Department of HUMAN SERVICES

INFORMATIONAL LETTER NO. 2192-MC-FFS

DATE: November 30, 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: January 2021 Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: January 1, 2021

1. **Changes to the Preferred Drug List (PDL) Effective January 1, 2021.** Refer to the PDL website[1] to review the complete PDL.

Preferred	**Non-Preferred**	**Non-Recommended**
Abilify Maintena[2]	AirDuo Digihaler	Inqovi[1]
Ajovy[1]	Armonair Digihaler	Onureg[1]
Anoro Ellipta	Bafiertam[1]	Qinlock[1]
Baqsimi[3]	Breztri	Retevmo[1]
Bonjesta	Ciprofloxacin / Dexamethasone Otic	Rukobia
Ciprodex	Cosentyx[1]	
Concerta[1]	Cystadrops	
Dimethyl Fumarate[1]	Diclegis	
Evamist	Efavirenz / Lamivudine / Tenofovir	
Fasenra Auto-Injector[1]	Emtricitabine	
Fulphila[1]	Enspryng	

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

Insulin Aspart 70/30 Vial	Evrysdi[1]	
Insulin Aspart FlexPen	Fintepla	
Insulin Aspart PenFill	Hemady	
Insulin Aspart Protamine Flexpen	Ilevro	
Insulin Aspart Vial	Kesimpta[1]	
Invokamet	Kynmobi	
Invokana	Lydexa	
Kitabis	Methylin Oral Solution[1]	
Methylphenidate ER Caps (CD)[1]	NovoLog FlexPen	
Methylphenidate ER Caps (LA)[1]	NovoLog Mix FlexPen	
Methylphenidate ER Tabs 10mg[1]	NovoLog Mix Vial	
Nevanac	NovoLog PenFill	
Nivestym[1]	NovoLog Vial	
Nplate[1]	Ortikos	
Nurtec ODT[1]	Ozempic[1]	
Nuvessa	Pantoprazole Oral Packet[1]	
Ongentys	Quillivant XR[1]	
Spiriva Respimat	Ruconest	
Taltz[1,4]	Semglee Vial & Pen	
Trulicity[1]	Stiolto Respimat	
Ziextenzo[1]	Tecfidera[1]	
	Tolvaptan	
	Xcopri	
	Zeposia[1]	
	Zilxi[1]	

[1]Clinical PA Criteria Apply
[2]Step 2
[3]Step through a Preferred Reconstitution Product
[4]Step through a Preferred TNF

2. New Drug Prior Authorization Criteria- See complete prior authorization criteria under the Prior Authorization Criteria tab[2].

- **Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors:**
  Prior authorization (PA) is required for adenosine triphosphate-citrate lyase (ACL) inhibitors. Payment will be considered under the following conditions:
  1. Patient meets the FDA approved age; and
  2. Documentation of adherence to prescribed lipid lowering medications (including a maximally tolerated statin), prior to ACL inhibitor therapy, for the previous 90 days is provided (further defined below, by diagnosis); and
  3. Documentation is provided that medication will be used in combination with a maximally tolerated statin; and
  4. A baseline and current lipid profile is provided. Baseline lipid profile is defined as a lipid profile obtained prior to pharmacologic therapy; and
  5. Patient will continue to follow an appropriate low fat diet; and
  6. Is prescribed by or in consultation with a lipidologist, cardiologist, or endocrinologist; and
  7. If patient is taking in combination with:
     a. Simvastatin, dose does not exceed 20mg per day; or
     b. Pravastatin, dose does not exceed 40 mg per day; and
  8. Concurrent use with a PCSK9 inhibitor will not be considered; and
  9. Goal is defined as a 50% reduction in untreated baseline LDL-C; and
  10. Is prescribed for one of the following diagnoses:
      a. Heterozygous Familial Hypercholesterolemia (HeFH):
         i. Documentation is provided verifying diagnosis (attach documentation/results), as evidenced by:
            1. Clinical manifestations of HeFH (e.g. tendon xanthomas, cutaneous xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma); or
            2. Confirmation of diagnosis by gene or receptor testing; and
         ii. Documentation of untreated LDL-C ≥ 190 mg-dL; and
         iii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily; or
      b. Clinical Atherosclerotic Cardiovascular Disease (ASCVD):
         i. History of MI, angina, coronary or other arterial revascularization, stroke, TIA, or PVD of atherosclerotic origin; and

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

ii. Patient is unable to reach LDL-C goal with a minimum of two separate, chemically distinct statin trials used in combination with other lipid lowering medications. Trials are defined as: concurrent use of a maximally tolerated dose of a statin (must include atorvastatin and rosuvastatin), PLUS ezetimibe 10mg daily.

