IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, August 7, 2019. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Benzodiazepines; Lupron Depot – Adult; Dupilumab (Dupixent); Cannabidiol (Epidiolex): and Growth Hormones. The DUR Commission members also discussed a proposed ProDUR edit limiting initial opioid prescriptions to a seven-day supply. The following recommendations have been made by the DUR Commission:

The DUR Commission reviewed comments received from the medical/pharmacy associations in response to a May 7, 2019 letter that was sent to them detailing the proposed criteria for Benzodiazepines; Lupron Depot – Adult; Dupilumab (Dupixent); Cannabidiol (Epidiolex): and Growth Hormones in addition to the proposed ProDUR edit for an initial seven-day opioid supply limit.

Benzodiazepines

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization is required for non-preferred benzodiazepines. Payment for non-preferred benzodiazepines will be authorized in cases with documentation of previous trial and therapy failure with two preferred products. If a long-acting medication is requested, one of the therapeutic trials must include the immediate release form of the requested benzodiazepine. *The prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website and determine if the use of a benzodiazepine is appropriate for this member.*

~~Requests for clobazam (ONFI) will be considered for a diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age and older when used as an adjunctive treatment.~~ Prior authorization will be approved for up to 12 months for documented:

1. Generalized anxiety disorder.
2. Panic attack with or without agoraphobia.
3. Seizure.
4. Non-progressive motor disorder.
5. Dystonia.

Prior authorization requests will be approved for up to a three-month period for all other diagnoses related to the use of benzodiazepines.

For patients taking concurrent opioids, the prescriber must document the following:

1. *The risks of using opioids and benzodiazepines concurrently has been discussed with the patient; and*
2. *Documentation as to why concurrent use is medically necessary is provided; and*
3. *A plan to taper the opioid or benzodiazepine is provided, if appropriate.*

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

Lupron Depot - Adult

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. Patient *meets the FDA approved* ~~is 18 years of~~ age ~~or older~~; and
2. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility; and
3. Patient has a diagnosis of endometriosis for ~~whom~~ *which concurrent* therapy with *a preferred* NSAID~~s~~ and at least one preferred 3 month ~~course of a~~ continuous *course of* hormonal contraceptive has failed; or
4. Patient has a diagnosis of uterine leiomyomata with anemia (hematocrit < 30 g/dL or hemoglobin < 10 g/dL) that did not respond to treatment with at least a one month trial of iron and is to be used preoperatively; or
5. Patient has a diagnosis of advanced prostate cancer.

Therapy will be limited as follows:

1. Endometriosis – initial 6 month approval. If symptoms of endometriosis recur after the first course of therapy, a second course of therapy with concomitant norethindrone acetate 5 mg daily will be considered. Retreatment is not recommended for longer than one additional 6 month course.
2. Uterine leiomyomata – 3 month approval.
3. Advanced prostate cancer – initial 6 month approval. Renewal requests must document suppression of testosterone levels towards a castrate level of < 50 ng/dL (attach lab).

Dupilumab (Dupixent)

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization is required for Dupixent (dupilumab). Payment will be considered ~~for patients when~~ *under* the following *conditions* ~~criteria are met~~:

1. Patient is within the FDA labeled age *for indication*; and
2. Patient has a diagnosis of moderate-to-severe atopic dermatitis; and
    a. Is prescribed by or in consultation with a dermatologist*, allergist, or immunologist*; and
    b. Patient has failed to respond to good skin care and regular use of emollients; and
    c. Patient has documentation of an adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
    d. Patient has documentation of a previous trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and
    e. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
    f. Patient will continue with skin care regimen and regular use of emollients; ~~and~~ *or*
    ~~g. Dose does not exceed an initial one-time dose of 600mg and maintenance dose of 300mg thereafter given every other week.~~
3. *Patient has a diagnosis of moderate to severe asthma with an eosinophilic phenotype (with a pretreatment eosinophil count ≥ 150 cells/mcL within the previous 6 weeks) OR with oral corticosteroid dependent asthma; and*
    a. *Is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; and*
    b. *Has a pretreatment forced expiratory volume in 1 second (FEV_1) ≤ 80% predicted; and*
    c. *Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (e.g. long acting $beta_2$ agonist [LABA], leukotriene receptor antagonist [LTRA], oral theophylline) for a minimum of 3 consecutive months. Patient must be compliant with therapy, based on pharmacy claims; and*
    d. *Patient must have one of the following, in addition to the regular maintenance medications defined above:*
        i. *Two (2) or more exacerbations in the previous year or*
        ii. *Require daily oral corticosteroids for at least 3 days; and*
4. *Dose does not exceed the FDA approved dosing for indication.*

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy.

