Department of HUMAN SERVICES

**INFORMATIONAL LETTER NO. 2263-MC-FFS**

**DATE:** August 26, 2021

**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 and Physician Assistants

**APPLIES TO:** Managed Care (MC) and Fee-for-Service (FFS)

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

**RE:** October 2021 Iowa Medicaid Pharmacy Program Changes

**EFFECTIVE:** October 1, 2021

**The purpose of this Informational Letter (IL) is to communicate changes to the Iowa Medicaid Preferred Drug List (PDL). This IL breaks down these changes into categories, and where possible, shows changes preserving the wording and formatting of the PDL.**

1. **New Drug Prior Authorization (PA) Criteria –** See complete PA criteria under the Prior Authorization Criteria tab[1].

   - **Mannitol Inhalation Powder (Bronchitol):**
     PA is required for mannitol inhalation powder (Bronchitol). Payment will be considered when the following criteria are met:
     1. Patient has a diagnosis of cystic fibrosis; and
     2. Patient meets the Food and Drug Administration (FDA) approved age; and
     3. Prescriber is a cystic fibrosis specialist or pulmonologist; and
     4. Documentation is provided that patient has successfully completed the Bronchitol tolerance test (BTT); and

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

5. Patient will pre-medicate with a short-acting bronchodilator; and
6. Dose does not exceed the FDA approved dose.

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:
1. Adherence to mannitol inhalation powder (Bronchitol) therapy is confirmed; and
2. Patient has demonstrated improvement or stability of disease symptoms, such as improvement in $FEV_1$, decrease in pulmonary exacerbations, decrease in hospitalizations, or improved quality of life.

- **Risdiplam (Evrysdi):**
  PA is required for risdiplam (Evrysdi). Payment will be considered under the following conditions:
  1. Patient has a diagnosis of spinal muscular atrophy (SMA); and
  2. Patient meets the FDA approved age for diagnosis; and
  3. Dosing follows FDA approved dose for age and weight; and
  4. A negative pregnancy test for females of reproductive potential prior to initiating treatment; and
  5. Female patients of reproductive potential have been advised to use effective contraception during treatment and for at least one month after last dose and male patients of reproductive potential have been counseled on the potential effects on fertility; and
  6. Patient does not have impaired liver function; and
  7. Will not be prescribed concomitantly with other SMA treatments, such as Spinraza (nusinersen), Zolgensma (onasemnogene abeparvovec), or any other new products that are approved by the FDA and released; and
  8. Documentation of previous SMA therapies and response to therapy is provided; and
  a. For patients currently on Spinraza, documentation that Spinraza will be discontinued is provided, including date of last dose, and the appropriate interval based on the dosing frequency of the other drug has been met (i.e., four months from the last dose when on maintenance therapy); or
  b. For patients treated with Zolgensma, requests will not be considered; and
  9. Is prescribed by or in consultation with a neurologist; and
  10. Pharmacy will educate the member, or member's caregiver, on the storage and administration of Evrysdi, as replacements for improper storage or use will not be authorized.

  If the criteria for coverage are met, requests will be approved for one year. Requests for continuation of therapy will require documentation of a positive response to therapy including stabilization or improved function unless intercurrent event (fracture, illness, other) affects functional testing.

**2. Changes to Existing PA Criteria – *Changes are italicized or stricken.*** See complete PA criteria under the Prior Authorization Criteria tab[2].

- **Binge Eating Disorder:**
  Binge Eating Disorder (Vyvanse only)
  - e. Prescription is written by a psychiatrist*,* psychiatric nurse practitioner*, or psychiatric physician assistant*; and