If criteria for coverage are met, requests will be approved for 3 months. Additional authorizations will be considered at yearly intervals under the following conditions:

a. Patient continues therapy with a maximally tolerated statin dose and remains at goal; and
b. Patient continues to follow an appropriate low fat diet; and
c. Documentation of LDL reduction is provided.

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

- **Peanut Allergen Powder-dnfp (Palforzia):**
  Prior authorization (PA) is required for Peanut (*Arachis hypogaea*) Allergen Powder-dnfp (Palforzia). Payment will be considered under the following conditions:
  1. Patient has a confirmed diagnosis of peanut allergy, as documented by a skin prick test to peanut ≥ 3 mm compared to control or a peanut-specific serum IgE ≥ 0.35 kUA/L (kilos of allergen-specific units per liter); and
  2. Patient is 4 to 17 years of age at initiation of therapy or 4 years of age and older for continued up-dosing and maintenance therapy; and
  3. Prescribed by or in consultation with an allergist or immunologist; and
  4. Patient has access to injectable epinephrine; and
  5. Will be used in conjunction with a peanut-avoidant diet; and
  6. Patient does not have any of the following:
     a. Uncontrolled asthma; and/or
     b. A history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; and
  7. Patient will adhere to the complex up-dosing schedule that requires frequent visits to the administering healthcare facility; and
  8. The initial dose escalation and the first dose of each new up-dosing level is administered under the supervision of a health care professional in a health care setting with the ability to manage potentially severe allergic reactions, including anaphylaxis. Initial dose escalation and the first dose of all up-dosing levels is not to be billed to the Iowa Medicaid outpatient pharmacy program as the initial dose escalation is administered in the provider office and should be billed via the medical benefit and the first dose of all up-dosing levels is provided via the Office Dose Kit; and

9. Follows FDA approved dosing; and
10. PA is required for all up-dosing dose levels (dose level 1 through 11); and
11. Maintenance dosing will be considered with documentation patient has successfully completed all dose levels of up-dosing.

3. Changes to Existing Prior Authorization Criteria- *Changes are italicized or stricken*. See complete prior authorization criteria under the Prior Authorization Criteria tab[3].

- **Acute Migraine Treatments (formerly Serotonin 5_HT-1-Receptor Agonists):**
  *No p*rior authorization (PA) *is required for preferred acute migraine treatments, as indicated on the Preferred Drug List (PDL). PA* is required for *acute migraine treatments under the following conditions:*
  1. *A diagnosis of acute migraine; and*
  2. *Patient meets the FDA approved age for requested agent; and*
  3. *For preferred acute migraine treatments where PA is required, as indicated on the PDL, documentation of previous trials and therapy failures with two preferred agents that do not require PA; and/or*
  4. *F*or *non*-preferred *acute migraine treatments,* documentation of previous trials and therapy failures with two preferred agents *that do not require PA. Requests for non-preferred CGRP inhibitors will also require documentation of a trial and therapy failure with a preferred CGRP inhibitor; and/or*
  5. *F*or quantities exceeding *the established quantity limit for each agent,* documentation of current prophylactic therapy or documentation of previous trials and therapy failures with two different prophylactic medications*; and/or*
  6. For *non*-preferred combination products*,* documen*tation of* separate trials and therapy failures with the individual ingredients, *in addition to the above criteria for preferred or non-preferred acute migraine treatments requiring PA*.

