Iowa Medicaid
IOWA HHS

INFORMATIONAL LETTER NO. 2370-MC-FFS

DATE: August 29, 2022

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, Indian Health Service, Maternal Health Centers, Certified Nurse Midwife, Community Mental Health, Family Planning, Residential Care Facilities, Intermediate Care Facilities for Individuals with Intellectual Disability (ICF/ID) State and Community-Based ICF/ID Providers, and Physician Assistants

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

FROM: Iowa Department of Health and Human Services (HHS), Iowa Medicaid

RE: October 2022 Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: October 1, 2022

1. Changes to the preferred drug list (PDL) effective October 1, 2022. Refer to the PDL website[1] to review the complete PDL.

Preferred	Non-Preferred	Recommended	Non-Recommended
Lacosamide	Apomorphine	Besremi[1]	Vonjo[1]
Potassium Iodide Oral Solution	Baclofen Oral Solution[1]		
	Bexarotene Gel		
	Cibinqo[1]		
	Cyclobenzaprine Caps[1]		
	Cyclosporine Ophth Emulsion		
	Dartisla[1]		

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

	Diclofenac Potassium Caps[1]		
	Epsolay[1]		
	Fleqsuvy[1]		
	Fluticasone Propionate HFA		
	Fluticasone/ Vilanterol		
	Ibsrela[1]		
	Invega Hafyera[3]		
	Isosorbide/ Hydralazine		
	Lenalidomide[1]		
	Levamlodipine		
	Lyvispah[1]		
	Maraviroc		
	Metformin Oral Soln		
	Nalmefene Injection		
	Norliqva[1]		
	Pirfenidone[1]		
	Pyrukynd		
	Releuko[1]		
	Seglentis[1]		
	Tarpeyo		
	Tlando[1]		
	Tramadol Oral Soln[1]		
	Twyneo[1]		
	Vijoice		
	Vimpat[2]		
	Zimhi		

[1] Clinical prior authorization (PA) criteria apply

[2] Grandfather established users with seizure diagnosis

[3] Step 3

2. New Drug PA Criteria – See complete PA criteria under the Prior Authorization Criteria tab[2].

- Ophthalmic Agents for Presbyopia:
  PA is required for ophthalmic agents indicated for presbyopia. Requests will be considered when the patient has an Food and Drug Administration (FDA)-approved or compendia indication for the requested drug. Payment for a non-preferred agent will be considered when there is documentation of a previous trial and therapy failure with a preferred agent. Payment will be considered under the following conditions:
  1. Request adheres to all FDA-approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
  2. Patient has a documented diagnosis of presbyopia; and
  3. Patient is aged 40 to 55 years old at start of therapy; and
  4. Is prescribed by or in consultation with an ophthalmologist or optometrist; and
  5. Patient has documentation of a therapeutic failure with corrective lenses (eyeglasses or contact lenses), unless contraindicated or clinically significant intolerance.

  If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered under the following conditions:
  1. Patient has a documented improvement in presbyopia defined as the patient gained 3 lines or more in mesopic, high contrast, binocular distance corrected near visual acuity (DCNVA), without losing more than 1 line (5 letters) of corrected distance visual acuity (CDVA); and
  2. Patient is not experiencing adverse effects from the drug.

- Tralokinumab-ldrm (Adbry):
  PA is required for tralokinumab-ldrm (Adbry). Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA-approved or compendia-indicated diagnosis for the requested drug when the following conditions are met:
  1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
  2. Patient has a diagnosis of moderate to severe atopic dermatitis; and
  3. Is prescribed by or in consultation with a dermatologist; and

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

4. Patient has failed to respond to good skin care and regular use of emollients, and
5. Patient has documentation of an adequate trial and therapy failure with at least one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and
6. Patient has documentation of a previous trial and therapy failure with a preferred topical immunomodulator for a minimum of 4 weeks; and
7. Patient has documentation of a previous trial and therapy failure with cyclosporine or azathioprine; and
8. Patient will continue with skin care regimen and regular use of emollients.

