Department of HUMAN SERVICES

INFORMATIONAL LETTER NO. 2074-MC-FFS

DATE: November 27, 2019

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, Physician Assistants

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

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

RE: January 2020 Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: January 1, 2020

1. **Changes to the Preferred Drug List (PDL) Effective January 1, 2020.** Refer to the PDL website[1] to review the complete PDL.

Preferred	**Non-Preferred**	**Non-Recommended**
Afstyla	Abilify Maintena[2,6]	Inrebic[1]
Ambrisentan[1]	Adhansia XR[1]	Kaletra
Buprenorphine Tabs[1]	Ampyra[1]	Nubeqa[1]
Combivent Respimat	Apokyn	Piqray[1]
Complera	Aptensio XR[1]	Rozlytrek[1]
Cyproheptadine	Baqsimi[1]	Turalio[1]
Dalfampridine ER[1]	Clocortolone[1]	Xpovio[1]
Danazol	Concerta[1]	Zidovudine
Delstrigo	Daytrana[1,6]	
Dexmethylphenidate ER[1]	Diacomit	
Dextroamphetamine ER[1]	Doxylamine/ Pyridoxine	
Dextroamphetamine Tabs[1]	Elidel[1]	

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

Efavirenz	Ezallor Sprinkle Caps[1]	
Epogen[1]	Febuxostat[1]	
Fluticasone and Salmeterol	Fiasp FlexTouch[1]	
Fycompa	Fiasp Vials	
Humulin R U-500	Firazyr[1]	
Humulin R U-500 KwikPen	Focalin XR[1]	
Icatibant[3]	Granix[1]	
Ingrezza[1]	Halcinonide[1]	
Insulin Lispro	Humalog Vials	
Insulin Lispro KwikPen	Humulin 70/30	
Kogenate FS	Humulin N	
Lidocaine 5% Patch[1]	Humulin R	
Linzess 145mcg&290mcg[1]	Jornay PM[1]	
Methylphenidate ER Tabs Osmotic[4]	Katerzia	
Methylphenidate Oral Solution[1]	Letairis[1]	
Neupogen Syringes[1]	Meperidine Tabs[1]	
Nuwiq	Methitest[1]	
Pimecrolimus Cream[5]	Naproxen Oral Suspension[1]	
Pregabalin[1]	Nayzilam	
Retacrit[1]	Norvir	
Ritonavir	Nucala Auto-Injector & Prefilled Syringe[1]	
Sevelamer Carbonate Tabs	Nuzyra	
Solifenacin	Oxervate	
Stiolto Respimat	Pennsaid[1]	
Tadalafil[1]	Praluent[1]	
Takhzyro[3]	Procrit[1]	
Topiramate Sprinkle Caps	Ramelteon[1]	
Utibron Neohaler	Renagel	
Xarelto 2.5mg Tabs	Rinvoq[1]	
	Ruzurgi	
	Sildenafil Oral Suspension[1]	
	Sklice	
	Slynd	

	Sunosi[1]	
	Sustiva	
	Symjepi	
	Synjardy XR[1]	
	Tosymra[1]	
	Tresiba FlexTouch[1]	
	Tresiba Vials	
	Vesicare	
	Viberzi[1]	
	Vyndamax	
	Xigduo XR[1]	
	Zyprexa Relprevv[2]	

[1]Clinical PA Criteria Apply
[2]Step 3
[3]PA for diagnosis confirmation
[4]PA required, labeler 10147 Preferred
[5]PA required, labeler 68682 Preferred
[6]Grandfather Existing Users

2. **Pharmacy Benefit Policy Changes:** Effective January 1, 2020, coverage for the drugs listed below will be removed under the pharmacy benefit. Coverage will continue, however, to be available through the medical benefit for Bivigam, Carimune Nanofiltered, Cytogam, Ephedrine Sulfate, Fentanyl Injection Solution, Flebogamma, Gammagard S/D, Gammaplex, Hectorol, Hepagam B, Herceptin Hylecta, Hydromorphone Injection Solution, Nalbuphine Injection Solution, Octagam, and Privigen.

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

- **Aripiprazole Tablets with Sensor (Abilify MyCite):**
  Prior authorization is required for aripiprazole tablets with sensor (Abilify MyCite). Payment will be considered under the following conditions:
  1. Patient has a diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder; and
  2. Patient meets the FDA approved age for use of the Abilify MyCite device; and
  3. Dosing follows the FDA approved dose for the submitted diagnosis; and
  4. Documentation of patient adherence to generic aripiprazole tablets is less than 80% within the past six months (prescriber must provide

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

documentation of the previous six months' worth of pharmacy claims for aripiprazole documenting non-adherence); and

5. Documentation all the following strategies to improve patient adherence have been tried without success:
    a. Utilization of a pill box.
    b. Utilization of a reminder device (e.g., alarm, application, or text reminder).
    c. Involving family members or friends to assist.
    d. Coordinating timing of dose with dosing of another daily medication; and
6. Documentation of a trial and intolerance to a preferred long-acting aripiprazole injectable agent; and
7. Prescriber agrees to track and document adherence of Abilify MyCite through the web-based portal for health care providers and transition member to generic aripiprazole tablets after a maximum of four months use of Abilify MyCite. Initial approvals will be given for one month. Prescriber must review member adherence in the web-based portal and document adherence for additional consideration. If non-adherence continues, prescriber must document a plan to improve adherence. If adherence is improved, consideration to switch member to generic aripiprazole tablets must be considered. Note, the ability of the Abilify MyCite to improve patient compliance has not been established.
8. Requests will not be considered for patients in long-term care facilities.
9. A once per lifetime approval will be allowed.

