INFORMATIONAL LETTER NO.1579

DATE: November 25, 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: January 1, 2016

1. **Changes to the Preferred Drug List (PDL) Effective January 1, 2016.** Refer to complete PDL located at www.iowamedicaidpdl.com.

Preferred	Non-Preferred	Recommended	Non-Recommended
Adapalene Gel[1]	Absorica[1]	Norvir Tablets	Advate
Amlodipine Besylate-Benazepril	Actimmune	Xyntha	Farydak
Ampicillin & Sulbactam Sodium	Almotriptan[1]		Ixinity
Azelastine 0.1% Nasal Solution	Alosetron		
Benzoyl Peroxide 7% Cleanser[1]	Aptensio XR[1]		
Besivance	ASA/Dipyridamole		
Betaseron	Atralin[1]		
Carbamazepine ER Capsules	Bexarotene		
Clindamycin Palmitate Oral Solution	Betamethasone Dipropionate Lotion[1]		
Colistimethate Sodium	Bromocriptine 5mg Capsules		
Cosentyx[7]	Carbatrol[2]		
Desogest-ethin est tab 0.1-0.025/0.125-	Cleocin Oral Solution		

0.025/0.15- 0.025mg-mg			
Desogestrel-ethinyl estradiol (biphasic)	Climara		
Dexmethylphenidate[1]	Coly-Mycin-M		
Diltiazem ER, 24 hr CD & 24 hr ER	Cyclessa		
Drospirenone-ethinyl estradiol tab 3-0.03 mg	Daklinza[1]		
Enoxaparin Vials	Depo-Medrol		
Epiduo[1]	Dilantin Chewable Tablets & Oral Suspension[2]		
Estradiol Weekly Transdermal	Diprolene Lotion[1]		
Fluorometholone Ophthalmic	Duac[1]		
Fluticasone Cream & Ointment	Durezol		
Gianvi	Entresto		
Guanfacine ER[1]	Eurax		
Janumet XR[1]	Extavia		
Jentadueto[1]	Fluocinolone Topical[1]		
Linezolid[6]	Fluticasone Lotion[1]		
Lotemax	FML Forte		
Memantine[5]	Focalin[1]		
Methylin Oral Solution[1]	Glatopa		
Methylprednisolone Acetate	Ilevro		
Methylprednisolone Sodium Succinate	Kombiglyze[1]		
Metronidazole 0.75% Cream[1]	Lotrel		
Naratriptan[1]	Lovenox Vials		
Norethindrone-eth estradiol tab 0.5-35/1-35/0.5-35 mg-mcg	Methylphenidate ER 10mg & 20mg Tablets[1,4]		
Oxcarbazepine Oral Suspension	MetroCream[1]		
Permethrin 5% Cream	Mircette		
Phenytoin Chewable Tablets & Oral Suspension	Modicon		
Piperacillin & Tazobactam	Movantik[1]		

Prednisolone Acetate Ophthalmic	Moxeza		
Rebif	Namenda Tablets[5]		
Riluzole[1]	Ofloxacin Otic		
Rizatriptan ODT[1]	Onexton[1]		
Targretin	Onglyza[1]		
Technivie[1]	Orkambi[1]		
Tradjenta[1]	Oxytrol		
Trandolapril-Verapamil ER	Parnate		
Triamcinolone Lotion	Phenoxybenzamine		
	Praluent		
	Pyridostigmine ER		
	Relpax[1,4]		
	Repatha		
	Rexulti[3]		
	Rilutek[1]		
	Saphris[3]		
	Stiolto Respimat		
	Suprax Oral Suspension		
	Synjardy[1]		
	Tarka		
	Tetrabenazine		
	Tiazac		
	Toviaz		
	Tretinoin Topical[1]		
	Trianex[1]		
	Trileptal Oral Suspension[2]		
	Tri-Norinyl		
	Ultravate[1]		
	Unasyn		
	Vigamox		
	Yasmin		
	Yaz		
	Zarxio[1]		
	Zecuity[1]		
	Zovirax 5% Ointment		
	Zyvox[1]		

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

[6]Authorized Generic Only
[7]Preferred after step through Humira

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

- **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 12 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
  5. Baseline percent predicted forced expiratory volume ($ppFEV_1$) 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
  2. Response to therapy is documented by prescriber (e.g., improved $ppFEV_1$ from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and
  3. Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