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

Cannabidiol (Epidiolex)

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for cannabidiol (Epidiolex). Payment will be considered under the following conditions:

1. Patient meets the FDA approved age; and
2. Baseline serum transaminases (ALT and AST) and total bilirubin levels have been obtained prior to initiating therapy (attach results); and

3. A diagnosis of Lenox-Gastaut syndrome with documentation of an adequate trial and inadequate response with at least two concomitant antiepileptic drugs (AEDs) from the following:
    a. Valproic acid,
    b. Lamotrigine,
    c. Topiramate,
    d. Felbamate,
    e. Rufinamide,
    f. Clobazam, or
4. A diagnosis of Dravet syndrome with documentation of an adequate trial and inadequate response with at least two concomitant AEDs from the following:
    a. Clobazam,
    b. Valproic acid,
    c. Levetiracetam,
    d. Topiramate, and
5. Is prescribed by or in consultation with a neurologist; and
6. The total daily dose does not exceed 20mg/kg/day.

If criteria for coverage are met, initial requests will be approved for 3 months. Additional prior authorization requests will be considered when the following criteria are met:

1. Documentation of clinical response to therapy (i.e. reduction in the frequency of seizures); and
2. The total daily dose does not exceed 20mg/kg/day.

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

Growth Hormone

Proposed Clinical Prior Authorization Criteria (changes italicized/highlighted or stricken)
Prior authorization *(PA)* is required for therapy with growth hormones. *Requests will only be considered for FDA approved dosing.* 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. 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). *Payment will be considered under the following conditions* ~~All of the following criteria must be met for approval for prescribing of growth hormones~~:

Children with Growth Hormone Deficiency

1. Standard deviation of 2.0 or more below mean height for chronological age*; and*~~.~~
2. No *expanding* intracranial lesion or tumor diagnosed by MRI*; and*~~.~~
3. Growth rate below five centimeters per year*; and*~~.~~
4. Failure of any two stimuli tests to raise the serum growth hormone level above ten nanograms per milliliter*; and*~~. 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*; and*~~.~~
6. Epiphyses open.

Pediatric Chronic Kidney Disease

1. *Is prescribed by or in consultation with a nephrologist; and*
2. *Standard deviation of 2.0 or more below mean height for chronological age; and*
3. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
4. *Growth rate below five centimeters per year; and*
5. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
6. *Epiphyses open.*

Turner's Syndrome

1. *Chromosomal abnormality showing Turner's syndrome; and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Standard deviation of 2.0 or more below mean height for chronological age; and*
4. *No expanding intracranial lesion or tumor diagnosed by MRI; and*
5. *Growth rate below five centimeters per year; and*
6. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
7. *Epiphyses open.*

Prader Willi Syndrome

1. *Diagnosis is confirmed by appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
4. *Epiphyses open.*

Noonan Syndrome

1. *Diagnosis is confirmed by the appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Standard deviation of 2.0 or more below mean height for chronological age; and*
4. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
5. *Epiphyses open.*

SHOX (Short Stature Homeobox)

1. *Diagnosis is confirmed by the appropriate genetic testing (attach results); and*
2. *Prescribed by or in consultation with an endocrinologist; and*
3. *Bone age of 14-15 years or less in females and 15-16 years or less in males; and*
4. *Epiphyses open.*

Adults with Growth Hormone Deficiency

1. *Patients who were growth hormone deficient during childhood (childhood onset) and who have a continued deficiency; or*
2. *Patients who have growth hormone deficiency (adult onset) as a result of pituitary or hypothalamic disease (e.g., panhypopituitarism, pituitary adenoma, trauma, cranial irradiation, pituitary surgery); and*
3. *Failure of at least one growth hormone stimulation test as an adult with a peak growth hormone value of ≤5 mcg/L after stimulation.*

Adults with AIDS Wasting/Cachexia

1. *Greater than 10% of baseline weight loss over 12 months that cannot be explained by a concurrent illness other than HIV infection; and*
2. *Patient is currently being treated with antiviral agents; and*
3. *Patient has documentation of a previous trial and therapy failure with an appetite*

stimulant (i.e. dronabinol or megestrol).

Short Bowel Syndrome
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. *PA will be considered for a maximum of 4 weeks.*

If the criteria for coverage is met, initial requests ~~Prior authorization~~ will be ~~granted~~ *given* for 12-month~~s periods per patient as needed~~*, unless otherwise stated above. Additional prior authorizations will be considered upon documentation of clinical response to therapy and patient continues to meet the criteria for the submitted diagnosis.*

ProDUR Edit Recommendations

The DUR Commission recommended implementing an initial seven-day opioid supply limit. The hard edit would stop claims for opioid naïve members, defined as not having an opioid in their claims history in the previous 60 days, to allow pharmacist and prescriber DUR interventions at the point of sale (POS).

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Benzodiazepines; Lupron Depot – Adult; Dupilumab (Dupixent); Cannabidiol (Epidiolex): and Growth Hormones in addition to the proposed ProDUR edit for an initial seven-day opioid supply limit.

Sincerely,

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