INFORMATIONAL LETTER NO.1769-MC-FFS-D

DATE: February 20, 2017

TO: Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse Practitioners, Therapeutically Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics, Skilled Nursing Facilities, Intermediate Care Facilities, Nursing Facilities-Mental ILL, Federally Qualified Health Centers (FQHC), Indian Health Service, Maternal Health Centers, Certified Nurse Midwife, Community Mental Health, Family Planning, Residential Care Facilities, ICF/ID State and Community Based ICF/ID Providers

APPLIES TO: Managed Care, Fee-for-Service and Dental

FROM: Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: April 1, 2017

1. **New Drug Prior Authorization Criteria-** See complete prior authorization criteria under the Prior Authorization Criteria tab[1].

   - **Daclizumab (Zinbryta):**
     Prior authorization is required for daclizumab (Zinbryta). Payment will be considered under the following conditions:
     1. Patient has a diagnosis of a relapsing form of multiple sclerosis (MS); and
     2. Patient is 18 years of age or older; and
     3. Patient has documentation of previous trials and therapy failures with two or more drugs indicated for the treatment of MS; and
     4. Patient does not have pre-existing hepatic disease or hepatic impairment (including hepatitis B or C); and
     5. Baseline transaminases (ALT, AST) and bilirubin levels are obtained; and
     6. Patient does not have an ALT or AST at least two times the upper limit of normal (ULN); and
     7. Patient does not have a history of autoimmune hepatitis or other autoimmune condition involving the liver, and
     8. Patient has been screened for TB and treated for TB if positive; and
     9. Daclizumab will be used as monotherapy; and
     10. Daclizumab will be dosed as 150 mg once monthly; and

[1] http://www.iowamedicaidpdl.com/pa_criteria

11. Prescriber, patient, and pharmacy are enrolled in the Zinbryta REMS program.
12. The 72-hour emergency supply rule does not apply to daclizumab.
13. Lost or stolen medication replacement requests will not be authorized.

If criteria for coverage are met, an initial authorization will be given for 12 months. Additional authorizations will be considered when documentation of a positive clinical response to daclizumab therapy is provided.

- **Narcan (Naloxone) Nasal Spray:**
  Prior authorization is required for a patient requiring more than two doses of Narcan (naloxone) nasal spray per 365 days. Requests for quantities greater than two doses per 365 days will be considered under the following conditions:
  1. Documentation is provided indicating why patient needs additional doses of Narcan (naloxone) nasal spray (accidental overdose, intentional overdose, other reason); and
  2. Narcan (naloxone) nasal spray is to be used solely for the patient it is prescribed for; and
  3. The patient is receiving an opioid as verified in pharmacy claims; and
  4. Patient has been reeducated on opioid overdose prevention; and
  5. Documentation is provided on the steps taken to decrease the chance of opioid overdose again; and
  6. A treatment plan is included documenting a plan to lower the opioid dose.

2. Changes to Existing Prior Authorization Criteria- *Changes are italicized.* See complete prior authorization criteria under the Prior Authorization Criteria tab[2].

- **Alpha$_2$ Agonists, Extended Release:**
  Prior authorization is required for extended-release alpha$_2$ agonists. Payment will be considered for patients when the following is met:
  1. The patient has a diagnosis of ADHD and is between 6 and 17 years of age; and
  2. Previous trial with the preferred immediate release product of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance; and
  3. Previous trial and therapy failure at a therapeutic dose with one preferred amphetamine and one preferred non-amphetamine stimulant.~~; *and*~~
  ~~*4. Previous trial and therapy failure at a therapeutic dose with atomoxetine (Strattera®).*~~
  The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

[2] http://www.iowamedicaidpdl.com/pa_criteria

- **Buprenorphine Transdermal System & Buccal Film:**
  Current clinical prior authorization criteria to be removed. Buprenorphine transdermal system and buccal film will be subject to the long-acting opioids criteria.

