POLICY Document for PRALUENT AND REPATHA CareFirst Formulary 2 and Formulary 3

The overall objective of this policy is to support the appropriate and cost effective use of the medication and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
PCSK9i

PREFERRED PRODUCT: Repatha

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY
This program applies to the PCSK9i products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table 1. PCSK9i

	Product(s)
Preferred	• **Repatha** (evolocumab)
Targeted	• **Praluent** (alirocumab)

II. EXCEPTION CRITERIA

Coverage for the targeted product, Praluent, is provided when the member has failed treatment with Repatha due to a documented intolerable adverse event and the prescriber has a compelling medical rationale for not expecting the same event to occur with Praluent.

Section 2: Clinical Criteria

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
V.

SECTION 1:

1. Repatha [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2017.
2. Praluent [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; September 2017.

SECTION 2:

3. Repatha [package insert]. Thousand Oaks, CA: Amgen, Inc.; December 2017.
4. Praluent [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; September 2017.
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13. Sabatine MC, Giugliano RP, Keech AC, et al. Evolocumab and clinical outcomes in patients with cardiovascular disease. New England Journal of Medicine. 2017; Published online before print.
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16. Robinson, J. G., Rogers, W. J., Nedergaard, B. S., Fialkow, J., Neutel, J. M., Ramstad, D., Somaratne, R., Legg, J. C., Nelson, P., Scott, R., Wasserman, S. M. and Weiss, R. (2014), Rationale and Design of LAPLACE-2: A Phase 3, Randomized, Double-Blind, Placebo- and Ezetimibe-Controlled Trial Evaluating the Efficacy and Safety of Evolocumab in Subjects With Hypercholesterolemia on Background Statin Therapy. Clin Cardiol, 37: 195–203.