IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
Des Moines, Iowa 50315

Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, April 5, 2017. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Insulin, Pre-Filled Pens; Hepatitis C Treatments; Eteplirsen (Exondys 51); and Lumacaftor/Ivacaftor (Orkambi). Additionally, the DUR Commission members made a recommendation to remove Colchicine from prior authorization. Finally, the DUR Commission members made a recommendation to implement ProDUR quantity limits on select oral and topical GI agents. 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 February 6, 2016 letter that was sent to them detailing the proposed criteria for Insulin, Pre-Filled Pens; Hepatitis C Treatments; Eteplirsen (Exondys51); and Lumacaftor/Ivacaftor (Orkambi); the removal of prior authorization criteria for Colchicine; as well as the proposed ProDUR quantity limits on the oral and topical GI agents.

Insulin, Pre-Filled Pens

Proposed Clinical Prior Authorization Criteria (changes italicized or stricken)
Prior authorization is required for *all* pre-filled insulin pens. *For pre-filled insulin pens where the requested insulin is available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:* ~~*Prior* authorization is granted when documentation indicates~~:

- The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and
- There is no caregiver available to provide assistance, *and*
- Patient does not reside in a long-term care facility; *and*

- *For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).*

For pre-filled insulin pens where the requested insulin is not available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- *Preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and*
- *Non-preferred pre-filled insulin pens - Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).*
- *Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.*

Hepatitis C Treatments

Proposed Clinical Prior Authorization Criteria (changes italicized)

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 has had testing for hepatitis C virus (HCV) genotype; and
3. Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment; and
4. *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*
5. Viral load will be submitted by prescriber 12 weeks after completion of therapy; and
6. Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:
    - Liver biopsy confirming Metavir score ≥ F3; or
    - Transient elastography (FibroScan) score ≥ 9.5kPa; or
    - FibroSURE (FibroTest) score ≥ 0.58; or
    - APRI score > 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.

7. Patient's prior treatment history is provided (treatment naïve or treatment experienced); and
8. 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
9. 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
10. For regimens containing sofosbuvir, patient does not have severe renal impairment (creatinine clearance < 30ml/min) or end stage renal disease requiring hemodialysis; and
11. HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and
12. 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
13. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.
14. Documentation is provided for patients who are ineligible to receive ~~interferon or~~ ribavirin.
15. Non-FDA approved or non-compendia indicated combination therapy regimens will not be approved.
16. 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.
17. Lost or stolen medication replacement requests will not be authorized.
18. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Eteplirsen (E*xondys 51)*

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Exondys 51 (eteplirsen). Payment will be considered for patients when the following criteria are met:

1. Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 51 skipping confirmed by genetic testing (attach results of genetic testing); and
2. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and
3. Patient is currently ambulatory; and
4. A baseline 6-Minute Walk Distance (6MWD) is provided and patient is able to achieve a distance of at least 180 meters while walking independently; and
5. Patient is currently stable on an oral corticosteroid regimen for at least 6 months; and

6. Is dosed based on FDA approved dosing: 30 mg/kg once weekly; and
7. Medication is to be administered by a healthcare professional in member's home by home health or in a long-term care facility.

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

When criteria for coverage are met, an initial authorization will be given for 6 months. Requests for continuation of therapy will be considered at 6 month intervals when the following criteria are met:

1. Patient has demonstrated a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair dependent); and
2. An updated 6MWD is provided documenting patient is able to achieve a distance of at least 180 meters.

Lumacaftor/Ivacaftor (Orkambi)

Proposed Clinical Prior Authorization Criteria (changes italicized or stricken)

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

1. Patient is *6* ~~12~~ years of age or older; and
2. Has a diagnosis of cystic fibrosis; and
3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and
4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
5. ~~Baseline percent predicted forced expiratory volume (ppFEV1) is provided and is greater than or equal to (≥) 40; and~~
6. Prescriber is a CF specialist or pulmonologist.~~; and~~
7. ~~Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus.~~

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:

1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and
2. ~~Response to therapy is documented by prescriber (e.g., improved ppFEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and~~
3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

In addition to the above recommendations for prior authorization, the DUR Commission made a recommendation to remove the Colchicine prior authorization requirement.

Additionally, the DUR Commission made a recommendation to implement ProDUR quantity limits on the following oral and topical GI agents:

Drug	**Proposed Quantity Limit**
Apriso 0.375 g	4 capsules per day
Azulfidine 500 mg	8 tablets per day
Azulfidine EN-tabs 500 mg	8 tablets per day
Canasa 1000 mg	1 suppository per day
Delzicol 400 mg	6 capsules per day
Dipentum 250 mg	4 capsules per day
Giazo 1.1 g	6 tablets per day
Lialda 1.2 g	4 tablets per day
Pentasa 250 mg	16 capsules per day
Pentasa 500 mg	8 capsules per day
Rowasa, SfRowasa 4 g/60 mL	1680 mL per 28 days
Uceris 9 mg	1 tablet per day

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Insulin, Pre-Filled Pens; Hepatitis C Treatments; Eteplirsen (Exondys 51); and Lumacaftor/Ivacaftor (Orkambi), removal of Colchicine prior authorization criteria, and the ProDUR quantity limits on select oral and topical GI agents.

Sincerely,

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Cc: Erin Halverson, R.Ph, IME
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