STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEMPEDOIC ACID AND EZETIMIBE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEMPEDOIC ACID AND EZETIMIBE	NEXLIZET	46386		GPI-10 (3999100220)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have **ONE** of the following diagnoses?
   - Established cardiovascular disease (e.g., history of myocardial infarction or other acute coronary syndrome, coronary or other revascularization procedure, transient ischemic attack, ischemic stroke, atherosclerotic peripheral arterial disease, coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, carotid plaque with 50% or more stenosis)
   - Heterozygous familial hypercholesterolemia [HeFH]

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is prescribed by or given in consultation with a cardiologist, endocrinologist, or lipidologist
   - The patient had a previous trial of ezetimibe
   - The patient has an LDL-cholesterol level greater than or equal to 70 mg/dL

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient meet **ONE** of the following criteria?
   - The patient had a trial of a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
   - The patient has been taking a maximally tolerated dose of any statin given that the patient cannot tolerate a high-intensity statin (i.e., atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

   If yes, continue to #4
   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

4. Will the patient continue statin treatment as described above in combination with Nexlizet?

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal for established cardiovascular disease or heterozygous familial hypercholesterolemia [HeFH] requires the patient has experienced LDL-C lowering AND meets ONE of the following criteria: 1) The patient will continue therapy with a maximally tolerated dose of any statin, 2) The patient has an absolute contraindication to statin therapy, OR 3) The patient has complete statin intolerance.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

5. Does the patient meet **ONE** of the following criteria?
   - The patient has an absolute contraindication to statin therapy (e.g., active decompensated liver disease, nursing female, pregnancy or plans to become pregnant, hypersensitivity reaction)
   - The patient has complete statin intolerance as defined by severe and intolerable adverse effects (e.g., creatinine kinase elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis, severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group) that have occurred with trials of at least two separate statins and have improved with the discontinuation of each statin

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   APPROVAL TEXT: Renewal for established cardiovascular disease or heterozygous familial hypercholesterolemia [HeFH] requires the patient has experienced LDL-C lowering AND meets ONE of the following criteria: 1) The patient will continue therapy with a maximally tolerated dose of any statin, 2) The patient has an absolute contraindication to statin therapy, OR 3) The patient has complete statin intolerance.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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BEMPEDOIC ACID AND EZETIMIBE

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart) such as history of myocardial infarction (heart attack) or other acute coronary syndrome, coronary or other revascularization procedure (restoring blood flow to heart and other areas), transient ischemic attack (short, stroke-like attack), ischemic stroke (arteries to your brain become narrowed or blocked), atherosclerotic peripheral arterial disease (arteries get blocked with fats and plaques), coronary atherosclerosis (heart arteries get blocked with fats and plaques), renal atherosclerosis (kidney arteries get blocked with fats and plaques), aortic aneurysm secondary to atherosclerosis (fat and plaque buildup causes enlargement of a heart artery), carotid plaque with 50% or more stenosis (narrowing of blood vessel)
   2. Heterozygous familial hypercholesterolemia [HeFH: type of inherited high cholesterol]

B. You are 18 years of age or older

C. The medication is prescribed by or given in consultation with a cardiologist (heart doctor), endocrinologist (hormone doctor), or lipidologist (cholesterol management doctor)

D. You previously had a trial of ezetimibe

E. You have a LDL (low density lipoprotein)-cholesterol level greater than or equal to 70 mg/dL

F. **If you are statin tolerant, approval also requires:**
   1. You will continue statin treatment in combination with Nexlizet
   2. You meet ONE of the following:
      a. You have been taking a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)
      b. You have been taking a maximally tolerated dose of any statin given that you cannot tolerate a high-intensity statin (atorvastatin 40-80 mg daily, rosuvastatin 20-40 mg daily)

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INITIAL CRITERIA (CONTINUED)

G. **If you are statin intolerant, approval also requires ONE of the following:**
   1. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy (such as active decompensated liver disease: you have symptoms related to liver damage, nursing female, pregnancy or plans to become pregnant, or hypersensitivity [allergic] reaction)
   2. You have complete statin intolerance as defined by severe and intolerable adverse effects that has occurred with trials of at least two separate statins, and the side effects have improved when you stopped each statin. Some adverse effects include: creatinine kinase (type of protein) elevation greater than or equal to 10 times the upper limit of normal, liver function test elevation greater than or equal to 3 times the upper limit of normal, rhabdomyolysis (severe muscle break down), severe muscle weakness leading to temporary disability, fall, or inability to use a major muscle group

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of established cardiovascular disease OR heterozygous familial hypercholesterolemia [HeFH] and meet the following criterion?
   - The patient has experienced LDL-C lowering

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has continued therapy with a maximally tolerated dose of any statin
   - The patient has an absolute contraindication to statin therapy
   - The patient has complete statin intolerance

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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BEMPEDOIC ACID AND EZETIMIBE

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEMPEDOIC ACID AND EZETIMIBE (Nexlizet)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Established cardiovascular disease (health problems related to narrow or blocked blood vessels of the heart)
   2. Heterozygous familial hypercholesterolemia ([HeFH]: type of inherited high cholesterol)
B. You have experienced low density lipoprotein-cholesterol (LDL-C) lowering
C. You meet ONE of the following:
   1. You have continued therapy with a maximally tolerated dose of any statin
   2. You have an absolute contraindication (a medical reason why you cannot use) to statin therapy
   3. You have complete statin intolerance

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nexlizet.

REFERENCES

Nexlizet [Prescribing Information]. Ann Arbor, MI: Esperion Therapeutics Inc., February 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/05/20
Created: 06/20
Client Approval: 01/20
P&T Approval: 01/20