IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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February 9, 2018

Susan L. Parker, R.Ph, Pharm.D.
Pharmacy Director
Iowa Medicaid Enterprise
100 Army Post Road
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, February 7, 2018. At this meeting, the DUR Commission members discussed the proposed prior authorization (PA) criteria for Buprenorphine/Naloxone; Immunomodulators, Topical; Ivacaftor (Kalydeco); Lidocaine Patch; Topical Acne and Rosacea Products. The DUR Commission also discussed removal of clinical prior authorization for the following: Smoking Cessation Therapy, Oral; Nicotine Replacement Therapy; and Angiotensin Receptor Blocker Before ACE Inhibitor. Finally, the DUR Commission discussed implementing a ProDUR quantity limit for the Smoking Cessation Therapy, Oral and Nicotine Replacement Therapy with the removal of prior authorization criteria. The following recommendations have been made by the DUR Commission:

No comments were received from the medical/pharmacy associations in response to a December 12, 2017 letter that was sent to them detailing the proposed criteria for Buprenorphine/Naloxone; Immunomodulators, Topical; Ivacaftor (Kalydeco); Lidocaine Patch; Topical Acne and Rosacea Products; removal of clinical prior authorization for Smoking Cessation Therapy, Oral; Nicotine Replacement Therapy; and Angiotensin Receptor Blocker Before ACE Inhibitor; and the ProDUR quantity limit for the Smoking Cessation Therapy, Oral and Nicotine Replacement Therapy with the removal of prior authorization criteria.

Buprenorphine/Naloxone

Proposed Clinical Prior Authorization (changes highlighted/italicized/stricken)
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~~,~~ *or* 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 *meets the FDA approved age* ~~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. *Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances; and*
5. 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
6. *A treatment plan is provided for patients taking buprenorphine in combination with a benzodiazepine or central nervous system (CNS) depressant, including:*
   - *Documentation patient has been educated on the serious risks of combined use;*
   - *A plan to taper the benzodiazepine or CNS depressant to discontinuation, if possible;*
   - *Consideration of alternate anxiety or insomnia treatment options when the benzodiazepine or CNS depressant is used for anxiety or insomnia; and*
   - *Other prescribers involved in the care of the patient are aware of the patient's use of buprenorphine; AND*
7. Documentation is provided that transmucosal buprenorphine will not be used concomitantly with the buprenorphine implant.
8. Requests for *single ingredient* buprenorphine will only be considered for pregnant patients.

Requests for renewal must include:

1. An updated treatment plan *documenting the following*~~, including~~*:*
   a. Consideration of a medical taper to the lowest effective dose based on a self-assessment scale *and*
   b. *Assessment of concomitant benzodiazepine or CNS depressant use (if applicable) as outlined above*, *AND*
2. Documentation the Iowa Prescription Monitoring Program website has been reviewed for the patient's use of controlled substances since the last prior authorization request, *AND*
3. Documentation of a current, negative drug screen, *AND*
4. Documentation the patient has been compliant with office visits and counseling/psychosocial therapy visits, *AND*
5. Documentation the patient is not using transmucosal buprenorphine with the buprenorphine implant.

Immunomodulators - Topical

Proposed Clinical Prior Authorization Criteria (changes highlighted, italicized, or stricken)
Prior authorization is required for topical immunomodulators. Payment for pimecrolimus (Elidel®) or tacrolimus (Protopic®) 0.03% will be considered for non-immunocompromised patients two years of age and older and tacrolimus (Protopic®) 0.1% for patients 16 years of age and older when there is an adequate trial and therapy failure with ~~two~~ *one* preferred medium to high potency topical corticosteroid~~s~~, *except on face or groin*. If criteria for coverage are met, requests will be approved for one tube per 90 days to ensure appropriate short-term and intermittent utilization of the medication. Quantities will be limited to 30 grams for use on the face, neck, and groin, and 60 grams or 100 grams for all other areas. The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Ivacaftor (Kalydeco)

Proposed Clinical Prior Authorization Criteria (changes highlighted, italicized, or stricken)
Prior authorization is required for Kalydeco™ (ivacaftor). Payment will be considered for patients when the following criteria are met:

