Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Nexletol (bempedoic acid)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Nexletol (bempedoic acid)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Nexletol (bempedoic acid) may be approved when the following criteria are met:

I. Individual is at high risk for atherosclerotic cardiovascular disease (ASCVD) events as identified by one of the following:
   A. Individual has Heterozygous Familial Hypercholesterolemia (HeFH) confirmed by (Singh 2015; WHO 1999):
      1. Presence of a mutation in LDLR, ApoB, PCSK9 or ARH adaptor protein (LDLRAP1) gene; **OR**
      2. WHO/Dutch Lipid Clinic Network criteria with score of greater than eight points;

   OR

   B. Individual has a history of clinical atherosclerotic cardiovascular disease (ASCVD), including **one or more** of the following (AHA/ACC 2018):
      1. Acute coronary syndrome;
      2. Coronary artery disease (CAD);
      3. History of myocardial infarction (MI);
      4. Stable or unstable angina;
      5. Coronary or other arterial revascularization;
      6. Stroke;
      7. Transient ischemic attack (TIA);
      8. Peripheral arterial disease (PAD);

AND

II. Individual meets one of the following:
   A. Individual is on concomitant statin therapy at the maximum tolerated dose; **OR**
   B. Individual is statin intolerant based on one of the following:
      1. Inability to tolerate at least two statins, with at least one started at the

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

lowest starting daily dose, demonstrated by intolerable symptoms or clinically significant biomarker changes (NLA 2014); **OR**

2. Statin associated rhabdomyolysis after a trial of one statin;

OR

C. Individual has a contraindication for statin therapy including active liver disease, unexplained persistent elevation of hepatic transaminases or pregnancy;

AND

III. Individual meets one of the following:
   A. Individual is on concomitant ezetimibe therapy (AHA/ACC 2018); **OR**
   B. Individual has had a trial of and was unable to tolerate ezetimibe therapy;

AND

IV. Individual has achieved suboptimal lipid lowering response to lipid lowering therapy and lifestyle modifications as defined (AHA/ACC 2018):
   A. For individuals where initial LDL-C is known:
      1. Less than 50% reduction in LDL-C;

   OR

   B. For individuals where initial LDL-C is unknown:
      1. ASCVD and LDL-C remains greater than or equal to 70 mg/dL; **OR**
      2. No history of ASCVD and LDL-C remains greater than or equal to 100 mg/dL.

Continuation requests for Nexletol (bempedoic acid) may be approved when the following criteria are met:

I. Individual continues to receive concomitant maximally tolerated statin therapy (unless contraindicated or not tolerated); **AND**
II. Individual continues to receive concomitant ezetimibe therapy (unless contraindicated or not tolerated); **AND**
III. Confirmation of LDL reduction has been provided.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 1, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.