Department of HUMAN SERVICES

INFORMATIONAL LETTER NO. 2352-MC-FFS

DATE: June 22, 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 (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, and Physician Assistants

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

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

RE: August 2022 Iowa Medicaid Pharmacy Program Changes

EFFECTIVE: August 1, 2022

1. **New Drug Prior Authorization (PA) Criteria –** See complete PA criteria under the Prior Authorization Criteria tab[1].

   - **Finerenone (Kerendia):**
     PA is required for finerenone (Kerendia). Payment will be considered under the following conditions:
     1. Request adheres to all Food and Drug Administration (FDA)-approved labeling, including age, dosing, contraindications, warnings and precautions, and drug interactions; and
     2. Patient has a diagnosis of chronic kidney disease (CKD) associated with Type 2 Diabetes (T2D); and
     3. Patient is currently receiving a maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB); and
     4. Patient is currently receiving a maximally tolerated dose of a sodium-glucose co-transporter 2 (SGLT2) inhibitor indicated to reduce the risk of

[1] Prior Authorization Criteria | Iowa Medicaid PDL

sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease [i.e., dapagliflozin (Farxiga)]; and

5. Patient has the following baseline tests prior to initiation of treatment with finerenone:
    a. Serum potassium is ≤ 5.0 mEq/L; and
    b. Estimated glomerular filtration rate (eGFR) is ≥ 25 mL/min/1.73m^2; and
    c. Urine albumin to creatinine ration (UACR) is ≥ 30 mg/g.

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

Initial authorizations will be approved for six months. Additional PAs will be considered with the following documentation:

1. Patient's serum potassium is < 5.5 mEq/L; and
2. Patient's eGFR is ≥ 25 mL/min/1.73m^2; and
3. Patient remains on a maximally tolerated dose of an ACEi or ARB; and
4. Patient remains on a maximally tolerated dose of an SGLT2 inhibitor.

- **Odevixibat (Bylvay):**

PA is required for odevixibat (Bylvay). Payment will be considered under the following conditions:

1. Request adheres to all FDA-approved labeling including age, dosing, contraindications, warnings and precautions, and drug interactions; and
2. Patient has a diagnosis of genetically confirmed progressive familial intrahepatic cholestasis (PFIC) type 1 or type 2; and
3. Genetic testing does not indicate PFIC type 2 with ABCB 11 variants encoding for nonfunction or absence of bile salt export pump protein (BSEP-3); and
4. Patient has moderate to severe pruritus associated with PFIC; and
5. Patient's current weight in kg is provided; and
6. Is prescribed by or in consultation with a hepatologist or gastroenterologist.

Initial authorizations will be approved for 3 months for initial treatment or after a dose increase. Additional authorizations will be considered when the following criteria are met:

1. Patient's current weight in kg is provided; and
2. Documentation is provided the patient has responded to therapy and pruritis has improved. If there is no improvement in pruritus after 3 months of treatment with the maximum 120 mcg/kg/day dose, further approval of odevixibat will not be granted.

- **Pegcetacoplan (Empaveli):**
  PA is required for pegcetacoplan (Empaveli). Payment will be considered under the following conditions:
  1. Request adheres to all FDA-approved labeling including age, dosing, contraindications, and warnings and precautions; and
  2. Patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); and
  3. Flow cytometry shows detectable glycosylphosphatidylinositol (GPI)-deficient hematopoietic clones or ≥ 10% PNH cells; and
  4. History of at least one red blood cell transfusion in the previous 12 months; and
  5. Documentation of hemoglobin < 10.5 g/dL; and
  6. Is not prescribed concurrently with eculizumab (Soliris) or ravulizumab (Ultomiris), unless the patient is in a 4 week period of cross-titration between eculizumab (Soliris) and pegcetacoplan (Empaveli); and
  7. Is prescribed by or in consultation with a hematologist; and
  8. Medication will be administered in the member's home; and
  9. Member or member's care giver has been properly trained in subcutaneous infusion and prescriber has determined home administration is appropriate.

  Initial authorizations will be approved for 4 weeks if within cross-titration period with eculizumab (Soliris) to verify eculizumab has been discontinued, or for 6 months otherwise. Additional authorizations will be considered when the following criteria are met:
  1. Documentation of a positive clinical response to therapy (e.g., increased or stabilization of hemoglobin levels or reduction in transfusions); and
  2. Is not prescribed concurrently with eculizumab (Soliris) or ravulizumab (Ultomiris).

2. Changes to Existing PA Criteria – *Changes are italicized or stricken.* See complete prior authorization criteria under the Prior Authorization Criteria tab[2].

