Niacin Agents

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

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

APPROVAL CRITERIA

Requests for a niacin extended release agents may be approved when the following criteria are met:

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

Preferred statins: atorvastatin, fluvastatin, fluvastatin ER, lovastatin, pravastatin, rosuvastatin, 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 adverse effects associated with statin therapy that resolve or improve with dose reduction or discontinuation (NLA 2022); **OR**
   B. Statin associated rhabdomyolysis or immune-mediated necrotizing myopathy (IMNM) after a trial of one statin. Medication samples/coupons/discount cards are excluded from consideration as a trial.;

AND

III. Individual has had a trial and inadequate response (did not achieve LDL cholesterol goal) or intolerance to ezetimibe (AHA/ACC 2018). Medication samples/coupons/discount cards are excluded from consideration as a trial.;

OR

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

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

Preferred fibrate agents: generic fenofibrate (except 40 mg and 120 mg), generic

fenofibric acid, generic gemfibrozil, generic micronized fenofibrate.

OR

VI. Individual has a contraindication to fenofibrate therapy including, but not limited to:
   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 (AHA/ACC 2018).

Key References:

1. Cheeley MK, Saseen JJ, Agarwala A, et. al. NLA scientific statement on statin intolerance: a new definition and key considerations for ASCVD risk reduction in the statin intolerant patient. *J Clin Lipidol*. 2022. https://doi.org/10.1016/j.jacl.2022.05.068.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 16, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019;73:e285–350.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.