INFORMATIONAL LETTER NO.1552

DATE: September 17, 2015

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

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

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: October 1, 2015

*******This letter replaces Informational Letter No.1542 dated September 1, 2015*******

1. **Changes to the Preferred Drug List (PDL) Effective October 1, 2015.** Refer to complete PDL located at www.iowamedicaidpdl.com.

Preferred	Non-Preferred	Recommended	Non-Recommended
Calcitonin Salmon Nasal Spray	Aripiprazole[3]	Ibrance	Lenvima
Divalproex ER Tablets	Aromasin		Novoeight
Edurant	Asmanex HFA		Vitekta
Epzicom	Auryxia		
Evotaz	Bimatoprost		
Exemestane	Camptosar		
Exjade[1]	Capecitabine		
Gemcitabine	Cefixime Oral Suspension		
Hydroxyurea	Cholbam		
Hydroxyzine HCL 25mg & 50mg Tablets	Clozapine ODT[1]		
Invega Trinza[5]	Combivir		
Irinotecan	Complera[4]		
Isentress	Corlanor		

Kitabis Pak	Cosentyx[1]		

Lamivudine/ Zidovudine	Depakote ER[2]		
Letrozole	Duopa		
Lomustine	Evekeo[1]		
Mercaptopurine	Fanapt[3, 4]		
Methotrexate	Felbatol[2]		
Metoprolol Succinate	Femara		
Montelukast Granules[6]	Gemzar		
Tivicay	Gleostine		
Truvada	Glyxambi[1]		
Vinorelbine	Hydrea		
Xeloda	Jadenu[1]		
	Miacalcin Nasal Spray		
	Namzaric[6]		
	Natesto[1]		
	Natpara		
	Navelbine		
	Nuvessa		
	Pazeo		
	Phoslo		
	Prezcobix		
	Primlev[1]		
	ProAir RespiClick		
	Purinethol		
	Revatio[7]		
	Risedronate		
	Sabril		
	Singulair Granules		
	Sotylize		
	Spiriva Respimat		
	Stribild[4]		
	Tivorbex[1]		
	Tolcapone		
	Toprol XL		
	Toujeo SoloStar[1]		
	Trexall		
	Triumeq[4]		

[1]Clinical PA Criteria Apply
[2]Grandfather Existing Users with Seizure Diagnosis
[3]Step 3
[4]Grandfather Existing Users
[5]Step 2

[6]Age Edit
[7]Remove Grandfathering

2. New Drug Prior Authorization Criteria- See complete prior authorization criteria posted at www.iowamedicaidpdl.com under the Prior Authorization Criteria tab.

- **Edoxaban (Savaysa®):**

  Prior authorization is required for edoxaban (Savaysa®). Payment will be considered for patients when the following criteria are met:

  1. Patient does not have a mechanical heart valve; and
  2. Patient does not have moderate to severe mitral stenosis; and
  3. Patient does not have active pathological bleeding; and
  4. A recent creatinine clearance (CrCl) is provided and is within specified range listed below; and
  5. Patient does not have moderate or severe hepatic impairment (Child-Pugh B or C); and
  6. Patient has documentation of a previous trial and therapy failure with warfarin (TIA, stroke, or inability to maintain a therapeutic INR with a minimum 6 month trial); and
  7. Patient has documentation of a previous trial and therapy failure with apixaban or rivaroxaban, where applicable.

  Atrial Fibrillation

  1. Patient has documentation of a diagnosis of non-valvular atrial fibrillation; with
  2. Presence of at least one additional risk factor for stroke, with a $CHADS_2$ score ≥1; and
  3. Patient does not have a creatinine clearance (CrCl) > 95 mL/min.
  4. Requests will be considered for the following dosing:
     a. 60mg once daily in patients with a CrCl of > 50 mL/min to ≤ 95 mL/min; or
     b. 30mg once daily in patients with a CrCl of 15 to 50 mL/min