If criteria for coverage are met, initial authorization will be given for 16 weeks to assess the response to treatment. Request for continuation of therapy will require documentation of a positive response to therapy and documentation patient will continue with skin care regimen and regular use of emollients.

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 PA Criteria – *Changes are italicized or stricken.* See complete PA criteria under the Prior Authorization Criteria tab[3].

- Biologicals for Hidradenitis Suppurativa (HS):
  PA is required for biologicals FDA-approved *or compendia-indicated* for the treatment of HS. *Payment for non-preferred biologic agents will be considered only for cases in which there is documentation of a previous trial and therapy failure with a preferred biologic agent.* Patients initiating therapy with a biological agent must:

  Payment will be considered under the following conditions:
  1. *Request adheres to all FDA-approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
  3. Patient is 18 years of age or older; and
  5. Patient has documentation of adequate trials and therapy failures with the following:
     a. Daily treatment with topical clindamycin;
     b. Oral clindamycin plus rifampin;
     c. Maintenance therapy with *a preferred* tetracycline.

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

- Crisaborole (Eucrisa):
  PA is required for Eucrisa (crisaborole). Payment will be considered when *patient has an FDA-approved or compendia indication for the requested drug when* the following criteria are met:
  1. *Request adheres to all FDA-approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
  3. Patient is within the FDA-labeled age; and
  5. Patient has documentation of an adequate trial and therapy failure with *one* two preferred medium to high potency topical corticosteroids for a minimum of 2 consecutive weeks; and

- Extended-Release Formulations:
  Payment for a non-preferred extended release formulation will be considered *for an FDA-approved or compendia-indicated diagnosis for the requested drug* when the following conditions are met:
  1. *Request adheres to all FDA-approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*

- Hepatitis C Treatments, Direct Acting Antivirals:
  PA is required for hepatitis C *direct-acting antivirals (DAA)*. 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:
  6. Patient's prior *HCV DAA* treatment history is provided (treatment naïve or treatment experienced); and
  8. Patient has *been evaluated to determine the patient's readiness for HCV treatment with scales or assessment tools, such as the SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools*[4] *and the Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C)*[5]*; and*
  9. *Patient has been educated on the importance of abstinence from IV drug use and alcohol use, the importance of compliance with HCV treatment, and how to prevent HCV transmission. If patient is currently using IV drugs and/or alcohol, recommend the patient participate in alcohol and/or substance abuse counseling* and abstained from

[4] Screening and Assessment Tools Chart | National Institute on Drug Abuse (NIDA) (nih.gov)
[5] PREP-C » Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (prepc.org)

the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and

11. *DAAs approved for pediatric use will be considered for those under the age of 18 when used in accordance with current American Association for the Study of Liver Diseases (AASLD) guidelines including for indication and age; and*
13. Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the *DAA; and*
19. The 72-hour emergency supply rule does not apply to *DAAs*.

Only one treatment attempt will be allowed per calendar year, regardless of compliance.

Requests for treatment-experienced patients (with previous DAA) will be considered under the following conditions:

1. *Patient must meet all criteria for treatment approval above; and*
2. *Patients who previously achieved SVR that have HCV recurrence due to IV drug use must have documentation that the patient has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment, and can be managed as an initial infection; and*
3. *The requested therapy is FDA-approved as therapy for treatment-experienced patients and follows current AASLD guidelines; and*
4. *Patient has not been previously treated with and failed the requested DAA therapy; and*
5. *Documentation is provided patient has a documented presence of detectable HCV RNA at least 12 weeks after completing previous DAA treatment.*