- **PCSK9 Inhibitors:**
  Prior authorization is required for PCSK9 Inhibitors. *Payment for a non-preferred PCSK9 Inhibitor 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 under the following conditions:
  1. Patient *meets the FDA-approved age for indication*; AND
  2. *Dosing follows the FDA-approved dose for the submitted diagnosis; AND*

[2] Prior Authorization Criteria | Iowa Medicaid PDL

~~7. Is prescribed by a lipidologist, cardiologist, or endocrinologist.~~

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH)

2. Unable to reach goal LDL-C with a minimum of *one high-intensity* statin *(atorvastatin 40-80 mg or rosuvastatin 20-40 mg)* used in combination with ezetimibe 10mg daily. *If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)

2. Unable to reach goal LDL-C with a minimum of *one high-intensity* statin *(atorvastatin 40-80 mg or rosuvastatin 20-40 mg)* used in combination with ezetimibe 10mg daily. *If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

Diagnosis of Primary Hyperlipidemia (not associated with ASCVD or HeFH)

2. Unable to reach goal LDL-C < 100mg/dL while on high-intensity statin therapy (atorvastatin 40-80 mg or rosuvastatin 20-40 mg) used in combination with ezetimibe 10 mg daily. If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.

Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)

3. Unable to reach goal LDL-C with a minimum of *one high-intensity* statin *(atorvastatin 40-80 mg or rosuvastatin 20-40 mg)* used in combination with ezetimibe 10mg daily. *If patient is unable to tolerate high-intensity statin therapy, a trial with a moderate-intensity statin (e.g., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, pravastatin 40-80mg, lovastatin 40-80 mg, fluvastatin 80 mg, pitavastatin 1-4 mg, simvastatin 20-40 mg) used in combination with ezetimibe.*

The required trials ~~(excluding the statin trial)~~ may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Initial requests will be approved for 6 months. Additional requests will be considered under the following conditions:

1. *Documentation of positive clinical response to PCSK9 Inhibitor therapy (current LDL-C lab provided); and*
2. *Patient continues therapy with a maximally tolerated statin; and*
3. *Patient has continued compliance with a low-fat diet.*

3. 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[3].

Drug	Quantity limit per 30 days
Praluent 75 mg/mL	2 mL
Praluent 150 mg/mL	2 mL
Repatha 140 mg/mL syringe/autoinjector	3 mL
Repatha 420 mg/3.5 mL Pushtronex system	3.5 mL
Dilantin 100 mg capsule (phenytoin)	180
Dilantin 125 mg/5mL Suspension (phenytoin)	750 mL
Dilantin 30 mg capsule (phenytoin)	180
Dilantin 50 mg chewable Infatab (phenytoin)	180
Phenytek 200 mg capsule (phenytoin)	90
Phenytek 300 mg capsule (phenytoin)	60
Zarontin 250 mg capsule (ethosuximide)	180
Zarontin 250 mg/5mL syrup (ethosuximide)	900 mL
Celontin 300 mg capsule (methsuximide)	120
Tranxene-T 3.75 mg tablet (clorazepate)	180
Tranxene-T 7.5 mg tablet (clorazepate)	180
Tranxene-T 15 mg tablet (clorazepate)	180
Briviact 10 mg tablet (brivaracetam)	60
Briviact 25 mg tablet (brivaracetam)	60
Briviact 50 mg tablet (brivaracetam)	60
Briviact 75 mg tablet (brivaracetam)	60
Briviact 100 mg tablet (brivaracetam)	60

[3] Billing/Quantity Limits | Iowa Medicaid PDL

Briviact 10 mg/mL solution (brivaracetam)	600 mL
Carbatrol ER 100 mg capsule (carbamazepine ER)	120
Carbatrol ER 200 mg capsule (carbamazepine ER)	240
Carbatrol ER 300 mg capsule (carbamazepine ER)	150
Epitol 200 mg tablet (carbamazepine)	240
Equetro 100 mg capsule (carbamazepine ER)	120
Equetro 200 mg capsule (carbamazepine ER)	240
Equetro 300 mg capsule (carbamazepine ER)	150
Tegretol 100 mg chewable tablet (carbamazepine)	240
Tegretol 200 mg tablet (carbamazepine)	240
Tegretol 100 mg/5 mL suspension (carbamazepine)	2400 mL
Tegretol XR 100 mg tablet (carbamazepine)	60
Tegretol XR 200 mg tablet (carbamazepine)	60
Tegretol XR 400 mg tablet (carbamazepine)	120
Xcopri 50 mg tablet (cenobamate)	30
Xcopri 100 mg tablet (cenobamate)	30
Xcopri 150 mg tablet (cenobamate)	60
Xcopri 200 mg tablet (cenobamate)	60
Aptiom 200 mg tablet (eslicarbazepine)	30
Aptiom 400 mg tablet (eslicarbazepine)	30
Aptiom 600 mg tablet (eslicarbazepine)	60
Aptiom 800 mg tablet (eslicarbazepine)	60
Felbatol 400 mg tablet (felbamate)	180
Felbatol 600 mg tablet (felbamate)	180
Felbatol 600 mg/5 mL suspension (felbamate)	900 mL
Lamictal 5 mg chewable tablet (lamotrigine)	240
Lamictal 25 mg chewable tablet (lamotrigine)	120
Lamictal 25 mg tablet & ODT (lamotrigine)	60
Lamictal 50 mg ODT (lamotrigine)	60
Lamictal 100 mg tablet & ODT (lamotrigine)	60
Lamictal 150 mg tablet (lamotrigine)	30
Lamictal 200 mg tablet & ODT (lamotrigine)	60
Lamictal XR 25 mg tablet (lamotrigine)	60
Lamictal XR 50 mg tablet (lamotrigine)	60
Lamictal XR 100 mg tablet (lamotrigine)	60
Lamictal XR 200 mg tablet (lamotrigine)	60
Lamictal XR 250 mg tablet (lamotrigine)	60
Lamictal XR 300 mg tablet (lamotrigine)	60
Keppra 250 mg tablet (levetiracetam)	60
Keppra 500 mg tablet (levetiracetam)	60
Keppra 750 mg tablet (levetiracetam)	60

