criteria below. Payment will be considered when the following is met:

1. Requests for non-preferred opioids meet criteria for coverage (see criteria for Long-Acting Opioids and/or Short-Acting Opioids); and

2. Patient has a diagnosis of severe, chronic pain with a supporting ICD-10 code. Requests for a diagnosis of fibromyalgia or migraine will not be considered; and
3. 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
4. Patient has tried and failed at least two nonopioid pharmacologic therapies (acetaminophen, NSAIDs, or selected antidepressants and anticonvulsants; and
5. There is documentation demonstrating an appropriate upward titration or an appropriate conversion from other opioid medications; and
6. Pain was inadequately controlled at the maximum allowed dose without prior authorization for the requested opioid(s); and
7. Pain was inadequately controlled by 2 other chemically distinct preferred long-acting opioids at the maximum allowed dose without prior authorization; and
8. Chart notes from a recent office visit for pain management is included documenting the following:
    a. Treatment plan – including all therapies to be used concurrently (pharmacologic and non-pharmacologic); and
    b. Treatment goals; and
9. Patient has been informed of the risks of high-dose opioid therapy; and
10. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that use of high-dose opioid therapy is appropriate for this patient; and
11. The patient's risk for opioid addiction, abuse and misuse has been reviewed and prescriber has determined the patient is a candidate for high-dose opioid therapy; and
12. A signed chronic opioid therapy management plan between the prescriber and patient dated within 12 months of this request is included; and
13. The requested dosing interval is no more frequent than the maximum FDA-approved dosing interval; and
14. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
15. Patient has been educated on opioid overdose prevention; and
16. Patient's household members have been educated on the signs of opioid overdose and how to administer naloxone; and
17. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with initial and subsequent requests; and
18. A documented dose reduction is attempted at least annually.

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of high-dose opioid therapy will be considered every 6 months with the following:

1. High-dose opioid therapy continues to meet treatment goals, including sustained improvement in pain and function; and
2. Patient has not experienced an overdose or other serious adverse event; and

3. Patient is not exhibiting warning signs of opioid use disorder; and
4. The benefits of opioids continue to outweigh the risks; and
5. A documented dose reduction has been attempted at least annually, and the prescriber has determined the dose cannot be reduced at this time; and
6. The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determined that continued use of high-dose opioid therapy is appropriate for this patient; and
7. Patient will not be using opioids and benzodiazepines concurrently or a taper plan to discontinue the benzodiazepine must be submitted with subsequent requests.
8. Patient has been provided a prescription for a preferred naloxone product for the emergency treatment of an opioid overdose; and
9. Patient has been reeducated on opioid overdose prevention; and
10. Patient's household members have been reeducated on the signs of opioid overdose and how to administer naloxone.

Deflazacort (Emflaza)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Emflaza (deflazacort). Payment will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with documented mutation of the dystrophin gene; and
2. Patient is within the FDA labeled age; and
3. Patient experienced onset of weakness before 5 years of age; and
4. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and
5. Patient has documentation of an adequate trial and therapy failure, intolerance, or significant weight gain (significant weight gain defined as 1 standard deviation above baseline percentile rank weight for height) while on prednisone at a therapeutic dose; and
6. Is dosed based on FDA approved dosing.

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

Hepatitis C Treatments

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

Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient ~~is 18 years of age or older~~ ~~and~~ has a diagnosis of chronic hepatitis C *and*
2. *Patient's age and/or weight is within the FDA labeled age and/or weight*; and
3. Patient has had testing for hepatitis C virus (HCV) genotype; and

4. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
5. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and
6. Viral load will be submitted by prescriber 12 weeks after completion of therapy; and
7. Patient has advanced liver disease corresponding to a Metavir score of *2* ~~3~~ or greater fibrosis as confirmed by one of the following:
    - Liver biopsy confirming Metavir score ≥ *F2* ~~F3~~; or
    - Transient elastography (FibroScan) score ≥ *7.5* ~~9.5~~kPa; or
    - FibroSURE (FibroTest) score ≥ *0.48* ~~0.58~~; or
    - APRI score > *0.7* ~~1.5~~; or
    - Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or
    - Physical findings or clinical evidence consistent with cirrhosis; or
    - Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephritic syndrome, or membranoproliferative glomerulonephritis.
8. Patient's prior treatment history is provided (treatment naïve or treatment experienced); and
9. If patient has a history of non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
10. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
11. For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and
12. HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and
13. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
    a) Patient is not a pregnant female or male with a pregnant female partner; and
    b) Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
    c) Monthly pregnancy tests will be performed during treatment; and
14. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
15. Documentation is provided for patients who are ineligible to receive ~~interferon or~~ ribavirin.
16. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.
17. *Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions.*
18. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on

therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on length of therapy for the particular treatment.

19. Lost or stolen medication replacement requests will not be authorized.
20. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Crisaborole (Eucrisa)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Eucrisa (crisaborole). Payment will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of mild to moderate atopic dermatitis; and
2. Patient is within the FDA labeled age; and
3. Patient has failed to respond to good skin care and regular use of emollients; and
4. Patient has documentation of an adequate trial and therapy failure with two preferred medium to high potency topical corticosteroids for a minimum of 2 consecutive weeks; and
5. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
6. Patient will continue with skin care regimen and regular use of emollients.
7. Quantities will be limited to 60 grams for use on the face, neck, and groin and 100 grams for all other areas, per 30 days.

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

Eluxadoline (Viberzi)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted)

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. *Patient is without a gallbladder.*
    b. Known or suspected biliary duct obstruction, or sphincter of Oddi disease/dysfunction.
    c. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic beverages per day.
    d. A history of pancreatitis or structural diseases of the pancreas (including known or suspected pancreatic duct obstruction).
    e. Severe hepatic impairment (Child-Pugh Class C).
    f. Severe constipation or sequelae from constipation.
    g. 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.

New to Market Drugs

Newly Proposed Prior Authorization Criteria

Prior authorization is required for newly marketed drugs. Payment will be considered for patients when the following criteria are met:

1. Patient has an FDA approved or compendia indication for the requested drug; and
2. If the requested drug falls in a therapeutic category/class with existing prior authorization criteria, the requested drug must meet the criteria for the same indication; or
3. If no clinical criteria are established for the requested drug, patient has tried and failed at least two preferred drugs, when available, from the Iowa Medicaid Preferred Drug List (PDL) for the submitted indication; and
4. Request must adhere to all FDA approved labeling.

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

Once newly marketed drugs are reviewed by the Pharmaceutical & Therapeutics Committee, they will be placed on the PDL which will dictate ongoing PA criteria, if applicable.

Additionally, the DUR Commission made a recommendation to remove PA criteria and coverage of omalizumab (Xolair) through the outpatient pharmacy program due to the black box warning stating Xolair should only be administered in a healthcare setting by healthcare providers. The medication would continue to be available through the medical benefit.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for High Dose Opioids; Deflazacort (Emflaza); Hepatitis C Treatments; Crisaborole (Eucrisa); Eluxadoline (Viberzi); and New to Market Drugs and removal of coverage of Omalizumab (Xolair) from the outpatient pharmacy benefit.

Sincerely,

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