Clinical Policy: Lovastatin ER (Altoprev)

Reference Number: HIM.PA.127
Effective Date: 12.01.17
Last Review Date:
Line of Business: Health Insurance Marketplace

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Lovastatin ER [extended-release] (Altoprev®) is an HMG-CoA reductase inhibitor (statin). Prior authorization is required for the 60 mg tablet.

FDA Approved Indication(s)

Altoprev is indicated to:

- Reduce the risk of myocardial infarction, revascularization procedures, and angina in patients without coronary heart disease, but with multiple risk factors
- Slow the progression of coronary atherosclerosis in patients with coronary heart disease as part of a treatment strategy to lower total cholesterol and low-density lipoprotein cholesterol (LDL-C)
- Reduce elevated total cholesterol, LDL-C, apolipoprotein B, and triglyceride levels and increase high-density lipoprotein cholesterol in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia

Limitation(s) of use: Altoprev has not been studied in Fredrickson types I, III, and V dyslipidemias.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Lipid Lowering (must meet all)**:**

1. Prescribed for lipid lowering;
2. Age ≥ 18 years;
3. Member meets both of the following (a and b):
   a. Failure of lovastatin 40 mg, unless contraindicated or clinically significant adverse effects are experienced to its excipients;
   b. Failure of at least 2 other formulary generic statins* at maximum indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   **Formulary generic statins include: atorvastatin, fluvastatin, pravastatin, rosuvastatin, and simvastatin*
4. At the time of request, member has none of the following contraindications:
   a. Concomitant administration of strong CYP3A inhibitors or erythromycin;
   b. Current pregnancy;

5. Dose does not exceed 60 mg/day (1 tablet/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Lipid Lowering (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., improvement in lipid levels, absence of atherosclerotic cardiovascular disease events);
3. If request is for a dose increase, new dose does not exceed 60 mg/day (1 tablet/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

LDL-C: low-density lipoprotein cholesterol

Appendix B: High-, Moderate-, and Low-Intensity Statin Therapy

- High-Intensity Statin Therapy
  Daily dose shown to lower LDL-C, on average, by approximately ≥ 50%
  - Atorvastatin 40-80 mg
  - Rosuvastatin 20-40 mg
- Moderate-Intensity Statin Therapy
  Daily dose shown to lower LDL-C, on average, by approximately 30% to 50%
  - Atorvastatin 10-20mg
  - Fluvastatin XL 80 mg
  - Fluvastatin 40 mg 2x/day
  - Lovastatin 40 mg*
  - Pitavastatin 2-4 mg
  - Pravastatin 40-80 mg
  - Rosuvastatin 5-10 mg
  - Simvastatin 20-40 mg
- Low-Intensity Statin Therapy
  Daily dose shown to lower LDL-C, on average, by < 30%

- Fluvastatin 20–40 mg
- Lovastatin 20 mg
- Simvastatin 10 mg
- Pitavastatin 1 mg
- Pravastatin 10–20 mg

**Although lovastatin 60 mg is not included in this table from the American College of Cardiology/American Heart Association 2013 guidelines on the treatment of blood cholesterol, it was shown to reduce LDL-C by 40.8% in clinical trials. This would put in the moderate-intensity statin therapy category along with lovastatin 40 mg, which was shown to reduce LDL-C by 35.8% in clinical trials.*

Appendix C: Statin Risk Factors

The presence of the following characteristics increase the risk of adverse effects to statin therapy and may affect the ability to use high-intensity statins:

- Multiple or serious comorbidities, including impaired renal or hepatic function
- History of previous stain intolerance or muscle disorders
- Unexplained alanine aminotransferase elevation > 3 times upper limit of normal
- Patient characteristics or concomitant use of drugs affecting statin metabolism
- Age > 75 years
- History of hemorrhage stroke
- Asian ancestry

V. References

1. Altoprev Prescribing Information. Zug, Switzerland: Covis Pharma; April 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021316s034lbl.pdf. Accessed August 23, 2017.
2. Stone NJ, Robisnon J, Licthenstein 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. Circulation. 2013. DOI: 10.1161/01.cir.0000437738.63853.7a

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.23.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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