- **Multiple Sclerosis Agents-Oral:**
  Prior authorization is required for fingolimod (Gilenya™), teriflunomide (Aubagio®), or dimethyl fumarate (Tecfidera™). Payment will be considered for patients 18 years of age and older under the following conditions:
  3. Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent.

  For patients initiating therapy with fingolimod (Gilenya™), *a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims*, documentation of the following must be provided:

- **Omalizumab (Xolair):**
  Prior authorization is required for Xolair®. Payment for Xolair® will be authorized when the following criteria are met:

  <u>Moderate to Severe Persistent Asthma</u>
  2. Patient is *6* years of age or older; and
  3. *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*
  4. Pretreatment IgE level is *within the following range*:
     a. *Adults and adolescent patients 12 years of age or older* - 30 IU/mL *to* 700 IU/mL; *or*
     b. *Pediatric patients 6 to less than 12 years of age - 30 IU/mL to 1300 IU/mL; and*
  5. Patient's weight *is within the following range:*
     a. *Adults and adolescent patients 12 years of age or older* - 30 kg *to* 150 kg; *or*
     b. *Pediatric patients 6 to less than 12 years of age - 20 kg to 150kg; and*
  8. Patient is currently using a high dose inhaled corticosteroid, long-acting beta-agonist, *AND a leukotriene receptor antagonist, and* is compliant with therapy and asthma symptoms are not adequately controlled after at least three (3) months of therapy*; and*
  9. Is dosed according to manufacturer labeling based on pretreatment serum IgE and body weight.
  10. Patient has access to an *epinephrine injection* to treat allergic reactions that may occur after administration of Xolair®.

  If the criteria for coverage are met, the initial authorization will be given for 16 weeks

to assess the need for continued therapy. Requests for continuation of therapy will not be granted for patients who have not shown adequate response to Xolair® therapy and for patients who do not continue concurrent use with a high dose corticosteroid, long-acting beta-agonist, *and leukotriene receptor antagonist.*

Chronic Idiopathic Urticaria

3. *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*
4. Patient has documentation of a trial and therapy failure with at least one *preferred* second-generation antihistamine, one of which must be cetirizine at a dose up to 20 mg per day; and
5. Patient has documentation of a trial and therapy failure with at least one *preferred* first-generation antihistamine; and
6. Patient has documentation of a trial and therapy failure with at least one *preferred* potent H1 receptor antagonist (hydroxyzine and/or doxepin); and

- **Oral Constipation Agents:**
  Prior authorization is required for *oral constipation agents*. Payment will be considered under the following conditions:
  2. Patient must have documentation of adequate trials and therapy failures with *both of* the following:
     a. *Stimulant laxative (senna) plus* saline laxative (milk of magnesia); and
     b. *Stimulant laxative (senna) plus* osmotic laxative (polyethylene glycol or lactulose).
  4. Patient has one of the following diagnoses:
     c. A diagnosis of opioid-induced constipation with chronic, non-cancer pain (Amitiza®, Movantik™ or *Relistor*®)
     iii. Patient has documentation of an adequate trial and therapy failure with Amitiza®, if prior authorization request is for a different oral constipation agent.

3. Preferred Brand Name Drugs on the PDL-Pharmacy Clarification
When a status change occurs for a previously preferred brand name drug to non-preferred status, up to a *minimum* of 30 days transition period is given to pharmacies to help utilize existing brand name product in stock in an effort to decrease a pharmacy's remaining brand name drug inventory (see PDL comment section regarding transition periods exceeding 30 days). If additional stock remains beyond this time period, pharmacies may call the POS Helpdesk at 877-463-7671 or 515-256-4608 (local) to request an override for the non-preferred brand name drug with a recent status change.

4. DUR Update: The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website[3] under the "Newsletters" link.

[3] http://www.iadur.org/

We encourage providers to go to the PDL website[4] to view all recent changes to the PDL. If you have questions regarding Fee for Service members, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or email info@iowamedicaidpdl.com. Questions regarding Managed Care members should be directed to the specific MCO.

[4] http://www.iowamedicaidpdl.com/