This policy applies to the following:

 ms poncy applies to the following.								
Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
Preferred Drug Plan Design (PDPD)	✓	Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
Advanced Control Specialty (ACSF)		New to Market (NTM)		VF Chart (VFC)		Medical Benefit: Add-on		Medicare Part B: Advanced Biosimilars First
Value (VF)	✓	Aetna Health Exchange (AHE)				Medical Benefit: Managed Medicaid		
	<b>✓</b>	IVL						

Reference #	
4280-D	

# **EXCEPTIONS CRITERIA**

**PCSK9** inhibitors

PREFERRED PRODUCT: PRALUENT

### **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 PCSK9 inhibitor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a 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. PCSK9 inhibitor products

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

<sup>\*:</sup> Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

#### II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for the targeted product is provided when either of the following criteria is met:

- A. Member has failed treatment with Praluent due to a documented intolerable adverse event and the prescriber has a compelling medical rationale for not expecting the same event to occur with Repatha.
- B. Member is 10 years old to less than 18 years old and the requested product is being requested for the treatment of heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia.

### **REFERENCES**

- 1. Praluent [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC; April 2021.
- 2. Repatha [package insert]. Thousand Oaks, CA: Amgen, Inc; September 2021.

Specialty Exceptions PCSK9i MF-IVL-AHE 4280-D P2023a.docx

© 2023 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

