INFORMATIONAL LETTER NO.1786-MC-FFS

Governor

DATE: April 27, 2017

TO: Iowa Medicaid Physicians, Dentists, Advanced Registered Nurse

Practitioners, Therapeutically Certified Optometrists, Podiatrists, Pharmacies, Home Health Agencies, Rural Health Clinics, Clinics,

Lt. Governor

Director

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

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

RE: Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: June 1, 2017

1. Changes to the Preferred Drug List (PDL) Effective June 1, 2017. Refer to the PDL website¹ to review the complete PDL.

Preferred	Non-Preferred		
Abacavir-Lamivudine	Adlyxin ¹		
Amlodipine-Olmesartan ¹	Aprepritant ¹		
Eliquis	Basaglar KwikPen ¹		
Generess	BromSite		
Lopinavir-Ritonavir	Cuvitru		
Norethindrone Acetate &	Drosperinone-Ethinyl Estradiol-Levomefolate		
Ethinyl Estradiol 1mg-20mcg			
Tablets			
Norethindrone Acetate &	Exondys 51 ¹		
Ethinyl Estradiol 1.5mg-30mcg			
Tablets			
	Ezetimibe		
	GoNitro		
	Gris-Peg ¹		
	Inflectra ¹		
	Invokamet XR ¹		

¹ http://www.iowamedicaidpdl.com/

Levalbuterol Tartrate ¹	
Mesalamine DR Tablets	
Methadone ¹	
Mytesi	
Nuplazid	
Olmesartan ¹	
Olmesartan-Amlodipine- HCTZ ¹	
Olmesartan-HCTZ ¹	
Oseltamivir	
Prestalia	
Quetiapine ER ²	
Rasagiline	
Rayaldee	
Soliqua ¹	
Tigecycline	
Tolak	
Yosprala	
Yuvafem	
Zurampic	

¹Clinical PA Criteria Apply

2. New Drug Prior Authorization Criteria- See complete prior authorization criteria under the Prior Authorization Criteria tab².

Eteplirsen (Exondys 51):

Prior authorization is required for Exondys 51 (eteplirsen). Payment will be considered for patients when the following criteria are met:

- Patient has a diagnosis of Duchenne muscular dystrophy (DMD) with mutation amenable to exon 51 skipping confirmed by genetic testing (attach results of genetic testing); and
- 2. Is prescribed by or in consultation with a physician who specializes in treatment of Duchenne muscular dystrophy; and
- 3. Patient is currently ambulatory; and
- 4. A baseline 6-Minute Walk Distance (6MWD) is provided and patient is able to achieve a distance of at least 180 meters while walking independently; and
- 5. Patient is currently stable on an oral corticosteroid regimen for at least six months; and
- 6. Is dosed based on FDA approved dosing: 30 mg/kg once weekly; and
- 7. Medication is to be administered by a healthcare professional in member's home by home health or in a long-term care facility.

²Step 3

² http://www.iowamedicaidpdl.com/pa criteria

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

When criteria for coverage are met, an initial authorization will be given for six months. Requests for continuation of therapy will be considered at six month intervals when the following criteria are met:

- Patient has demonstrated a response to therapy as evidenced by remaining ambulatory (able to walk with or without assistance, not wheelchair dependent);
- 2. An updated 6MWD is provided documenting patient is able to achieve a distance of at least 180 meters.
- 3. Changes to Existing Prior Authorization Criteria- Changes are italicized. See complete prior authorization criteria under the Prior Authorization Criteria tab³.
 - Colchicine: Existing PA criteria is removed.

Hepatitis C Treatments:

Prior authorization is required for hepatitis C treatments. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

- 4. Patient has been tested for hepatitis B (HBV) prior to initiating treatment of HCV and individuals with active HBV infection are treated (either at same time as HCV therapy or before HCV therapy is started); and
- 14. Documentation is provided for patients who are ineligible to receive ribavirin.

Insulin, Pre-Filled Pens:

Prior authorization is required for *all* pre-filled insulin pens. For pre-filled insulin pens where the requested insulin <u>is</u> available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- The patient's visual or motor skills are impaired to such that they cannot accurately draw up their own insulin (not applicable for pediatric patients), and
- There is no caregiver available to provide assistance, and
- Patient does not reside in a long-term care facility; and
- For requests for non-preferred pre-filled insulin pens, patient has documentation of a previous trial and therapy failure with a preferred pre-filled insulin pen within the same class (i.e. rapid, regular or basal).

³ http://www.iowamedicaidpdl.com/pa criteria

For pre-filled insulin pens where the requested insulin <u>is not</u> available in a vial, payment will be considered for a diagnosis of diabetes mellitus and FDA approved age in addition to the following criteria:

- Preferred pre-filled insulin pens Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal) or clinical rationale as to why the patient cannot use a preferred insulin agent, and
- Non-preferred pre-filled insulin pens Patient has documentation of a previous trial and therapy failure with a preferred insulin agent within the same class (i.e. rapid, regular or basal).
- Requests for Toujeo will require clinical rationale as to why the patient cannot use Lantus and patient must be using a minimum of 100 units of Lantus per day.

Lumacaftor/Ivacaftor (Orkambi):

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met:

- 1. Patient is six years of age or older; and
- 2. Has a diagnosis of cystic fibrosis; and
- 3. Patient is homozygous for the *F508del* mutation in the *CFTR* gene as confirmed by a FDA-cleared CF mutation test; and
- 4. Baseline liver function tests (AST/ALT) and bilirubin levels are provided and
- Baseline percent predicted forced expiratory volume (ppFEV1) is provided and is greater than or equal to (≥) 40; and
- 6. Prescriber is a CF specialist or pulmonologist.; and
- 7. 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 three months. Additional approvals will be granted for six months at a time if the following criteria are met:

- 1. Adherence to lumacaftor/ivacaftor therapy is confirmed; and
- Response to therapy is documented by prescriber (e.g., improved ppFEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and
- Liver function tests (AST/ALT) and bilirubin are assessed every three months during the first year of treatment and annually thereafter.

4. Point of Sale Billing Issues:

ProDUR Quantity Limits: The following quantity limit edits will be implemented effective *June 1, 2017*. A comprehensive list of all quantity limit edits appears on the Quantity Limit Chart⁴.

Drug Product	Quantity	Days Supply
Amlodipine-Olmesartan 5-20mg	30	30
Amlodipine-Olmesartan 5-40mg	30	30
Amlodipine-Olmesartan 10-20mg	30	30
Amlodipine-Olmesartan 10-40mg	30	30
Apriso 0.375mg	120	30
Azulfidine 500mg	240	30
Azulfidine EN 500mg	240	30
Canasa 1000mg	30	30
Colcrys 0.6mg	60	30
Delzicol 400mg	180	30
Dipentum 250mg	120	30
Giazo 1.1gm	180	30
Lialda 1.2gm	120	30
Mitigare 0.6mg	60	30
Pentasa 250mg	480	30
Pentasa 500mg	240	30
Rowasa, SfRowasa 4gm/60mL	1680	28
Uceris 9mg	30	30

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 lowa DUR website⁵ under the "Newsletters" link.

We encourage providers to go to the <u>PDL website</u>⁶ 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)

⁴ http://www.iowamedicaidpdl.com/billing_quantity_limits

⁵ http://www.iadur.org/

⁶ http://www.iowamedicaidpdl.com/