



# Iowa Department of Human Services

## INFORMATIONAL LETTER NO.1943-MC-FFS

**DATE:** August 29, 2018

**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

**APPLIES TO:** Managed Care (MC), Fee-for-Service (FFS)

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

**RE:** Iowa Medicaid Pharmacy Program Changes

**EFFECTIVE:** October 1, 2018

- 1. Changes to the Preferred Drug List (PDL) Effective October 1, 2018.** Refer to the [PDL website](#)<sup>1</sup> to review the complete PDL.

Preferred	Non-Preferred	Recommended	Non-Recommended
Alprolix	Balcoltra	Erleada <sup>1</sup>	Yonsa <sup>1</sup>
Cimduo	Bonjesta	Norvir Oral Powder Packets	Zytiga <sup>1</sup>
Diglegis	Colesevelam	Xtandi <sup>1</sup>	
Neupogen Vials <sup>1,2</sup>	Gocovri <sup>1</sup>		
Norvir Tablets	Jynarque		
Prasugrel	Lonhala Magnair		
Rhopressa	Lucemyra		
Symfi Lo	Memantine ER <sup>1</sup>		
Welchol	Miglustat		
	Osmolex ER <sup>1</sup>		
	Palynziq		

<sup>1</sup> <http://www.iowamedicaidpdl.com/>

	Praziquantel		
	Ritonavir		
	Symdeko <sup>1</sup>		
	Tiagabine		
	Xhance		
	Zypitamag		

<sup>1</sup>Clinical PA Criteria Apply

<sup>2</sup>Preferred for members less than 18 years of age

**2. New Drug Prior Authorization Criteria-** See complete prior authorization criteria under the [Prior Authorization Criteria tab<sup>2</sup>](#).

▪ **Letemovir (Prevymis):**

Prior authorization is required for oral letemovir. Requests for intravenous letemovir should be directed to the member's medical benefit. Payment will be considered under the following conditions:

1. Medication is to be used for the prophylaxis of cytomegalovirus (CMV) infection and disease; and
2. Patient or donor is CMV-seropositive R+ (attach documentation); and
3. Patient has received an allogeneic hematopoietic stem cell transplant (HSCT) within the last 28 days (provide date patient received HSCT); and
4. Is prescribed by or in consultation with a hematologist, oncologist, infectious disease or transplant specialist; and
5. Patient is 18 years of age or older; and
6. Dose does not exceed:
  - a. 240mg once daily when co-administered with cyclosporine;
  - b. 480mg once daily; and
7. Patient must not be taking the following medications:
  - a. Pimozide; or
  - b. Ergot alkaloids (e.g., ergotamine, dihydroergotamine); or
  - c. Rifampin; or
  - d. Atorvastatin, lovastatin, pitavastatin, simvastatin, or repaglinide when co-administered with cyclosporine; and
8. Patient does not have severe (Child-Pugh Class C) hepatic impairment (provide score); and
9. Therapy duration will not exceed 100 days post-transplantation.

▪ **Tezacaftor/Ivacaftor (Symdeko):**

Prior authorization is required for Symdeko (tezacaftor/ivacaftor). 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

<sup>2</sup> [http://www.iowamedicaidpdl.com/pa\\_criteria](http://www.iowamedicaidpdl.com/pa_criteria)

3. Patient is homozygous for the F508del mutation or patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor (listed in the FDA approved labeling) based on *in vitro* data and/or clinical evidence.
4. Prescriber is a CF specialist or pulmonologist; and
5. Baseline liver function tests (AST/ALT) are provided.

If the criteria for coverage are met, an initial authorization will be given for 6 months. Additional approvals will be granted if the following criteria are met:

1. Adherence to tezacaftor/ivacaftor therapy is confirmed; and
2. Liver function tests (AST/ALT) are assessed every 3 months during the first year of treatment and annually thereafter.