- **IL-5 Antagonists:**
  PA is required for IL-5 antagonists. Requests will not be considered with concurrent use with another monoclonal antibody. *Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent.* Payment will be considered under the following conditions:
  1. *Is requested for an FDA approved or compendia indicated diagnosis; and*
  2. Patient meets the FDA approved *or compendia indicated* age *and dose* for submitted diagnosis; and
  3. Patient has a diagnosis of severe asthma with an eosinophilic phenotype, and
     a. Patient has a pretreatment blood eosinophil count of ≥ 150 cells*/mcL* within the previous 6 weeks or blood eosinophils ≥ 300 cells*/mcL* within 12 months prior to initiation of therapy; and
     b. Symptoms are inadequately controlled with documentation of current treatment with a high-dose inhaled corticosteroid (ICS) given in combination with a controller medication (long-acting beta2-agonist [LABA] and leukotriene receptor antagonist [LTRA]) for a minimum of 3 consecutive months, with or without oral corticosteroids. Patient must be compliant with therapy, based on pharmacy claims; and
     c. Patient has a history of two (2) or more exacerbations in the previous year despite regular use of high-dose ICS plus a LABA and LTRA; and
     d. A pretreatment forced expiratory volume in 1 second ($FEV_1$) < 80% predicted in adults and < 90% in adolescents; or
  4. Patient has a diagnosis of eosinophilic granulomatosis with polyangiitis, and
     a. Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and
     b. One of the following:
        i. Eosinophil count >1000 cells/mcL; or
        ii. Eosinophil count > 10% of the total leukocyte count; *or*
  5. *Patient has a diagnosis of hypereosinophilic syndrome (HES); and*
     a. *Patient has been diagnosed with HES for ≥ 6 months prior to starting treatment; and*
     b. *Documentation that non-hematologic secondary causes of HES have been ruled out; and*
     c. *Documentation patient does not have FIP1L1-PDGFR□ kinase-positive HES; and*

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

d. *Documentation of ≥ 2 HES flares within the previous 12 months while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive, or cytotoxic therapy); and*
e. *Patient has a blood eosinophil count ≥ 1,000 cells/mcL; and*
f. *Medication will be used in combination with stable doses of at least one other HES therapy; and*

6. Prescribed by or in consultation with an allergist, *hematologist,* immunologist, pulmonologist, or rheumatologist.

If criteria for coverage are met, an initial authorization will be given for 3 months *for a diagnosis of severe asthma with an eosinophilic phenotype and eosinophilic granulomatosis with polyangiitis or 6 months for a diagnosis of hypereosinophilic syndrome* to assess the need for continued therapy. Requests for continuation of therapy will be based on continued medical necessity and will be considered when the following criteria are met:
Severe Asthma with an Eosinophilic Phenotype:
1. Patient continues to receive therapy with an ICS, LABA and LTRA; and
2. Patient has experienced a reduction in asthma signs and symptoms including wheezing, chest tightness, coughing, shortness of breath; or
3. Patient has experienced a decrease in administration of rescue medication (albuterol); or
4. Patient has experienced a decrease in exacerbation frequency; or
5. Patient has experienced an increase in predicted $FEV_1$ from the pretreatment baseline.

Eosinophilic Granulomatosis with Polyangiitis:
1. Patient has demonstrated a positive clinical response to therapy (increase in remission time).

*Hypereosinophilic Syndrome:*
*1. Patient has demonstrated a positive clinical response to therapy (improvement of symptoms and/or reduction in the number of flares); and*
*2. Medication continues to be used in combination with stable doses of at least one other HES therapy.*

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

- **Isotretinoin (Oral):**
PA is required for oral isotretinoin therapy. Payment for non-preferred oral isotretinoin products will be authorized only for cases in which there is documentation of trial(s) and therapy failure with a preferred agent(s). Payment will be *considered* for preferred oral isotretinoin products for *moderate to severe* acne under the following conditions:
1. There are documented trials and therapy failures of systemic antibiotic therapy and topical *vitamin A derivative (*tretinoin *or adapalene)* therapy. Documented trials and therapy failures of systemic antibiotic therapy and topical *vitamin A*

*derivative* therapy are not required for approval for treatment of acne *conglobata; and*
2. *Prescriber attests patient has enrolled in and meets all requirements of the iPLEDGE program.*

Initial authorization will be granted for up to *24* weeks. A minimum of *8 weeks* without therapy is required to consider subsequent authorizations.

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

- **Multiple Sclerosis Agents (Oral):**
  For patients initiating therapy with a preferred oral *multiple sclerosis agent* medication, a manual PA 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:
  1. A diagnosis of relapsing forms of multiple sclerosis; and
  2. *Request must adhere to all FDA approved labeling, including indication, age, dosing, contraindications, and warnings and precautions*; and
  3. *Documentation of a* previous trial and therapy failure with a preferred interferon or non-interferon used to treat multiple sclerosis.

