Reference number(s)
2574-A

SPECIALTY GUIDELINE MANAGEMENT

PCSK9i
PRALUENT (alirocumab), REPATHA (evolocumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
A. Members with established atherosclerotic cardiovascular disease.
B. Members with an untreated LDL-C of greater than, or equal to, 190 mg/dL.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Clinical atherosclerotic cardiovascular disease (ASCVD)
Authorization of 12 months may be granted for treatment of ASCVD when all of the following criteria are met:
1. The member has a history of clinical atherosclerotic cardiovascular disease or has experienced a cardiovascular event
2. The member has a current LDL-C level greater than, or equal to, 70 mg/dL
3. The member is receiving maximally tolerated statin therapy or is statin intolerant

B. Primary or familial hyperlipidemia
Authorization of 12 months may be granted for treatment of primary or familial hyperlipidemia when all of the following criteria are met:
1. The member had an untreated (before any lipid lowering therapy) LDL-C level greater than, or equal to, 190 mg/dL
2. The member has a current LDL-C level greater than, or equal to, 100 mg/dL
3. The member is receiving maximally tolerated statin therapy or is statin intolerant

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members who are continuing therapy with a PCSK9i.

IV. REFERENCES

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13. Min JK, Labounty TM, Gomez MJ, et al. Incremental prognostic value of coronary computed tomographic angiography over coronary artery calcium score for risk predication of major adverse cardiac events in asymptomatic diabetic individuals. Atherosclerosis. 2014;232(2):298-304.
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