IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION
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Susan L. Parker, R.Ph., Pharm.D.
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Dear Susan:

The Iowa Medicaid Drug Utilization Review (DUR) Commission met on Wednesday, October 1, 2014. At this meeting, the DUR Commission members discussed the proposed prior authorization criteria for Chronic Pain Syndromes, Oral Immunotherapy, Methotrexate Injection, Tasimelteon (Hetlioz™), Apremilast (Otezla®), and Palivizumab (Synagis®). The Commission also made a recommendation for the Iowa Medicaid Pharmaceutical and Therapeutics (P&T) Committee to change the status of niacin products to non-preferred on the Preferred Drug List (PDL) and to implement a quantity limit across all short-acting opioids of 120 units per 30 days. 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 12, 2014 letter that was sent to them detailing the proposed criteria for Chronic Pain Syndromes, Oral Immunotherapy, Methotrexate Injection, Tasimelteon (Hetlioz™), Apremilast (Otezla®), and Palivizumab (Synagis®).

Chronic Pain Syndromes

Proposed Prior Authorization Criteria *(changes italicized)*
A prior authorization is required for duloxetine (Cymbalta®), pregabalin (Lyrica®), and milnacipran (Savella™). *For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization.* Payment will be considered under the following conditions:

1. A diagnosis of **fibromyalgia** (Cymbalta®, Lyrica®, and Savella™)

a. A trial and therapy failure at a therapeutic dose with *gabapentin plus one of* the following: tricyclic antidepressant, SSRI, *or* SNRI, **WITH**

b. Documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.), **AND**

c. Documentation of a previous trial and therapy failure at a therapeutic dose with Savella™ when Cymbalta® and Lyrica® are requested.

2. A diagnosis of **postherpetic neuralgia** (Lyrica®)

   A trial and therapy failure at a therapeutic dose with *gabapentin plus one of* the following: tricyclic antidepressant, topical lidocaine, valproate, *or* carbamazepine.

3. A diagnosis of **diabetic peripheral neuropathy** (Cymbalta® and Lyrica®)

   A trial and therapy failure at a therapeutic dose *with gabapentin plus one of* the following: tricyclic antidepressant *or* topical lidocaine.

4. A diagnosis of **partial onset seizures**, as adjunct therapy (Lyrica®)

5. A diagnosis of **major depressive disorder** or **generalized anxiety disorder** (Cymbalta®)

6. A diagnosis of **chronic musculoskeletal pain** (Cymbalta®)

   A trial and therapy failure at a therapeutic dose with at least *two* drugs from *two* distinct therapeutic classes from the following: NSAIDs, opioids, tramadol, or tricyclic antidepressants.

Requests for concomitant use of these agents for an indicated chronic pain diagnosis may only be considered once each agent has been tried at maximum tolerated dose separately. Duplicate use of drugs from the same therapeutic category will not be considered. *Requests for doses above the manufacturer recommended dose will not be considered.*

Oral Immunotherapy

Newly Proposed Prior Authorization Criteria

Prior authorization is required for sublingual allergen immunotherapy. Payment will be considered under the following conditions:

1. Medication is prescribed in consultation with an allergist; and
2. Patient is diagnosed with pollen-induced allergic rhinitis with or without conjunctivitis; and
3. Patient has documented trials and therapy failures with allergen avoidance and pharmacotherapy (intranasal corticosteroids and antihistamines); and
4. Patient has a documented intolerance to immunotherapy injections; and
5. The first dose has been administered under the supervision of a health care provider to observe for allergic reactions (date of administration and response required prior to consideration).
6. If patient receives other immunotherapy by subcutaneous allergen immunotherapy (SCIT), treatment of allergic rhinitis with sublingual allergen immunotherapy (SLIT) will not be approved.

Short Ragweed Pollen (Ragwitek®) In addition to the above criteria being met:

- Patient is 18 through 65 years of age; and

- Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to short ragweed pollen.
- If criteria for coverage are met, authorization will be considered at least 12 weeks before the expected onset of ragweed pollen season and continued throughout the season.

Grass Pollen (Grastek® and Oralair®) In addition to the above criteria being met:

Oralair®

- Patient is 10 through 65 years of age (Oralair®); and
- Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to sweet vernal, orchard/cocksfoot, perennial rye, timothy, and Kentucky blue/June grass.
- If criteria for coverage are met, authorization will be considered at least 4 months prior to the expected onset of each grass pollen season and continued throughout the grass pollen season; or

Grastek®

- Patient is 5 through 65 year of age (Grastek®); and
- Patient has a positive skin test or in vitro testing (pollen-specific IgE antibodies) to timothy grass (or cross reactive grasses such as sweet vernal, orchard/cocksfoot, perennial rye, Kentucky blue/June, meadow fescue, and redtop).
- If criteria for coverage are met, authorization will be considered at least 12 weeks before the expected onset of each grass pollen season.

