IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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October 6, 2016

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, October 5, 2016. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Lupron Depot Pediatric; Lupon Depot Adult; Short-Acting Opioids; and Burenorphine/Naloxone. The DUR Commission members also made a recommendation to implement a ProDUR quantity limit on the following agents: loperamide 2mg tablet/capsule and loperamide 1mg/5ml. 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 August 8, 2016 letter that was sent to them detailing the proposed criteria for Lupron Depot Pediatric; Lupron Depot Adult; Short-Acting Opioids; and Burenorphine/Naloxone as well as the proposed quantity limits for: loperamide 2mg tablet/capsule, loperamide 1mg/5ml.

Lupron Depot - Pediatric

Newly Proposed Clinical Prior Authorization Criteria
Prior authorization is required for Lupron Depot-Ped. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of central precocious puberty (CPP); and
2. Patient has documentation of onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males; and
3. Patient is currently < 11 years of age for females or < 12 years of age for males; and
4. Confirmation of diagnosis by a pubertal response to a gonadotropin-releasing hormone (GnRH) stimulation test is provided (attach results); and
5. Documentation of advanced bone age (defined as greater than or equal to two standard deviations above the gender/age related mean); and

6. Baseline evaluations including the following have been conducted and/or evaluated:
   a. Height and weight measurements; and
   b. Sex steroid (testosterone or estradiol) levels have been obtained; and
   c. Appropriate diagnostic imaging of the brain has been conducted to rule out an intracranial tumor; and
   d. Pelvic/testicular/adrenal ultrasound has been conducted to rule out steroid secreting tumors; and
   e. Human chorionic gonadotropin levels have been obtained to rule out a chorionic gonadotropin secreting tumor; and
   f. Adrenal steroid levels have been obtained to rule out congenital adrenal hyperplasia; and
7. Medication is to be administered by a healthcare professional in the member's home by home health or in a long-term care facility.

When criteria for coverage are met, an initial authorization will be given for 6 months.

Additional approvals will be granted at 6 month intervals until the patient is ≥ 11 years of age for females and ≥ 12 years of age for males. If therapy beyond the aforementioned ages is required, documentation of medical necessity will be required.

Lupron Depot - Adult

Newly Proposed Clinical Prior Authorization Criteria

Prior authorization is required for Lupron Depot (leuprolide acetate). Payment will be considered for patients under the following conditions:

1. Patient 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 therapy with NSAIDs and at least one preferred 3 month course of a continuous 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:

- 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.
- Uterine leiomyomata – 3 month approval.
- 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).

Short- Acting Opioids

Proposed Prior Authorization Criteria (*changes italicized*)
Prior authorization is required for all non-preferred short acting *opioids*. Payment will be considered *under the following conditions:*

1. *Patient has pain severe enough to require opioid treatment; and*
2. *Patient has tried and failed at least two non-pharmacologic therapies (physical therapy; weight loss; alternative therapies such as manipulation, massage, and acupuncture; or psychological therapies such as cognitive behavior therapy [CBT]); and*
3. *Patient has tried and failed at least two non-opioid pharmacologic therapies (acetaminophen or NSAIDs); and*
4. *Patient has* documentation of previous trials and therapy failures with three (3) chemically distinct preferred short acting *opioids* (based on *opioid* ingredient only) at therapeutic doses; *and*
5. *The prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring program website and has determined that use of a short-acting opioid is appropriate for this member based on review of PMP and the patient's risk for opioid addiction, abuse and misuse prior to requesting prior authorization; and*
6. *Patient has been informed of the common adverse effects (constipation, dry mouth, nausea, vomiting, drowsiness, confusion, tolerance, physical dependence, and withdrawal symptoms when stopping opioids) and serious adverse effects (potentially fatal overdose and development of a potentially serious opioid use disorder) of opioids.*

If criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be considered if the following criteria are met:

1. *Patient has experienced improvement in pain control and level of functioning; and*
2. *Prescriber has reviewed the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/ and has determined continued use of a short-acting opioid is appropriate for this member.*

The required trials may be overridden when documented evidence is provided that use of these agents and/or non-pharmacologic therapies would be medically contraindicated.

Buprenorphine/Naloxone

Newly Proposed Clinical Prior Authorization Criteria (*changes italicized*)
Prior authorization is required for *oral* buprenorphine or buprenorphine/naloxone. Requests for doses above 24mg per day or greater than once daily dosing will not be considered. Initial requests will be considered for up to 3 months. Requests for maintenance doses above 16mg per day will not be considered on a long-term basis. Concomitant use with opioids, tramadol and hypnotics will be prohibited. Benzodiazepines will be allowed up to a cumulative 30 days per 12 month period. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent, unless evidence is provided that use of these agents would be medically contraindicated. *Requests for surgically implanted buprenorphine products will not be considered through the pharmacy benefit and should be directed to the member's*

medical benefit. Payment will be considered for patients when the following is met:

1. Patient has a diagnosis of opioid dependence and is 16 years of age or older: AND
2. Prescriber meets qualification criteria to prescribe buprenorphine/naloxone for opioid dependence and has a "X" DEA number; AND
3. Patient is participating in and compliant with formal substance abuse counseling/psychosocial therapy: AND
4. A projected treatment plan is provided, including:
   - Anticipated induction/stabilization dose,
   - Anticipated maintenance dose,
   - Expected frequency of office visits, and
   - Expected frequency of counseling/psychosocial therapy visits; AND
5. *Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.*
6. Requests for buprenorphine will only be considered for pregnant patients.

Requests for renewal must include:

- An updated treatment plan, including consideration of a medical taper to the lowest effective dose based on a self-assessment scale,
- Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request,
- Documentation of a current, negative drug screen,
- Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits.
- *Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.*

Additionally, the DUR Commission recommends ProDUR quantity limits on the following agents:

- loperamide 2mg tablet/capsule – 4 tablets/capsules per day (120 units/30days)
- loperamide 1mg/5ml – 40 ml per day (1200ml/30 days)

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Lupron Depot Pediatric; Lupon Depot Adult; Short-Acting Opioids; and Burenorphine/Naloxone as well as the recommended quantity limits for loperamide.

Sincerely,

Pamela Smith R.Ph.

Pamela Smith, R.Ph.
Drug Utilization Review Project Coordinator
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Cc: Erin Halverson, R.Ph, IME
Gina Tiernan, R.Ph, IME