▪ **Vesicular Monoamine Transporter (VMAT) 2 Inhibitors:**

Prior authorization is required for VMAT 2 inhibitors. Payment for non-preferred agents will be considered only for cases in which there is documentation of previous trial and therapy failure with a preferred agent (when applicable, based on diagnosis). Payment will be considered under the following conditions:

Tardive Dyskinesia (Ingrezza or Austedo)

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of tardive dyskinesia (TD) based on the presence of ALL of the following:
  - a. Involuntary athetoid or choreiform movements
  - b. Documentation or claims history of current or prior chronic use ( $\geq$  3 months or 1 month in patients  $\geq$  60 years old) of a dopamine receptor blocking agent (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)
  - c. Symptoms lasting longer than 4-8 weeks; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Prescriber has evaluated the patient's current medications for consideration of a dose reduction, withdrawal, or change of the dopamine receptor blocking agent causing the TD; and
5. Documentation of baseline AIMS (Abnormal Involuntary Movement Scale) Score (attach AIMS); and
6. For Ingrezza:
  - a. Will not be used concurrently with MAO inhibitors (e.g., isocarboxazid, phenelzine, rasagiline, safinamide, selegiline, tranlycypromine, etc.) or strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); and
  - b. Will not be used concurrently with other vesicular monoamine transporter 2 (VMAT2) inhibitors; and
  - c. Is prescribed within the FDA approved dosing; or

7. For Austedo:
  - a. Patient is not suicidal, or does not have untreated/inadequately treated depression;
  - b. Patient does not have hepatic impairment;
  - c. Will not be used concurrently with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
  - d. Patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed 36mg per day (18mg twice daily); and
  - e. Is prescribed within the FDA approved dosing.

If criteria for coverage are met, initial requests will be given for 3 months.

Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to meet the criteria for initial approval; and
2. Documentation of improvement in TD symptoms as evidenced by a reduction of AIMS score from baseline (attach current AIMS).

Chorea associated with Huntington's disease (Austedo or tetrabenazine)

1. Patient meets the FDA approved age; and
2. Patient has a diagnosis of Huntington's disease with chorea symptoms; and
3. Prescribed by or in consultation with a neurologist or psychiatrist; and
4. Is prescribed within the FDA approved dosing; and
5. Patient is not suicidal, or does not have untreated or inadequately treated depression; and
6. Patient does not have hepatic impairment; and
7. Patient does not have concurrent therapy with MAO inhibitors, reserpine, or other VMAT2 inhibitors; and
8. For tetrabenazine, patients requiring doses above 50mg per day have been tested and genotyped for the drug metabolizing enzyme CYP2D6 to determine if they are a poor metabolizer or extensive metabolizer; and
9. In patients that are taking a strong CYP2D6 inhibitor (e.g., quinidine, paroxetine, fluoxetine, bupropion) or are poor CYP2D6 metabolizers, the daily dose does not exceed the following:
  - a. Austedo - 36mg per day (18mg single dose) or
  - b. Tetrabenazine – 50mg per day (25mg single dose)

If criteria for coverage are met, initial requests will be given for 3 months.

Continuation of therapy will be considered when the following criteria are met:

1. Patient continues to meet the criteria for initial approval; and
2. Documentation of improvement in chorea symptoms is provided.

3. **Changes to Existing Prior Authorization Criteria - *Changes are italicized or stricken.*** See complete prior authorization criteria under the [Prior Authorization Criteria tab](#)<sup>3</sup>.

---

<sup>3</sup> [http://www.iowamedicaidpdl.com/pa\\_criteria](http://www.iowamedicaidpdl.com/pa_criteria)

- **Apremilast (Otezla):**

Prior authorization is required for apremilast (Otezla<sup>®</sup>). Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient has a diagnosis of active psoriatic arthritis ( $\geq 3$  swollen joints and  $\geq 3$  tender joints); or
3. Patient has a diagnosis of moderate to severe plaque psoriasis; and
4. ~~Prescribed by a rheumatologist or a dermatologist; and~~
5. Patient does not have severe renal impairment (CrCl  $< 30$  mL/min).

Psoriatic Arthritis

2. Patient has documentation of trials and therapy failures with two preferred biological agents *indicated* for psoriatic arthritis.

Plaque Psoriasis

2. Patient has documentation of trials and therapy failures with two preferred biological agents *indicated for plaque psoriasis*.

- **Biologicals for Arthritis:**

Prior authorization is required for biologicals used for arthritis. Request must adhere to all FDA approved labeling. Payment for non-preferred biologicals for arthritis will be considered only for cases in which there is documentation of previous trials and therapy failures with two preferred biological agents. Payment will be considered under the following conditions:

1. Patient has been screened for hepatitis B and C. *Patients with evidence of active hepatitis B infection (hepatitis surface antigen positive > 6 months) must have documentation they are receiving or have received effective antiviral treatment; and*
3. Patient has a diagnosis of rheumatoid arthritis (RA):  
A trial and inadequate response to two preferred disease modifying antirheumatic drugs (DMARD) used concurrently. The combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, or leflunomide, ~~or minocycline~~).