  Treatment of Deep Vein Thrombosis or Pulmonary Embolism

  1. Patient has documentation of a current deep vein thrombosis or pulmonary embolism; with
  2. Documentation patient has had 5 to 10 days of initial therapy with a parenteral anticoagulant (low molecular weight heparin or unfractionated heparin).
  3. Requests will be considered for the following dosing:
     a. 60mg once daily; or
     b. 30mg once daily in patients with any of the following:
        i. CrCl 15 mL/min to 50 mL/min
        ii. Body weight ≤60 kg

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

- **Idiopathic Pulmonary Fibrosis:**

  Prior authorization 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 is 40 years of age or older; and
2. Is prescribed by a pulmonologist; and
3. Patient has a diagnosis of idiopathic pulmonary fibrosis as confirmed by one of the following (attach documentation):
    - Findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP); or
    - A surgical lung biopsy demonstrating usual interstitial pneumonia (UIP); and
4. 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
5. Patient has documentation of pulmonary function tests within the prior 60 days with a forced vital capacity (FVC) ≥50% predicted; and
6. Patient has a carbon monoxide diffusion capacity (%DLco) of ≥30% predicted; and
7. Patient does not have hepatic impairment as defined below:
    - Nintedanib - Patient does not have moderate or severe hepatic impairment (Child Pugh B or C) or
    - Pifenidone - Patient does not have severe hepatic impairment (Child Pugh C); and
8. Patient does not have renal impairment as defined below:
    - Nintedanib - Patient does not have severe renal impairment (CrCl <30ml/min) or end-stage renal disease or
    - Pirfenidone – Patient does not have end-stage renal disease requiring dialysis; and
9. Patient is a nonsmoker or has been abstinent from smoking for at least six weeks.

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 nintedanib (Ofev®) is confirmed; and
2. Patient is tolerating treatment defined as improvement or maintenance of disease (<10% decline in percent predicted FVC or < 200 mL decrease in FVC); and
3. Documentation is provided that the patient has remained tobacco-free; and
4. ALT, AST, and bilirubin are assessed periodically during therapy.

- **Topical Corticosteroids:**

  Prior authorization is required for non-preferred topical corticosteroids. Payment will be considered for patients when there is documentation of adequate trials and therapy failures with at least two preferred, chemically distinct, topical corticosteroid agents within the same potency class or a higher potency class in the past 12 months. The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

3. **Changes to Existing Prior Authorization Criteria-** *Changes are italicized.* See complete prior authorization criteria posted at www.iowamedicaidpdl.com under the Prior Authorization Criteria tab.

- **Ivacaftor (Kalydeco®):**
  Prior authorization is required for Kalydeco™ (ivacaftor). Payment will be considered for patients when the following criteria are met:
  1. Patient is *2* years of age or older; and
  2. Has a diagnosis of cystic fibrosis with one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, and *R117H* as detected by a FDA-cleared CF mutation test; and
  3. Prescriber is a CF specialist or pulmonologist; and
  4. *Baseline liver function tests (AST/ALT) and FEV_1, if age appropriate, are provided; and*
  5. Patient does not have one of the following infections: *Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abcessus.*

  If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met:
  1. *Adherence to ivacaftor therapy is confirmed; and*
  2. *Response to therapy is documented by prescriber (e.g., improved FEV_1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and*
  3. *Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.*

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

a. ProDUR Quantity Limits: The following quantity limit edits will be implemented effective *October 1, 2015*. A comprehensive list of all quantity limit edits appears on our website, www.iowamedicaidpdl.com under the heading, “Quantity Limits”.

Drug Product	Quantity	Days Supply
Dulera 100/5	120 inhalations	30
Dulera 200/5	120 inhalations	30
Duloxetine 40mg	60	30
Invega Trinza	1 syringe	90
Invega Trinza	1 syringe	90
Invega Trinza	1 syringe	90
Invega Trinza	1 syringe	90
Symbicort 80/4.5	120 inhalations	30
Symbicort 160/4.5	120 inhalations	30

b. **Proper Billing of Synagis® and flu vaccines:** As a reminder, Synagis® 50mg Injection and most flu vaccines should be billed as 0.5mL.

5. **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.

6. **DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website, www.iadur.org under the "Newsletters" link.

We encourage providers to go to the website at www.iowamedicaidpdl.com 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.