Iowa Department of Human Services

Terry E. Branstad
Governor

Kim Reynolds
Lt. Governor

Charles M. Palmer
Director

INFORMATIONAL LETTER NO.1629

DATE: March 7, 2016

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

FROM: Iowa Department of Human Services, Iowa Medicaid Enterprise

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: April 11, 2016

1. **New Drug Prior Authorization Criteria-** See complete prior authorization criteria posted at www.iowamedicaidpdl.com under the Prior Authorization Criteria tab.

   - **Cholic Acid (Cholbam®)**
     Prior authorization is required for cholic acid (Cholbam). Payment will be considered under the following conditions:
     1. Is prescribed by a hepatologist or pediatric gastroenterologist; and
     2. Is prescribed for a diagnosis of bile acid synthesis disorder due to a single enzyme defect (SED) including:
        - 3-beta-hydroxy-delta-5C27-steroid oxidoreductase deficiency (3β-HSD),
        - aldo-keto reductase 1D1 (AKR1D1),
        - alpha-methylacyl-CoA racemase deficiency (AMACR deficiency),
        - sterol 27-hydroxylase deficiency (cerebrotendinous xanthomatosis [CTX]),
        - cytochrome P450 7A1 (CYP7A1),
        - 25-hydroxylation pathway (Smith-Lemli-Opitz); OR
     3. Is prescribed as an adjunctive treatment of a peroxisomal disorder (PD) in patients who exhibit manifestations of liver disease, steatorrhea, or complications from fat soluble vitamin absorption. Peroxisomal disorders include Zellweger syndrome (ZWS), neonatal adrenoleukodystrophy (NALD), or infantile refsum disease (IRD); and
     4. Diagnosis is confirmed by mass spectrometry or other biochemical testing or genetic testing (attach results); and
     5. Baseline liver function tests are taken prior to initiation of therapy (AST, ALT, GGT, ALP, total bilirubin, INR) and provided with request; and

6. Patient must have elevated serum aminotransferases (AST and ALT) with normal serum gamma glutamyltransferase (GTT); and
7. Patient is at least 3 weeks old.

When criteria for coverage are met, an initial authorization will be given for three months. Additional approvals will be granted for 12 months at a time requiring documentation of response to therapy by meeting two of the following criteria:

- Body weight has increased by 10 percent or is stable at ≥50th percentile,
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80 percent,
- Total bilirubin level reduced to ≤1mg/dL.

2. Changes to Existing Prior Authorization Criteria- *Changes are italicized.* See complete prior authorization criteria posted at https://www.iowamedicaidpdl.com/ under the Prior Authorization Criteria tab.

- **Binge Eating Disorder Agents:**

Prior authorization (PA) is required for Vyvanse for the treatment of Binge Eating Disorder (BED). Prior to requesting PA, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program (PMP) website at https://pmp.iowa.gov/IAPMPWebCenter/. Payment will be considered under the following conditions:

1. Patient is 18 to 55 years of age; and
2. Patient meets the DSM-5 criteria for BED; and
3. Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number must be reported); and
4. Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent three month period, that did not significantly reduce the number of binge eating episodes; and
5. Prescription is written by a psychiatrist or psychiatric nurse practitioner;
6. Patient has a BMI of 25 to 45; and
7. Patient does not have a personal history of cardiovascular disease; and
8. Patient has no history of substance abuse; and
9. Is not being prescribed for the treatment of obesity or weight loss; and
10. Doses above 70mg per day will not be considered.

- **Growth Hormone:**

Prior authorization is required for therapy with growth hormones. Payment for non-preferred growth hormones will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. All of the following criteria must be met for approval for prescribing of growth hormones:

4. Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter. *Stimuli testing will not be required for the following diagnoses: Turners Syndrome, chronic renal failure, and HIV/AIDS.*

The following FDA approved indications for Growth Hormone therapy are

considered not medically necessary and requests will be denied: Idiopathic Short Stature (ISS) *and Small for Gestational Age (SGA).*

3. Point of Sale Billing Issues:

a. ProDUR Quantity Limits: The following quantity limit edits will be implemented effective *April 11, 2016*. A comprehensive list of all quantity limit edits appears on our website, www.iowamedicaidpdl.com under the heading, "Quantity Limits".

Drug Product	Quantity	Days Supply
Ondansetron 4mg & 8mg tablet	60	30
Ondansetron 4mg & 8mg ODT	60	30

b. Age Edit: Desmopressin 0.1mg and 0.2mg tablets- Payable for members 6 years of age or older.

4. 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.

5. DUR Update: The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website, www.iadur.org under the "Newsletters" link.

We encourage providers to go to the website at www.iowamedicaidpdl.com 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.