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

- **Ospemifene (Osphena):**

Prior authorization is required for ospemifene (Osphena). Requests for a diagnosis of moderate to severe dyspareunia are considered not medically necessary and will be denied. Payment will be considered under the following conditions:

1. Patient is a post-menopausal woman with a diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy; and
2. Patient has documentation of an adequate trial and therapy failure with a preferred vaginal estrogen agent; and
3. Patient does not have any contraindications to ospemifene as listed in the FDA approved label; and
4. Will not be used with estrogens, estrogen agonist/antagonists, fluconazole, or rifampin; and
5. Patient does not have severe hepatic impairment (Child-Pugh Class C); and

6. Patient will be evaluated periodically as clinically appropriate to determine if treatment is still necessary as ospemifene should be used for the shortest duration consistent with treatment goals and risks for the individual woman; and
7. Dose does not exceed the FDA approved dose.

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

Initial requests will be approved for three months. Additional prior authorizations will be considered upon documentation of clinical response to therapy.

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

- **CGRP Inhibitors:**
  Prior authorization is required for CGRP Inhibitors. Payment will be considered for *a FDA approved or compendia indicated diagnosis under the following conditions*:
  1. Patient has *one of the following* ~~a~~ *diagnoses*:
     a. Chronic Migraine*, defined as:*
        i. ≥ 15 headache days per month for a minimum of 3 months; and
        ii. ≥ 8 migraine headaches days per month for a minimum of 3 months; or
     b. Episodic Migraine*, defined as:*
        i. 4 to 14 migraine days per month for a minimum of 3 months; *or*
     c. *Episodic Cluster Headache, defined as:*
        i. *Occurring with a frequency between one attack every other day and 8 attacks per day; and*
        ii. *With at least 2 cluster periods lasting 7 days to one year (when untreated) and separated by pain-free remission periods of ≥3 months; and*
        iii. *Patient does not have chronic cluster headache (attacks occurring without a remission period, or with remissions lasting <3 months, for at least 1 year); and*
  2. Patient meets the FDA approved age *for submitted diagnosis*; and

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

3. Patient has been evaluated for and does not have medication overuse headache; and
4. *For Episodic and Chronic Migraine, patient* has documentation of three trials and therapy failures, of at least 3 months per agent, at a maximally tolerated dose with a minimum of two different migraine prophylaxis drug classes (i.e. anticonvulsants [divalproex, valproate, topiramate], beta blockers [atenolol, metoprolol, nadolol, propranolol, timolol], antidepressants [amitriptyline, venlafaxine]); *or;*
5. *For Episodic Cluster Headache, patient has documentation of*
    a. *A previous trial and therapy failure at an adequate dose with glucocorticoids (prednisone 30mg per day or dexamethasone 8mg BID) started promptly at the start of a cluster period. Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamine, lidocaine) at least once daily for at least two days per week after the first full week of adequately dosed steroid therapy; and*
    b. *A previous trial and therapy failure at an adequate dose of verapamil for at least 3 weeks (total daily dose of 480 mg to 960 mg). Failure is defined as the need to use acute/abortive medications (oxygen, triptans, ergotamines, lidocaine) at least once daily for at least two days per week after three weeks of adequately dosed verapamil therapy.*
6. The requested dose does not exceed the maximum FDA labeled dose *for the submitted diagnosis*; and
7. Lost, stolen, or destroyed medication replacement requests will not be authorized.

Initial requests will be approved for 3 months. Additional prior authorizations will be considered upon documentation of clinical response to therapy (i.e., reduced migraine frequency, reduced migraine headache days*, reduced weekly cluster headache attack frequency*).

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

- **Multiple Sclerosis Agents (Oral):**
  For patients initiating therapy with a preferred oral medication, a manual prior authorization is not required if a preferred injectable interferon or non-interferon agent is found in the member's pharmacy claims history in the previous 12 months. If a preferred injectable agent is not found in the member's pharmacy claims, documentation of the following must be provided:

3. *Request is for FDA approved dosing; and*

For patients initiating therapy with cladribine (Mavenclad):

1. *Patient's current weight is provided; and*
2. *Patient does not have a current malignancy and patient is up to date on all age appropriate malignancy screening; and*
3. *Pregnancy has been excluded in females of reproductive potential; and*
4. *Women and men of reproductive potential must use effective contraception during treatment and for 6 months after the last dose in each treatment course; and*
5. *Women must not intend to breastfeed while being treated and for 10 days after the last dose; and*
6. *Patient does not have HIV infection; and*
7. *Patient does not have active chronic infection (e.g. hepatitis or tuberculosis); and*
8. *No more than two yearly treatment courses (i.e. two treatment courses consisting of two treatment cycles) will be considered.*

For patients initiating therapy on siponimod (Mayzent):

1. *Patient does not have a CYP2C9*3/*3 genotype; and*
2. *Patient does not have a recent (within past 6 months) occurrence of myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure; and*
3. *Patient does not have a presence of Mobitz Type II 2nd degree, 3rd degree AV block or sick sinus syndrome, unless the patient has a functioning pacemaker.*

5. Point of Sale Billing Issues:

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
Gabapentin 100mg	180	30
Gabapentin 300mg	270	30
Gabapentin 400mg	270	30
Gabapentin 600mg	180	30
Gabapentin 800mg	135	30
Gabapentin 50mg/mL	2160mL	30
Symjepi	2 units	30

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

b. **15 Day Initial Prescription Supply Limit List:** Effective **January 1, 2020,** the initial 15 day prescription limit list will be updated. Please refer to the updated list located at www.iowamedicaidpdl.com under the Preferred Drug List link.

6. **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 for the member's plan to request an override for the non-preferred brand name drug with a recent status change.

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

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

[5] http://www.iadur.org/
[6] http://www.iowamedicaidpdl.com/