- Janus Kinase Inhibitors:
  PA is required for Janus kinase (JAK) inhibitors. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agent(s) would be medically contraindicated. Payment will be considered for an FDA-approved or compendia-indicated diagnosis *for the requested drug* when the following conditions are met:
  1. Patient meets the FDA-approved age for indication; and
  2. Patient is not using or planning to use a JAK inhibitor in combination with other JAK inhibitors, *biological therapies,* or potent immunosuppressants (azathioprine or cyclosporine); and
  3. *Request adheres to all FDA-approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
  4. Has been tested for latent tuberculosis prior to initiating therapy and will be monitored for active tuberculosis during treatment; and

5. Recommended laboratory monitoring of lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids are being conducted according to the manufacturer labeling; and
6. Patient does not have a history of malignancy, except for those successfully treated for non-melanoma skin cancer (NMSC); and
7. Patient is not at an increased risk of gastrointestinal perforation; and
8. Patient does not have an active, serious infection, including localized infections; and
9. Medication will not be given concurrently with live vaccines; and
10. Follows FDA-approved dosing based on indication; and
11. Patient has a diagnosis of:
    e. *Ankylosing spondylitis (tofacitinib, upadacitinib); with*
        i. *A documented trial and inadequate response to at least two preferred non-steroidal anti-inflammatories (NSAIDs) at a maximally tolerated dose for a minimum of at least one month; and*
        ii. *A documented trial and inadequate response with at least one preferred TNF inhibitor; OR*
    f. *Atopic dermatitis; with*
        i. *Documentation patient has failed to respond to good skin care and regular use of emollients; and*
        ii. *A documented adequate trial and therapy failure with one preferred medium to high potency topical corticosteroid for a minimum of 2 consecutive weeks; and*
        iii. *A documented trial and therapy failure with a topical immunomodulator for a minimum of 4 weeks; and*
        iv. *For mild to moderate atopic dermatitis (ruxolitinib)*
            a. *A documented trial and therapy failure with crisaborole; and*
            b. *Affected area is less than 20% of body surface area (BSA); and*
            c. *Patient has been instructed to use no more than 60 grams of topical ruxolitinib per week; or*
        v. *For moderate to severe atopic dermatitis (abrocitinib, upadacitinib):*
            a. *A documented trial and therapy failure with cyclosporine or azathioprine; and*
            b. *Requests for upadacitinib for pediatric patients 12 to less than 18 years of age must include the patient's weight in kg.*

- Non-Preferred Drug:
  PA is required for non-preferred drugs as specified on the Iowa Medicaid Preferred Drug List. Payment for a non-preferred medication will be *considered for an FDA-approved or compendia-indicated diagnosis* only for cases in which there is documentation of previous trial and therapy failure with the preferred agent*(s)*,

unless evidence is provided that use of these agents would be medically contraindicated. *Request must adhere to all FDA-approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations.*

- Tasimelteon (Hetlioz):
  PA is required for tasimelteon (Hetlioz®). *Requests will be considered when patient has an FDA-approved or compendia indication for the requested drug.* Payment will be considered under the following conditions:
  1. *Request adheres to all FDA-approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and*
  2. Patient has a *documented* diagnosis of:
     a. Non-24-Hour Sleep-Wake Disorder (Non-24), as confirmed by a sleep specialist; and
        i. Patient is 18 years of age or older; and
        ii. Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and
        iii. Patient has a documented trial and therapy failure with ramelteon (Rozerem®)*; or*
     b. *Sleep disturbances in Smith-Magenis Syndrome (SMS); and*
        i. *Documentation of confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is provided (attach results); and*
        ii. *Patient has a documented trial and therapy failure with at least one other medication used for sleep disturbances; and*
  3. *Is prescribed by, or in consultation with a physician who specializes in the treatment of sleep disorders; and*
  4. *Will not be used concurrently with other sleep medications.*

If criteria for coverage are met, initial requests will be given for 3 months. Requests for continuation of therapy will be considered *under the following conditions:*

1. *Patient's use of tasimelteon (Hetlioz®) has been continuous without gaps in treatment;* when the patient has received 3 months of continuous therapy and
2. *Documentation* patient has *experienced a positive clinical response to therapy* with tasimelteon (Hetlioz®), such as entrainment, significant increases in nighttime sleep, significant decreases in daytime sleep, *and/or nighttime sleep quality*.

