



AETNA BETTER HEALTH®

Non-Formulary and Prior Authorization guideline for Antihyperlipidemics

Drugs Covered

- Rosuvastatin (formulary with step-therapy)
- Zetia (formulary with step-therapy)

Non-formulary Agents

- Epanova
- Lovaza
- Vascepa

Authorization guidelines

- A. Lovaza, Vascepa, or Epanova is approved for members 18 years of age or older when ALL of the following criteria are met:
 - a. For the treatment of severe hypertriglyceridemia (triglyceride level greater than or equal to 500 mg/dL)
 - b. Drug will be used as an add-on to lifestyle interventions to include diet and exercise
 - c. Trial and failure with an over-the-counter (OTC) fish oil AND a fibrate (e.g. fenofibrate, fenofibric acid, or gemfibrozil) or contraindication to all formulary agents
- B. Zetia requires step therapy:
 - a. If member has filled two (2) prescriptions for two (2) of the following statins: atorvastatin, simvastatin or rosuvastatin) within the past 130 days, the prescription will automatically process at the pharmacy.
 - b. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.
 - i. *In those cases, Zetia will be authorized upon receipt of documentation of a diagnosis of hyperlipidemia and trial and failure or contraindication to two (2) of the following statins: atorvastatin, simvastatin, and rosuvastatin.*
- C. Rosuvastatin requires step therapy:
 - a. If member has used any strength of atorvastatin for 60 days within the past 130 days, the prescription will automatically process at the pharmacy.
 - b. Prior Authorization will be required for prescriptions that do not process automatically at the pharmacy.

- i. *In those cases, rosuvastatin will be authorized upon receipt of documentation of a diagnosis of hyperlipidemia and trial and failure or contraindication to any strength of atorvastatin*

** Exception to statin therapy trials requires documentation of intolerance to at least two (2) statins (at least one trial being a moderate to high potency statin). Documentation will include chart notes supporting skeletal muscle related symptoms that resolved when statin therapy was discontinued; and documentation the member has been re-challenged at a lower dose or with a different statin.*

Additional Information:

Quantity Limits

- Lovaza/Vascepa, Epanova, and Omtryg: 4 capsules per day

These products are NOT covered for members with the following criteria:

- Use not approved by the FDA; **AND**
- The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

Approval Duration:

3 months

Renewal:

Indefinite

Renewals require improvement in fasting lipids (most recent lipid panel within previous 90days) and documentation of recommended safety monitoring parameters (such as liver enzymes), claims history indicative of adherence to therapy.

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member's family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.

All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:

- 1) Berglund L, et al. Evaluation and Treatment of Hypertriglyceridemia: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2012; 97(9): 2969–2989.
- 2) Cuchel M, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Concensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. *Eur Heart J.* 2014;
- 3) Goldberg AC, et al. Familial Hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Clin Lipidol.* 2011;(5):S1-S8.
- 4) Jacobson TA, et al. National lipid association recommendations for patient-centered management of dyslipidemia: Part 1 – executive summary. *J Clin Lipidol.* 2014;8:473-488.
- 5) Robinson JG. Management of familial hypercholesterolemia: a review of the recommendations from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Manag Care Pharm.* 2013;19(2):139-49.
- 6) Stone NJ, et al. 2013 ACC/AHA blood cholesterol guideline. *Circulation.* 2013;
- 7) Watts GF, et al. Integrated guidance on the care of familial hypercholesterolaemia from the International FH Foundation. *Int J Cardiol.* 2014;
- 8) Epanova, Lovaza, Vascepa, Omtryg, rosuvastatin. *Clinical Pharmacology* [database online]. Tampa, FL: Gold Standard, Inc. Available at: <http://www.clinicalpharmacology.com>. Accessed July 26, 2017.
- 9) Crestor [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; Revised August 2017.
- 10) Epanova [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; Revised March 2017.
- 11) Lovaza [package insert]. RTP, NC: GlaxoSmithKline; Revised May 2014.
- 12) Vascepa [package insert]. Bedminster, NJ: Amarin Pharmaceuticals; Revised February 2017.

- 13) Gidding SS, Champagne MA, Ferranti SD, et al. on behalf of the American Heart Association Atherosclerosis, Hypertension, and Obesity in the Young Committee of the Council on Cardiovascular Disease in the Young, Council on Cardiovascular and Stroke Nursing, Council on Functional Genomics and Translational Biology, and Council on Lifestyle and Cardiometabolic Health Circulation. 2015; 132:2167-2192. doi: 10.1161/CIR.000000000000297.
- 14) Juxtapid[®] [package insert]. Aegerion Pharmaceuticals, Inc., Cambridge, MA; August 2017. <http://www.juxtapidpro.com/prescribing-information>. Accessed November 6, 2017.
- 15) 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. Endocrine Practice, vol. 23, no. Supplement 2, 2017; 1–87. doi:10.4158/ep171764.appgl.
- 16) Kynamro[®] [package insert]. Kastle Therapeutics, LLC, Chicago, IL; May 2016. http://www.kynamro.com/media/pdfs/Kynamro_Prescribing_information.pdf. Accessed November 6, 2017.
- 17) Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statins Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways, In Journal of the American College of Cardiology, Volume 70, Issue 14, 2017; 1785-1822. doi.org/10.1016/j.jacc.2017.07.745.
- 18) Watts GF, Gidding S, Wierzbicki AS, et al. Integrated guidance on the care of familial hypercholesterolaemia from the International FH Foundation, In International Journal of Cardiology, Volume 171, Issue 3, 2014; 309-325. doi.org/10.1016/j.ijcard.2013.11.025.
- 19) Repatha [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; July 2016
- 20) Praluent [Prescribing Information]. Bridgewater, NJ,: Regeneron and Sanofi Aventis LLC; July 2017
- 21) Stone, NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2013; doi:10.1016/j.jacc.2013.11.002.
- 22) Management of familial hypercholesterolemia
<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=16222>
<http://www.google.com/url?url=http://www.amcp.org/WorkArea/DownloadAsset.aspx%3Fid%3D16222&rct=j&frm=1&q=&esrc=s&sa=U&ei=RJSUVf2bDsuTyATgvoHwAw&ved=0CEAQFjAG&u sg=AFQjCNEdp9VnIHhpJLov4D4IQgRPWNuQLQ>
- 23) Cuchel M, Bruckert E, Ginsberg HN, et al. [Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society](#). Eur Heart J. 2014 Aug 21;35(32):2146-57. doi: 10.1093/eurheartj/ehu274. Epub 2014 Jul 22

24) 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk; A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents