

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

## Niacin Agents

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

Medications	Quantity Limit
Niacor tablets Niaspan Extended Release tablets	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for a niacin agent (Niacor, Niaspan) may be approved when the following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of two preferred statins and did not achieve LDL cholesterol goal (AHA/ACC 2018);

Preferred statins: atorvastatin, lovastatin, pravastatin, simvastatin.

#### **OR**

- II. Individual is statin intolerant based on one of the following:
  - A. Inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, demonstrated by intolerable symptoms or clinically significant biomarker changes (NLA 2014); **OR**
  - B. Statin associated rhabdomyolysis after a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one statin; **AND**
- III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response (did not achieve LDL cholesterol goal) or intolerance to ezetimibe (AHA/ACC 2018);

#### **OR**

- IV. Individual is requesting niacin to treat high triglyceride levels (triglycerides greater than or equal to 500 mg/dL); **AND**

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- V. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response (did not achieve triglyceride goal) or intolerance to one preferred fenofibrate (AACE 2017, AHA/ACC 2018);

Preferred fenofibrate agents: Fenofibrate 43 mg, 48 mg, 54 mg, 67 mg, 134 mg, 160 mg, 200 mg; fenofibric acid 45 mg; gemfibrozil.

**OR**

- VI. Individual has a contraindication to fenofibrate therapy including:
- A. Severe renal dysfunction (CrCl less than 30 mL/min), including individuals receiving dialysis; **OR**
  - B. Gallbladder disease; **OR**
  - C. Nursing mother;

**AND**

- VII. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response (did not achieve triglyceride goal) or intolerance to one omega-3 fatty acid agent (AACE 2017, AHA/ACC 2018).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 9, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Guyton JR, Bays HE, Grundy SM, Jacobson TA. The National Lipid Association Statin Intolerance Panel. An assessment by the Statin Intolerance Panel: 2014 update. J Clin Lipidol. 2014;8(3 Suppl):S72–81.
4. 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. J Am Coll Cardiol. 2018. <https://doi.org/10.1016/j.jacc.2018.11.003>.
5. 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;23(Suppl 2):1-87.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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.