- **Chronic Pain Syndromes:**

A prior authorization is required for pregabalin (Lyrica<sup>®</sup>) and milnacipran (Savella<sup>™</sup>). These drugs will be considered for their FDA indications(s) and other conditions as listed in the compendia. Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. ~~There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization.~~ *Requests for renewal must include an updated opioid treatment plan and documentation of improvement in symptoms and quality of life.* Requests for non-preferred brand name drugs, when there is a preferred A-rated bioequivalent

generic product available, are also subject to the Selected Brand Name prior authorization criteria and must be included with this request. Payment will be considered under the following conditions:

3. A diagnosis of diabetic peripheral neuropathy (duloxetine and Lyrica<sup>®</sup>)  
A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or duloxetine or topical lidocaine.
5. A diagnosis of neuropathic pain associated with spinal cord injury (Lyrica<sup>®</sup>)

▪ **CNS Stimulants and Atomoxetine:**

Prior authorization (PA) is required for CNS stimulants and atomoxetine for patients 21 years of age or older. Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. \*If a non-preferred long-acting medication is requested, a trial with the preferred immediate-release and extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required. *Requests will be considered for a FDA approved age for the submitted diagnosis.* Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website. Payment for CNS stimulants and atomoxetine will be considered under the following conditions:

1. ~~Attention Deficit Disorder (ADD)~~ or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more **current** environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms *improvement in symptoms from baseline* will be required for renewals or patients newly eligible that are established on medication to treat ~~ADD~~/ADHD. *Adults (≥ 21 years of age) are limited to the use of long-acting agents only. If a supplemental dose with a short-acting agent is needed for an adult in the mid to late afternoon, requests will be considered under the following circumstances: the dose of the long-acting agent has been optimized, documentation is provided a short-acting agent of the same chemical entity is medically necessary (e.g. employed during the day with school in the evening), and will be limited to one unit dose per day.*

▪ **Janus Kinase Inhibitors:**

Prior authorization is required for Janus kinase (JAK) inhibitors. Payment will be considered when the following conditions are met:

1. Patient *meets the FDA approved age*; and
7. Patient *does not have an active, serious infection, including localized infections;*  
*and*
8. *Medication will not be given concurrently with live vaccines; and*
9. *Follows FDA approved dosing based on indication; and*
10. Patient has a diagnosis of:
  - a. Moderate to severe rheumatoid arthritis; *with*
    - i. A documented trial and inadequate response to two preferred oral disease modifying antirheumatic drugs (DMARD) used concurrently. The

combination must include methotrexate plus another preferred oral DMARD (hydroxychloroquine, sulfasalazine, or leflunomide, **or minocycline**); and

ii. A documented trial and inadequate response to two preferred biological DMARDs; OR

b. *Psoriatic arthritis with*

i. *A documented trial and inadequate response to therapy with the preferred oral DMARD, methotrexate (leflunomide or sulfasalazine may be used if methotrexate is contraindicated); and*

ii. *Documented trial and therapy failure with two preferred biological agents used for psoriatic arthritis.*

▪ **Methotrexate Injection:**

Prior authorization is required for non-preferred methotrexate injection. Payment will be considered under the following conditions:

1. Diagnosis of severe, active rheumatoid arthritis (RA) or polyarticular juvenile idiopathic arthritis (pJIA) and ALL of the following:

c. Patient has a documented trial and therapy failure or intolerance with at least one other non-biologic DMARD (hydroxychloroquine, leflunomide, **minocycline** or sulfasalazine); and

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

**ProDUR Quantity Limits:** The following quantity limit edits will be implemented effective *October 1, 2018*. A comprehensive list of all quantity limit edits appears on the [Quantity Limit Chart](#)<sup>4</sup>.

Drug Product	Quantity	Days Supply
Cimduo	30	30
Norvir 100mg	360	30
Symfi Lo	30	30
Welchol 625mg	180	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.

<sup>4</sup> [http://www.iowamedicaidpdl.com/billing\\_quantity\\_limits](http://www.iowamedicaidpdl.com/billing_quantity_limits)

6. **DUR Update:** The latest issue of the Drug Utilization Review (DUR) Digest is located at the [Iowa DUR website](#)<sup>5</sup> under the “Newsletters” link.

We encourage providers to go to the [PDL website](#)<sup>6</sup> 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](mailto:info@iowamedicaidpdl.com).

---

<sup>5</sup> <http://www.iadur.org/>

<sup>6</sup> <http://www.iowamedicaidpdl.com/>