UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2020 P 3146-1 |
| Program | Step Therapy |
| Medications | Nexletol (bempedoic acid), Nexlizet (bempedoic acid/ezetimibe) |
| P&T Approval Date | 8/2020 |
| Effective Date | 11/1/2020;<br>Oxford only: N/A |

**1. Background:**

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to have a trial of a maximally tolerated statin therapy and ezetimibe prior to coverage for Nexletol or Nexlizet.

**2. Coverage Criteria[a]:**

**A. Authorization**

**1. Nexletol or Nexlizet** will be approved based on **both** of the following criteria:

a. **One** of the following:

(1) Patient has been receiving at least 12 consecutive weeks of high-intensity statin therapy and will continue to receive high-intensity statin [i.e., atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at maximally tolerated dose

**-OR-**

(2) **Both** of the following:

(a) Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

**-AND-**

(b) **One** of the following:

i. Patient has been receiving at least 12 consecutive weeks of moderate-intensity statin therapy and will continue to receive a moderate-intensity statin [i.e., atorvastatin 10-20 mg, Crestor

(rosuvastatin) 5-10 mg, simvastatin ≥ 20 mg, pravastatin ≥ 40 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily or Livalo (pitavastatin) ≥ 2 mg] at maximally tolerated dose

**-OR-**

ii. Patient has been receiving at least 12 consecutive weeks of low-intensity statin therapy and will continue to receive a low-intensity statin [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1 mg] at maximally tolerated dose

**-OR-**

(3) Patient is unable to tolerate **low-, moderate-, or high-intensity statins** as evidenced by **one** of the following:

(a) One of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:
- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal [ULN])

**-OR-**

(b) Patient has a labeled contraindication to all statins

**-OR-**

(c) Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations > 10 times ULN

**-AND-**

b. Documentation of **one** of the following:

(1) Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia®) therapy as adjunct to maximally tolerated statin therapy

**-OR-**

(2) Patient has a history of contraindication, or intolerance to ezetimibe

**Authorization will be issued for 12 months.**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity and/or Supply limits may be in place.

**4. References:**


1. Nexletol [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; February 2020.
2. Nexlizet [package insert]. Ann Arbor, MI: Esperion Therapeutics, Inc; February 2020.
3. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2014;63:2889-934.
4. The Lipid Research Clinics Coronary Primary Prevention Trial results. II. The relationship of reduction in incidence of coronary heart disease to cholesterol lowering. JAMA. 1984;251:365-74.
5. ATP III Final Report PDF. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report. Circulation. 2002;106:3143-3421.
6. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American association of clinical endocrinologists and American college of endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. Endocr Pract. 2017; Suppl 2;23:1-87.
7. Lloyd-Jones D, Morris P, Ballantyne C, et al. 2017 Focused update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. J Am Coll Cardiol. 2017.
8. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA guideline on the management of blood cholesterol: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation. 2018; DOI: 10.1161/CIR.0000000000000625.


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| **Change Control** | |
| 8/2020 | New program. |