Department of HUMAN SERVICES

INFORMATIONAL LETTER NO. 2170-MC-FFS

DATE: September 23, 2020

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), Fee-for-Service (FFS),

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

RE: November 2020 Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: November 1, 2020

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

   - **Cystic Fibrosis Agents, Oral** (Applies to Kalydeco, Orkambi, Symdeko, and Trikafta)
     Prior authorization (PA) is required for oral cystic fibrosis agents. Payment will be considered for patients when the following criteria are met:
     1. Patient meets the FDA approved age; and
     2. Patient has a diagnosis of cystic fibrosis (CF); and
     3. Patient has a mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene confirmed by an FDA-cleared CF mutation test (attach test results) for which the requested drug is indicated; and
     4. Prescriber is a CF specialist or pulmonologist; and
     5. Baseline liver function tests (AST, ALT, and bilirubin) are provided; and
     6. Requests for Trikafta will not be considered for patients with severe hepatic impairment (Child-Pugh Class C); and
     7. Will not be used with other CFTR modulator therapies.

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

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

1. Adherence to oral cystic fibrosis therapy is confirmed; and
2. Liver function tests (AST, ALT, and bilirubin) are assessed every three months during the first year of treatment and annually thereafter.

- **Voxelotor (Oxbryta):**
  Prior authorization is required for Oxbryta (voxelotor). Payment will be considered for patients when the following criteria are met:
  1. Patient meets the FDA approved age; and
  2. Patient has a diagnosis of sickle cell disease (SCD); and
  3. Requested dose is within the FDA approved dosing; and
  4. Patient has experienced at least two sickle cell-related vasoocclusive crises within the past 12 months (documentation required); and
  5. Patient has documentation of an adequate trial and therapy failure with hydroxyurea; and
  6. Baseline hemoglobin (Hb) range is ≥5.5 to ≤10.5 g/dL; and
  7. Is prescribed by or in consultation with a hematologist; and
  8. Patient is not receiving concomitant blood transfusion therapy.

  If the criteria for coverage are met, an initial authorization will be given for six months. Additional approvals will be granted if the following criteria are met:
  1. Documentation of an increase in hemoglobin by ≥1 g/dL from baseline; and
  2. Documentation of a decrease in the number of sickle cell-related vasoocclusive crises.

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

2. Changes to Existing Prior Authorization Criteria- *Changes are italicized or stricken*. See complete prior authorization criteria under the Prior Authorization Criteria tab[1].

- **Direct Oral Anticoagulants (formerly Novel Oral Anticoagulants):**
  Prior authorization (PA) is not required for preferred *direct* oral anticoagulants (*DOACs*). PA is required for non-preferred *D*OACs. *Requests will be considered for FDA approved dosing and length of therapy for submitted diagnosis.* Requests for doses outside of the manufacturer recommended dose will not be considered. Payment will be considered for FDA approved or compendia indications *for the requested drug* under the following conditions:
  1. *Patient is within the FDA labeled age for indication; and*
  8. Patient has documentation of a trial and therapy failure at a therapeutic dose with at least two preferred *DOACs; and*

9. For requests for edoxaban, *when prescribed for the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE),* documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin) *is provided*.

- **IL-5 Antagonists:**
  Prior authorization is required for *IL-5 antagonists*. Requests will not be considered with concurrent use *with another monoclonal antibody*. Payment will be considered under the following conditions:
  1. Patient meets the FDA approved age *for submitted diagnosis*; and
  2. *Is dosed within FDA approved dosing for submitted diagnosis and age; and*
  3. Patient has a diagnosis of severe asthma with an eosinophilic phenotype, 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*
     d. *Patient has documentation of an adequate trial and therapy failure with systemic glucocorticoids; and*
     e. *One of the following:*
        i. Eosinophil count greater than 1000 cells/mcL; or
        ii. Eosinophil count greater than 10% of the total leukocyte count; and
  5. *Prescribed by or in consultation with* an allergist, immunologist, pulmonologist*, or rheumatologist.*

  If criteria for coverage are met, an initial authorization will be given for three months 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).*

- **Valsartan/Sacubitril (Entresto):**
  Prior authorization (PA) is required for valsartan/sacubitril (Entresto). Requests above the manufacturer recommended dose will not be considered. Payment will be considered for patients when the following criteria are met:
  1. *Patient is within the FDA labeled age for indication; and*
  2. Patient has a diagnosis of NYHA Functional Class II, III, or IV heart failure; and
     ~~a. Patient is 18 years of age or older; and~~
  3. *Pediatric patient has a diagnosis of symptomatic heart failure (NYHA/Ross Class II to IV) due to systemic left ventricular systolic dysfunction with documentation of a left ventricular ejection fraction ≤ 40%; and*
  ~~9. Prescriber is a cardiologist or has consulted with a cardiologist (telephone consultation is acceptable).~~

3. **Removal of Prior Authorization Criteria:** Clinical prior authorization criteria will be removed for pre-filled insulin pens and form 470-4111 Insulin, Pre-Filled Pens 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[2].

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.

We encourage providers to go to the PDL website[4] to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 877-776-1567 or 515-256-4607 (local in Des Moines) or email info@iowamedicaidpdl.com.

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