

## 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.

- 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 are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. Clinical atherosclerotic cardiovascular disease (ASCVD)

Authorization of 12 months may be granted 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 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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