- **Select Oncology Agents:**
  Prior authorization is required for select oncology agents. Patient must have a diagnosis that is indicated in the FDA approved package insert or the use is for an indication supported by the compendia (including National Comprehensive Cancer Network (NCCN) compendium level of evidence 1, 2A, or 2B). The following must be submitted with the prior authorization request: copies of medical records (i.e. diagnostic evaluations and recent chart notes), location of treatment (provider office, facility, home health, etc.) if medication requested is not an oral agent, the original prescription, and the most recent copies of related laboratory results. If criteria for coverage are met, initial authorization will be given for three (3) months. Additional authorizations will be considered for up to six (6) month intervals when criteria for coverage are met. Updates on disease progression must be provided with each renewal request. If disease progression is noted, therapy will not be continued unless otherwise justified.

- **Topical Antifungals for Onychomycosis:**
  Jublia® (efinaconazole) and Kerydin® (tavaborole) will be considered when the following criteria are met:
  1. Patient has a diagnosis of onychomycosis of the toenail(s) confirmed by a positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy (attach results) without dermatophytomas or lunula (matrix) involvement; and
  2. Patient is 18 years of age or older; and
  3. Patient has documentation of a complete trial and therapy failure or intolerance to oral terbinafine; and
  4. Patient has documentation of a complete trial and therapy failure or intolerance to ciclopirox 8% topical solution; and
  5. Patient is diabetic or immunosuppressed/immunocompromised.

  If the criteria for coverage are met, a one-time authorization of 48 weeks will be given. Requests for reoccurrence of infection will not be considered.

  The required trials may be overridden when documented evidence is provided that 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.

- **Alpha$_1$-Proteinase Inhibitor Enzymes:**
  Prior authorization is required for Alpha$_1$-Proteinase Inhibitor enzymes. Payment for a non-preferred Alpha$_1$-Proteinase Inhibitor enzyme will be authorized only for cases in which there is documentation of previous trial and therapy failure with a preferred agent. Payment will be considered for patients when the following is met:

  1. Patient has a diagnosis of congenital alpha$_1$-antitrypsin (AAT) deficiency; *with a pretreatment serum concentration of AAT less than 11µM/L or*
     - *80mg/dl if measured by radial immunodiffusion, or*
     - *50mg/dl if measured by nephelometry; and*
  2. *Patient has a high-risk AAT deficiency phenotype (PiZZ, PiZ (null), or PI (null)(null) or other phenotypes associated with serum AAT concentrations of less than 11µM/L, such as PiSZ or PiMZ); and*
  3. *Patient has documented progressive* panacinar emphysema *with a documented rate of decline in forced expiratory volume in 1 second (FEV_1); and*
  4. *Patient is 18 years of age or older; and*
  5. *Patient is currently a non-smoker; and*
  6. *Patient is currently on optimal supportive therapy for obstructive lung disease (inhaled bronchodilators, inhaled steroids); and*
  7. *Medication will be administered in the member's home by home health or in a long-term care facility.*

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. *Evidence of clinical efficacy, as documented by:*
    a. *An elevation of AAT levels (above protective threshold i.e., > 11µM/L); and*
    b. *A reduction in rate of deterioration of lung function as measured by a decrease in the FEV_1 rate of decline; and*
2. *Patient continues to be a non-smoker; and*
3. *Patient continues supportive therapy for obstructive lung disease.*

- **Biologicals for Ankylosing Spondylitis, Inflammatory Bowel Disease & Plaque Psoriasis:**

Patients initiating therapy with a biological agent must:

1. *Be screened for hepatitis B and C, patients with active hepatitis B will not be considered for coverage; and*
2. *Have not been treated for solid malignancies, nonmelanoma skin cancer, or lymphoproliferative malignancy within the last 5 years of starting or resuming treatment with a biological agent; and*
3. *Not have a diagnosis of congestive heart failure (CHF) that is New York Heart Association (NYHA) class III or IV and with an ejection fraction of 50% or less; and*
4. *Be screened for latent TB infection. Patients with latent TB will only be considered after one month of TB treatment while patients with active TB will only be considered upon completion of TB treatment.*

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

4. Point of Sale Billing Issues:

a. ProDUR Quantity Limits: The following quantity limit edits will be implemented effective *January 1, 2016*. 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
Fenofibrate 40mg Tablet	30	30
Premarin Vaginal Cream	30 grams	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.