Methotrexate Injection

Newly Proposed Prior Authorization Criteria

Prior authorization is required for non-preferred methotrexate injection. Payment will be considered under the following conditions:

1. Diagnosis of severe, active rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (pJIA) and ALL of the following:
    a. Prescribed by a rheumatologist; and
    b. Patient has a documented trial and intolerance with oral methotrexate; and
    c. Patient has a documented trial and therapy failure or intolerance with at least one other non-biologic DMARD (hydroxychloroquine, leflunomide, minocycline or sulfasalazine); and
    d. Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and
    e. Patient does not reside in a long-term care facility.
2. Diagnosis of severe, recalcitrant, disabling psoriasis and ALL of the following:
    a. Patient is 18 years of age or older; and
    b. Prescribed by a dermatologist; and
    c. Patient has documentation of an inadequate response to all other standard therapies (oral methotrexate, topical corticosteroids, vitamin D analogues, cyclosporine, systemic retinoids, tazarotene, and phototherapy).
    d. Patient's visual or motor skills are impaired to such that they cannot accurately draw up their own preferred generic methotrexate injection and there is no caregiver available to provide assistance; and
    e. Patient does not reside in a long-term care facility.

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

Tasimelteon (Hetlioz®)

Newly Proposed Prior Authorization Criteria
Prior authorization is required for tasimelteon (Hetlioz). Requests for doses above the manufacturer recommended dose will not be considered. Payment will be considered under the following conditions:

1. Patient has a diagnosis of Non-24-Hour Sleep-Wake Disorder (Non-24), as confirmed by a sleep specialist; and
2. Patient is 18 years of age or older; and
3. Documentation the patient is totally blind with no perception of light is provided; and
4. Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic – non-benzodiazepine agent; and
5. Patient has a documented trial and therapy failure with ramelteon (Rozerem®).

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered when the patient has received 3 months of continuous therapy and patient has achieved adequate results with tasimelteon (Hetlioz), such as entrainment, significant increases in nighttime sleep, and/or significant decreases in daytime sleep.

Apremilast (Otezla®)

Newly Proposed Prior Authorization Criteria
Prior authorization is required for apremilast (Otezla®). Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of active psoriatic arthritis (≥ 3 swollen joints and ≥ 3 tender joints); and
3. Prescribed by a rheumatologist or a dermatologist; and
4. Patient does not have severe renal impairment (CrCl < 30 mL/min); and
5. Patient has documentation of a trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and
6. Patient has documentation of trials and therapy failures with two preferred biological agents used for psoriatic arthritis.

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

Palivizumab (Synagis)

Proposed Prior Authorization Criteria (*changes italicized*)
Prior authorization is required for therapy with palivizumab. Prior authorizations will be approved *for administration during the RSV season* for a maximum of five doses per patient. No allowances will be made for a sixth dose. *Patients, who experience a breakthrough RSV hospitalization, should have their monthly prophylaxis discontinued,*

as there is an extremely low likelihood of a second RSV hospitalization in the same season. Payment for palivizumab will be considered for patients who meet one of the following criteria:

Chronic Lung Disease (CLD) *of Prematurity*

- Patient is less than *12* months of age at start of therapy and *develops CLD* of prematurity *(defined as gestational age less than 32 weeks and required greater than 21% oxygen for at least the first 28 days after birth).*
- *Requests for patients during their second year of life (12 months to < 24 months) will be considered for patients meeting the CLD of prematurity definition above and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season*.

Hemodynamically Significant Congenital Heart Disease (CHD)

- Patient is less than *12* months of age at start of therapy and has hemodynamically significant CHD further defined by any of the following:
  - *Patient with acyanotic heart disease who is* receiving medication to control congestive heart failure *and will require cardiac surgical procedures or*
  - *Patient with* moderate to severe pulmonary hypertension.
  - *Requests for patients with* cyanotic heart *defects will be considered with documentation of consultation with a pediatric cardiologist that recommends patient receive palivizumab prophylaxis.*

Premature Infants (without CLD of Prematurity or CHD)

- Patient is less than 12 months of age at start of therapy with a gestational age of less than 29 weeks.

Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder

- Patient is 12 months of age or younger at the start of therapy and has either severe neuromuscular disease or congenital *anomaly that impairs the ability to clear secretions from the upper airway due to an ineffective cough.*

Immunocompromised Children

- Patient is less than 24 months of age at start of therapy and *is profoundly immunocopromised during the RSV season* (e.g., severe combined immunodeficiency, advanced acquired immunodeficiency syndrome, *receiving chemotherapy*).

The DUR Commission reviewed clinical information regarding niacin. Recent studies have found niacin, added to a statin, failed to improve outcomes in patients with cardiovascular disease. Based on this information, the Commission made the recommendation that the Iowa Medicaid P&T Committee consider changing the status of niacin products to non-preferred on the PDL, requiring documentation of an intolerance to, or failure with, a preferred statin at an optimized dose.

The DUR Commission also reviewed recommendations they initially made in April 2012 to implement ProDUR edits on antipsychotics in members less than 18 years of age. Specifically, the recommendation was to 1) implement an age edit on risperidone for members less than five (5) years of age and an age edit on all other antipsychotics for members less than six (6) years of age; and 2) apply a duplicate therapy edit to all antipsychotics. After discussion, the Commission continues to support implemention the aforementioned ProDUR edits.

Finally, the Commission reviewed utilization of short-acting opioids and made the recommendation to implement a quantity limit of 120 units per 30 days across all short-acting opioids.

Thank you in advance for the Department's consideration of accepting the DUR Commission's recommendations for clinical prior authorization criteria for Chronic Pain Syndromes, Oral Immunotherapy, Methotrexate Injection, Tasimelteon (Hetlioz™), Apremilast (Otezla®), and Palivizumab (Synagis®), in addition to the quantity limit on short-acting opioids.

Sincerely,

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Cc: Erin Halverson, R.Ph., IME
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