Keppra 1000 mg tablet (levetiracetam)	90
Keppra Oral Soln 100 mg/mL (levetiracetam)	900 mL
Keppra XR 500 mg tablet (levetiracetam)	180
Keppra XR 750 mg tablet (levetiracetam)	120
Spritam 250 mg tablet disintegrating soluble (levetiracetam)	60
Spritam 500 mg tablet disintegrating soluble (levetiracetam)	60
Spritam 750 mg tablet disintegrating soluble (levetiracetam)	60
Spritam 1000 mg tablet disintegrating soluble (levetiracetam)	90
Trilepta 150 mg tablet (oxcarbazepine)	120
Trilepta 300 mg tablet (oxcarbazepine)	120
Trilepta 600 mg tablet (oxcarbazepine)	120
Trilepta 300 mg/mL suspension (oxcarbazepine)	1200 mL
Oxtellar XR 150 mg tablet (oxcarbazepine)	90
Oxtellar XR 300 mg tablet (oxcarbazepine)	90
Oxtellar XR 600 mg tablet (oxcarbazepine)	120
Fycompa 2 mg tablet (perampanel)	30
Fycompa 4 mg tablet (perampanel)	30
Fycompa 6 mg tablet (perampanel)	30
Fycompa 8 mg tablet (perampanel)	30
Fycompa 10 mg tablet (perampanel)	30
Fycompa 12 mg tablet (perampanel)	30
Fycompa 0.5 mg/mL suspension (perampanel)	720 mL
Mysoline 50 mg tablet (primidone)	240
Mysoline 250 mg tablet (primidone)	240
Banzel 200 mg tablet (rufinamide)	120
Banzel 400 mg tablet (rufinamide)	240
Banzel 40 mg/mL suspension (rufinamide)	2400 mL
Diacomit 250 mg capsule & packet (stiripentol)	90
Diacomit 500 mg capsule & packet (stiripentol)	180
Gabitril 2 mg tablet (tiagabine)	120
Gabitril 4 mg tablet (tiagabine)	120
Gabitril 12 mg tablet (tiagabine)	120
Gabitril 16 mg tablet (tiagabine)	90
Topamax 200 mg tablet (topiramate)	60
Topamax 15 mg sprinkle capsule (topiramate)	180
Topamax 25 mg sprinkle capsule (topiramate)	180
Qudexy XR 25 mg sprinkle capsule (topiramate)	30
Qudexy XR 50 mg sprinkle capsule (topiramate)	30

Qudexy XR 100 mg sprinkle capsule (topiramate)	30
Qudexy XR 150 mg sprinkle capsule (topiramate)	60
Qudexy XR 200 mg sprinkle capsule (topiramate)	60
Trokendi XR 25 mg capsule (topiramate)	30
Trokendi XR 50 mg capsule (topiramate)	30
Trokendi XR 100 mg capsule (topiramate)	90
Trokendi XR 200 mg capsule (topiramate)	60
Eprontia 25 mg/mL oral solution (topiramate)	460 mL
Sabril 500 mg packet (vigabatrin)	180
Sabril 500 mg tablet (vigabatrin)	180
Vigadrone 500 mg packet (vigabatrin)	180

4. **Drug Utilization Review (DUR) Update:** The latest issue of the DUR Digest is located on the Iowa DUR website[4] under the "Newsletters" link.

We encourage providers to visit the Preferred Drug List (PDL) website[5] 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.

[4] Iowa Medicaid Drug Utilization Review Commission | Iowa Medicaid Drug Utilization Review Commission (iadur.org)
[5] Iowa Medicaid PDL