4. Point of Sale Billing Updates:

   - 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[6].

Drug Product	Quantity	Days' Supply
Cibinqo 50 MG	30	30
Cibinqo 100 MG	30	30
Cibinqo 200 MG	30	30
Olumiant 1 MG	30	30
Olumiant 2 MG	30	30
Opzelura 1.5% Cream	240 GMS	30
ProAir HFA 8.5 GMS (albuterol)	2 inhalers (17 GMS)	30
ProAir Digihaler (albuterol)	2 inhalers	30
ProAir Respiclick (albuterol)	2 inahlers	30
Proventil HFA 6.7 GMS (albuterol)	2 inhalers (13.4 GMS)	30
Quetiapine 150MG	90	30
Rinvoq 15 MG	30	30
Rinvoq 30 MG	30	30
Rinvoq 45 MG	28	28
Triazolam 0.125 MG	30	30
Triazolam 0.25 MG	60	30
Ventolin HFA 18 GMS (albuterol)	2 inhalers (36 GMS)	30
Vuity 1.25% Ophth Soln	2.5 ML	30
Xeljanz 5 MG	60	30
Xeljanz 10 MG	60	30
Xeljanz XR 11 MG	30	30
Xeljanx XR 22 MG	30	30
Xopenex HFA 15 GMS (levalbuterol)	2 inhalers (30 GMS)	30

   - ProDUR Duplicate Therapy: Members 18 years of age and older will be limited to two chemically distinct antipsychotics. PA is required to exceed this limit and may be submitted on the Duplicate Therapy Edit Override PA form[7] located on the PDL website[8].

[6] http://www.iowamedicaidpdl.com/billing_quantity_limits
[7] http://iowamedicaidpdl.com/sites/default/files/ghs-files/prior-authorization-forms/2017-02-07/duplicate-therapy-edit-pa-form-npi-mar-17.pdf
[8] http://iowamedicaidpdl.com/

- 2022-2023 RSV Season:
  1. Start date – Approval periods will begin November 1, 2022, and will be considered through March 31, 2023, and as medically necessary based on RSV prevalence.
  2. Doses – A maximum of five (5) doses will be allowed per member per RSV season. No allowances will be made for a sixth dose, regardless of start date.
  3. PA submission – Requests may be submitted beginning October 10, 2022, for a therapy start date of November 1, 2022, using the Palivizumab (Synagis) PA Form[9].

- Off-Season RSV Surge:
  1. PA requests will be considered on a month to month basis for off-cycle surge for any child who fits the American Academy of Pediatrics (AAP) criteria and has not "aged out" of the criteria, and
  2. The National Respiratory and Enteric Virus Surveillance System (NREVSS) data reflects polymerase chain reaction (PCR) testing of >3% and more than 100 tests were done in that week, and
  3. The off-season doses will not count towards the normal maximum of five (5) doses for the 2022-2023 season; this is considered a separate season.

5. DUR Update: The latest issue of the Drug Utilization Review (DUR) Digest is located at the Iowa DUR website[10] under the "Newsletters" link.

We encourage providers to go to the PDL website[11] to view all recent changes to the PDL. If you have questions, please contact the Pharmacy Prior Authorization Helpdesk at 1-877-776-1567, locally in Des Moines at 515-256-4607, or by e-mail at info@iowamedicaidpdl.com.

[9] http://iowamedicaidpdl.com/sites/default/files/ghs-files/prior-authorization-forms/2014-10-15/pavilizumab-pa-form-npi-oct2014accepted.pdf
[10] http://www.iadur.org/
[11] http://www.iowamedicaidpdl.com/