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

Nexlizet (bempedoic acid/ezetimibe)

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

Medications	Quantity Limit
Nexlizet (bempedoic acid/ezetimibe)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Nexlizet (bempedoic acid/ezetimibe) 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 lowest starting daily dose, demonstrated by intolerable

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

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 has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of ezetimibe therapy and was unable to meet LDL-C goal (AHA/ACC 2018);

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 Nexlizet (bempedoic acid/ezetimibe) 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. Confirmation of LDL reduction has been provided.

Nexlizet (bempedoic acid/ezetimibe) may not be approved for the following:

I. Individual with moderate to severe hepatic impairment (Child-Pugh B or C).

Key References:

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

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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.