  Requests for a non-preferred oral multiple sclerosis agent must document a previous trial and therapy failure with a preferred oral multiple sclerosis agent. 9

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

- **Nonsteroidal Anti-Inflammatory Drugs:**
  PA is required for all non-preferred nonsteroidal anti-inflammatory drugs (*NSAID*s). *Payment for a non-preferred NSAID will be considered under the following conditions:*
  1. *Documentation of* previous trials and therapy failures with at least three preferred *NSAIDs; and*
  2. Requests for a non-preferred extended release *NSAID* must document previous trials and therapy failures with three preferred *NSAID*s, one of which must be the preferred immediate release *NSAID* of the same chemical entity at a therapeutic dose that resulted in a partial response with a documented intolerance.

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

- **Proton Pump Inhibitors:**
  PA is not required for preferred proton pump inhibitors (PPI) for doses within the established quantity limits of one unit per day.

  Requests for PPIs exceeding one unit per day will be considered for the following diagnoses with additional documentation regarding the medical necessity:
  1. Barrett's esophagus*, Erosive esophagitis, or Peptic stricture* (Please fax a copy of the scope results with the initial request)*; or*
  2. Hypersecretory conditions (Zollinger-Ellison syndrome, systemic mastocytosis, and multiple endocrine adenomas)*; or*
  3. Recurrent peptic ulcer disease*; or*
  4. Gastroesophageal reflux disease will be considered after documentation of a therapeutic trial and therapy failure with *the requested PPI at maximal dose within the established quantity limit of one unit per day. Requests* for PPIs exceeding one unit per day will be considered on a short term basis (up to 3 months). After the three month period, a *dose reduction to* the recommended once daily dosing will be required. A trial of the recommended once daily dosing will be required on an annual basis for those patients continuing to need doses beyond one unit per day*; or*
  5. Helicobacter pylori will be considered for up to 14 days of treatment with documentation of active infection.

  Payment for a non-preferred proton pump inhibitor will be authorized only for cases in which there is documentation of previous trials and therapy failures with three preferred products.

- **Vesicular Monoamine Transporter (VMAT) 2 Inhibitors:**
  Tardive Dyskinesia (Ingrezza or Austedo)
  7. For Austedo:
     ~~a. Patient is not suicidal, or does not have untreated/inadequately treated depression;~~

**3. Removal of Existing PA Criteria:**

Clinical PA criteria will be removed for the below categories and the PA forms will no longer be required. PA will continue to be required for non-preferred medications through the Preferred Drug List (PDL) using form 470-4108 Nonpreferred Drug[3].

- Alpha$_2$ Agonists, Extended Release, form 470-5018
- Valsartan/Sacubitril (Entresto), form 470-5398

[3] http://iowamedicaidpdl.com/sites/default/files/ghs-files/prior-authorization-forms/2011-06-16/non-preferred-drug-pa-form-npi-july-111.pdf

**4. Point of Sale Billing Updates:**

**a. ProDUR Quantity Limits:** The following quantity limit edits will be implemented. A comprehensive list of all quantity limit edits appears on the Quantity Limit Chart[4].

| Drug Product | Quantity | Days Supply |
|---|---|---|
| Dulera 50-5mcg, 100-5mcg, 200-5mcg | 240 inhalations | 30 |
| Entresto 24-26mg, 49-51mg, 97-103mg | 60 | 30 |
| Symbicort 80-4.5mcg, 160-4.5mcg | 240 inhalations | 30 |

**b. ProDUR Age Edit:** Alpha$_2$ agonists for ADHD will be considered for members 6 through 17 years of age.

**5. DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website[5] under the "Newsletters" link.

We encourage providers to go to the PDL website[6] to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization helpdesk at 877-776-1567, locally in Des Moines at 515-256-4607, or by email at info@iowamedicaidpdl.com.

[4] http://www.iowamedicaidpdl.com/billing_quantity_limits
[5] http://www.iadur.org/
[6] http://www.iowamedicaidpdl.com/