IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
100 Army Post Road – Des Moines, IA 50315 □ (515) 974-3131 □ Fax 1-866-626-0216

Brett Faine, Pharm.D.
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Brian Couse, M.D.
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Kellen Ludvigson, Pharm.D.
Susan Parker, R.Ph., Pharm.D.
Laurie Pestel, R.Ph., Pharm.D.
Daniel Gillette, M.D.
Jason Wilbur, M. D.

Professional Staff: Pam Smith, R.Ph.
DUR Project Coordinator

December 3, 2015

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, December 2, 2015. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Growth Hormone, Cholic Acid (Cholbam®), and Binge Eating Disorder Agents. The DUR Commission members also discussed implementing ProDUR edits; an age edit and quantity limit for desmopressin tablets and modifying the quantity limit for ondansetron tablets/ODT. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to an October 8, 2015 letter that was sent to them detailing the proposed criteria for Growth Hormone, Cholic Acid (Cholbam®), and Binge Eating Disorder Agents.

Growth Hormone

Proposed Prior Authorization Criteria (*changes italicized*)
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:

1. Standard deviation of 2.0 or more below mean height for chronological age.
2. No intracranial lesion or tumor diagnosed by MRI.
3. Growth rate below five centimeters per year.
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.*
5. Annual bone age testing is required for the diagnosis of Growth Hormone Deficiency. A bone age 14 to 15 years or less in females and 15 to 16 years or less in males is required.
6. Epiphyses open.

Prior authorization will be granted for 12-month periods per patient as needed.

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).*

If the request is for Zorbtive® [somatropin (rDNA origin) for injection] approval will be granted for the treatment of Short Bowel Syndrome in patients receiving specialized nutritional support. Zorbtive® therapy should be used in conjunction with optimal management of Short Bowel Syndrome.

Cholic Acid (Cholbam®)

Newly Proposed Prior Authorization Criteria (changes italicized)
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 3 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% or is stable at ≥50th percentile,
- Alanine aminotransferase (ALT) or aspartate aminotransferase (AST) < 50 U/L or baseline levels reduced by 80%,
- Total bilirubin level reduced to ≤1mg/dL.

Binge Eating Disorder Agents

Proposed Prior Authorization Criteria

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 3 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.

Initial requests will be approved for 12 weeks when criteria for coverage are met. Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

DSM-5 Criteria

1. Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and
2. The binge eating episodes are marked by at least three of the following:
    a. Eating more rapidly than normal,
    b. Eating until feeling uncomfortably full,
    c. Eating large amounts of food when not feeling physically hungry,
    d. Eating alone because of embarrassment by the amount of food consumed,
    e. Feeling disgusted with oneself, depressed, or guilty after overeating; and
3. Episodes occur at least 1 day a week for at least 3 months; and
4. No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and
5. Does not occur solely during the course of bulimia nervosa or anorexia nervosa.

The DUR Commission also made the following ProDUR edit recommendations:

- Quantity Limits

Drug/Strength	Proposed Quantity Limit per 30 Days
Ondansetron 4mg & 8mg tablet	60 tablets
Ondansetron 4mg & 8mg ODT tablet	60 tablets
Desmopressin 0.1mg tablet	90 tablets
Desmopressin 0.2mg tablet	90 tablets

- Age Edit
    - Desmopressin 0.1mg & 0.2mg tablets – Payable for members 6 years of age or older

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Growth Hormone, Cholic Acid (Cholbam®), and Binge Eating Disorder Agents in addition to the ProDUR edits recommended for ondansetron tablets/ODT and desmopressin tablets.

Sincerely,

Pamela Smith R.Ph.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
Iowa Medicaid Enterprise

Cc: Erin Halverson, R.Ph., IME
Gina Tiernan, R.Ph., IME