1. Patient is 2 years of age or older; and
2. *Patient* has a diagnosis of cystic fibrosis*;* and ~~*with* one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and R117H as detected by a FDA-cleared CF mutation test; and~~
3. *Patient has one of the CFTR gene mutations as indicated in the FDA approved label as detected by an FDA-cleared CF mutation test; and*
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST/ALT) ~~and FEV_1, if age appropriate~~, are provided.~~; and~~
6. ~~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 ivacaftor therapy is confirmed; and
2. ~~Response to therapy is documented by prescriber (e.g., improved FEV_1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and~~
3. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.

Lidocaine Patch

Proposed Clinical Prior Authorization Criteria (changes highlighted, italicized, or stricken)
Prior authorization is required for topical lidocaine patches ~~(Lidoderm®)~~. Payment will be considered *only for cases in which there is* ~~for~~ a diagnosis of pain associated with post-herpetic neuralgia. ~~following a previous treatment failure with a preferred agent at therapeutic dose from two of the following: tricyclic antidepressant, opioid, gabapentin, carbamazepine, or valproic acid.~~ A maximum of 30 patches may be dispensed with the initial prescription to determine efficacy.

Topical Acne and Rosacea Products

Proposed Clinical Prior Authorization Criteria (changes highlighted/italicized or stricken)
Prior authorization (PA) is required for topical acne agents (topical antibiotics and topical retinoids) and topical rosacea agents. Payment for topical acne and topical rosacea agents will be considered under the following conditions:

1. Documentation of diagnosis.
2. For the treatment of acne vulgaris, benzoyl peroxide is required for use with a topical antibiotic or topical retinoid ~~for moderate to severe acne~~.
3. Payment for non-preferred topical acne products will be authorized only for cases in which there is documentation of previous trials and therapy failures with two preferred topical agents of a different chemical entity from the requested topical class (topical antibiotic or topical retinoid).
4. Payment for non-preferred topical rosacea products will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred topical agent.
5. Requests for non-preferred combination products may only be considered after documented trials and therapy failures with two preferred combination products.
6. Requests for topical retinoid products for skin cancer, lamellar ichthyosis, and Darier's disease diagnoses will receive approval with documentation of submitted diagnosis.
7. Trial and therapy failure with a preferred topical antipsoriatic agent will not be required for the preferred tazarotene (Tazorac) product for a psoriasis diagnosis.
8. Duplicate therapy with agents in the same topical class (topical antibiotic or topical retinoid) will not be considered.

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

Removal of Prior Authorization Criteria

The DUR Commission made recommendations to remove clinical prior authorization criteria for the following:

- Smoking Cessation Therapy, Oral
- Nicotine Replacement Therapy
- Angiotensin Receptor Blocker before ACE Inhibitor

The DUR Commission anticipates the outcomes associated with the removal of clinical prior authorization for Smoking Cessation Therapy, Oral and Nicotine Replacement Therapy would be improved access to these medications, reduced administrative burden to prescribers, pharmacies and MCOs, and it will hopefully lessen future pharmacy and medical expenditures for resulting diseases such as chronic obstructive pulmonary disease (COPD) or myocardial infarction (MI).

ProDUR Edit

With the recommendation to remove prior authorization criteria for Smoking Cessation Therapy, Oral and Nicotine Replacement Therapy, the DUR Commission also recommended a ProDUR quantity limit of 24 weeks total treatment within a 12-month period for all covered tobacco cessation medications.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Buprenorphine/Naloxone; Immunomodulators, Topical; Ivacaftor (Kalydeco); Lidocaine Patch; Topical Acne and Rosacea Products; removal of clinical prior authorization for Smoking Cessation Therapy, Oral; Nicotine Replacement Therapy; and Angiotensin Receptor Blocker Before ACE Inhibitor; and a ProDUR quantity limit for the Smoking Cessation Therapy, Oral and Nicotine Replacement Therapy with the removal of prior authorization criteria.

Sincerely,

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Cc: Erin Halverson, R.Ph, IME
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