CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Redemplo (plozasiran)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Redemplo, approved by the FDA in 2025, is an apolipoprotein C-III (apoC-III)-directed small interfering ribonucleic acid (siRNA) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). Reduction of apoC-III protein leads to increased clearance of serum triglycerides.
FCS is a rare, monogenic form of severe hypertriglyceridemia (HTG). Chylomicronemia is the accumulation in the bloodstream of chylomicrons (large TG-rich lipoprotein particles). FCS is caused by biallelic defects in lipoprotein lipase (LPL) or other genes related to LPL function. LPL is an enzyme that catabolizes triglyceride-rich lipoproteins, in particular chylomicrons and VLDL. Triglycerides can accumulate to a degree that impairs blood flow to the pancreas, leading to severe acute pancreatitis. Other symptoms include xanthomas, lipemia retinalis, and hepatosplenomegaly. Standard lipid-lowering drugs are only minimally effective in FCS due to the compromised activity of LPL.
Approval of Redemplo was based on results of the phase 3 placebo-controlled PALISADE study.

Redemplo (plozasiran) will be considered for coverage when the following criteria are met:

Familial Chylomicronemia Syndrome (FCS)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist, cardiologist, or lipid specialist; AND
3. Labs show a fasting triglyceride (TG) level of at least 880 mg/dL (10 mmol/L) refractory to standard lipid-lowering therapy (e.g., fibrates, omega 3); AND
4. Member has a diagnosis of FCS confirmed by at least one of the following:
   a) Genetic test results (i.e., biallelic pathogenic gene mutations in *LPL, GPIHBP1, APOA5, APOC2,* or *LMF1*)
   b) North American FCS (NAFCS) Score of at least 45; AND
5. Documentation to show the member will maintain a low-fat diet (i.e., 20 g fat or less per day).
6. **Dosage allowed/Quantity limit:** 25 mg subcutaneously once every 3 months.
   QL: 1 syringe per 84 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show a clinically significant reduction of triglyceride levels in response to Redemplo; AND
2. Attestation that the member is continuing a diet with less than 20 g of fat per day.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Redemplo (plozasiran) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/15/2025	New policy created for Redemplo.

References:

1. Redemplo [prescribing information]. Arrowhead Pharmaceuticals, Inc.; 2025.
2. Hegele RA, Ahmad Z, Ashraf A, et al. Development and validation of clinical criteria to identify familial chylomicronemia syndrome (FCS) in North America. *J Clin Lipidol*. 2025;19(1):83-94. doi:10.1016/j.jacl.2024.09.008
3. Javed F, Hegele RA, Garg A, et al. Familial chylomicronemia syndrome: An expert clinical review from the National Lipid Association. *J Clin Lipidol*. 2025;19(3):382-403. doi:10.1016/j.jacl.2025.03.013

Effective date: 07/01/2026
Revised date: 12/15/2025