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

- **Pirfenidone (Esbriet) / Nintedanib (Ofev) (formerly Idiopathic Pulmonary Fibrosis):**
  Prior authorization (PA) is required for pirfenidone (Esbriet) and nintedanib (Ofev). Dosing outside of the FDA approved dosing will not be considered. Concomitant use of pirfenidone and nintedanib will not be considered. Payment will be considered for patients when the following criteria are met:
  1. Patient *meets the FDA approved age*; and
  2. Is prescribed by a pulmonologist; and
  3. Patient does not have hepatic impairment as defined below:

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

a. Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
b. Pirfenidone - Patient does not have severe hepatic impairment (Child Pugh C); and

4. Patient does not have renal impairment as defined below:
   a. Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or
   b. Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
5. Patient *does not utilize non-prescribed inhalants, such as vaping or other inhaled tobacco products, prior to initiating therapy and has been instructed to avoid tobacco products while using pirfenidone or nintedanib, and*
6. Patient has a diagnosis of idiopathic pulmonary fibrosis *(nintedanib or pirfenidone)* as confirmed by one of the following (attach documentation):
   a. Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
   b. A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and
   c. Prescriber has excluded other known causes of interstitial lung disease (ILD) such as domestic and occupational environmental exposures, connective tissue disease, and drug toxicity; and
   d. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and
   e. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; *or*
7. *Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) (nintedanib)as confirmed by the following (attach documentation:*
   a. Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and
   b. Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 40% predicted; and
   c. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-89% predicted; or
8. *Patient has a diagnosis of chronic fibrosing interstitial lung disease with a progressive phenotype (nintedanib) as confirmed by the following (attach documentation):*
   a. Documentation of a chest high resolution computed tomography (HRCT) scan showing fibrosis affecting ≥ 10% of the lungs; and
   b. Patient has documented pulmonary function tests within the prior 60 days showing FVC ≥ 45% predicted; and
   c. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥ 30-79% predicted; and

d. *Patient has at least one sign of clinical progression for interstitial lung disease within the last 24 months despite standard treatment with an agent other than nintedanib or pirfenidone:*
   i. *A relative decline in the FVC of at least 10% predicted; or*
   ii. *A relative decline in the FVC of 5-9% predicted combined with at least one of the following:*
      1. *Worsening respiratory symptoms; or*
      2. *Increased extent of fibrosis on HRCT; or*
   iii. *Worsening of respiratory symptoms and an increased extent of fibrotic changes on HRCT only.*

If the criteria for coverage are met, initial requests will be given for 6 months. Additional authorizations will be considered at 6 month intervals when the following criteria are met:

1. Adherence to pirfenidone (Esbriet) ~~and~~ *or* nintedanib (Ofev) is confirmed; and
2. *Documentation of a positive response to therapy, defined as meeting at least one of the following:*
   a. *Rate of lung function decline slowed; or*
   b. *Improved or no worsening of symptoms of cough or shortness of breath;* and
3. Documentation is provided that the patient has remained tobacco-free; and
4. ALT, AST, and bilirubin are assessed periodically during therapy.

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
Baclofen 5MG, 10MG & 20MG	120	30
Nurtec ODT 75MG	15	30
Reyvow 50MG & 100MG	8	30
Ubrelvy 50MG & 100MG	16	30

b. 2020 Pharmacy Cost of Dispensing Survey: The June 2020 Cost of Dispensing Report is complete and can be viewed here[5]. The report reflects

[4] http://www.iowamedicaidpdl.com/billing_quantity_limits
[5] https://www.mslc.com/iowa/CostofDispensingSurvey.aspx

the mean cost of dispensing, weighted by Medicaid volume, was $10.38 per prescription for all pharmacies including specialty pharmacies. For non-specialty pharmacies only, the mean cost of dispensing, weighted by Medicaid volume, was $9.71 per prescription.

The current dispensing fee of $10.07 will remain in place until additional state funding is appropriated by the Iowa Legislature[6] to increase the dispensing fee to $10.38. A state plan amendment would also be required if funding is approved and the increase would be prospective following CMS approval of the state plan amendment.

5. **DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website[7] under the "Newsletters" link.

We encourage providers to go to the PDL website[8] 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 e-mail info@iowamedicaidpdl.com.

[6] https://www.legis.iowa.gov/legislation/BillBook?ba=HF766&ga=88
[7] http://www.iadur.org/
[8] http://www.iowamedicaidpdl.com/