

Generic Name: Bempedoic acid/ezetimibe

Therapeutic Class or Brand Name: Nexlize™

Applicable Drugs (if Therapeutic Class): Lipid Lowering Agent

GPI Code: 39991002200320

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/7/2020

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - III are met)

- I. Documented diagnosis of one of the following conditions A Or B AND must meet criteria listed under applicable diagnosis:
 - A. Heterozygous familial hypercholesterolemia (HeFH) and following criterion and conditions are met:
 1. Diagnosed with genetic typing OR measured LDL-C \geq 190 mg/dL prior to treatment with a statin and the following criteria are met:
 2. Minimum age requirement: 18 years old.
 - B. Clinical atherosclerotic cardiovascular disease (ASCVD) and criterion 1 is met:
 1. Minimum age requirement: 18 years old.
- II. Documentation that patient meets the following criteria A and B
 - A. Treatment with maximally tolerated statin and ezetimibe daily for \geq 24 weeks and
 - B. LDL-C remains \geq 100 mg/dL or a 50% reduction in LDL-c has not been achieved.
- III. Documentation Prescriber must be a doctor of internal medicine, cardiologist, or endocrinologist.

EXCLUSION CRITERIA

- Concurrent use with simvastatin > 20mg or pravastatin > 40mg
- Concurrent use with fibrates (other than fenofibrate)
- Documented hypersensitivity reaction to ezetimibe.
- Documented history of gout or hyperuricemia.
- Documented history of tendon rupture or tendon disorders.
- Documented history of chronic liver disease or abnormal liver enzymes.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease: Bottle of 180/10 mg tablets (#30) for 30 days.

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Ballantyne CM, Laufs U, Ray KK, et al. Bempedoic acid plus ezetimibe fixed-dose combination in patients with hypercholesterolemia and high CVD risk treated with maximally tolerated statin therapy. *European Journal of Preventive Cardiology*. 2019;27(6):593-603.
2. Bempedoic acid/ezetimibe (NexlizeTM) [package insert]. Ann Arbor, MI; Esperion Therapeutics, Inc.
3. Medi-Span.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.