Bempedoic Acid

Goal(s):

- Promote use of bempedoic acid that is consistent with medical evidence.

Length of Authorization:

- Up to 12 months

Requires PA:

- Bempedoic Acid (Nexletol™)
- Bempedoic acid and ezetimibe (Nexlizet™)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code; go to #2	
2. Does the patient have clinical atherosclerotic cardiovascular disease (ASCVD), defined as documented history of one or more ASCVD events (see below) **OR** a diagnosis of homozygous or heterozygous familial hypercholesterolemia (HeFH or HoFH) OR at high risk for CVD, including those with: • Diabetes mellitus OR • 10-year ASCVD risk of 10% or greater? Major ASCVD events • Recent ACS (within past 12 months) • History of MI (other than recent ACS from above) • History of ischemic stroke • Symptomatic peripheral artery disease • Coronary artery disease	**Yes:** Go to #3	**No:** Pass to RPh; deny for medical appropriateness

Approval Criteria		
3. Has the patient taken a daily high-intensity statin (see table below) for at least 3 months with a LDL-C still ≥ 70 mg/dl with ASCVD or ≥ 100 mg/dl with HeFH or HoFH or high-risk CVD? Prescriber to submit chart documentation of: 1) Doses and dates initiated of statin 2) Baseline LDL-C (untreated) 3) Recent LDL-C	**Yes:** Confirm documentation; go to #5 1. Statin: Dose: Date Initiated: Baseline LDL-C _____ Date:_____ Recent LDL-C _____ Date:_____	**No:** Go to #4
4. Does the patient have a history of: • rhabdomyolysis caused by a statin, OR • a history of creatinine kinase (CK) levels >10-times upper limit of normal with muscle symptoms determined to be caused by a statin, OR • statin intolerance, defined as one or more adverse effects associated with statin therapy that improves with dose reduction or discontinuation and a trial of at least 2 statin medications at the lowest approved daily dose? Note: Prescriber must provide chart documentation of diagnosis or CK levels. A recent LDL-C level (within last 12 weeks) must also be submitted.	**Yes:** Confirm chart documentation of diagnosis or labs and go to #5 1. Statin #1: Dose: Date Initiated: 2. Statin #2 Dose: Date Initiated: Recent LDL-C _____ Date: _____	**No:** Pass to RPh; deny for medical appropriateness
5. Has the patient taken ezetimibe 10 mg daily for at least 3 months and still requires additional LDL-C lowering (LDL-C still ≥ 70 mg/dl with ASCVD or ≥ 100 mg/dl with HeFH or HoFH or high-risk CVD), **OR** have a contraindication to ezetimibe?	**Yes:** Go to #6	**No:** Pass to RPH; deny for medical appropriateness
6. Is the patient adherent with a high-intensity statin and/or ezetimibe?	**Yes:** Approve for up to 12 months Note: pharmacy profile may be reviewed to verify >80% adherence (both lipid-lowering prescriptions refilled 5 months' supply in last 6 months)	**No:** Pass to RPh; deny for medical appropriateness

High- and Moderate-intensity Statins.

High-intensity Statins (≥50% LDL-C Reduction)	**Moderate-intensity Statins** (30 to <50% LDL-C Reduction)	
Atorvastatin 40-80 mg Rosuvastatin 20-40 mg	Atorvastatin 10-20 mg Fluvastatin 80 mg Lovastatin 40-80 mg	Pitavastatin 1-4 mg Pravastatin 40-80 mg Simvastatin 20-40 mg Rosuvastatin 5-10 mg

P&T / DUR Review: *12/23 (MH), 08/20 (MH)*
Implementation: *1/1/24; 9/1/20*