Pharmacy Medical Necessity Guidelines:
Redemplo® (plozasiran)

Effective: June 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Redemplo (plozasiran) 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).

COVERAGE GUIDELINES

The plan may authorize coverage of Redemplo (plozasiran) for Members when the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of familial chylomicronemia syndrome (FCS) confirmed by ONE (1) of the following:
    a. Genetic testing results demonstrating biallelic pathogenetic variants in at least one gene known to cause FCS [for example, lipoprotein lipase (LPL), glycosylphosphatidylinositol-anchored HDL-binding protein 1 (GPIHBP1), apolipoprotein (apo) C-II (APOC2), apo A-V (APOA5), lipase maturation factor 1 (LMF1)]
    b. North American FCS (NAFCS) Score of at least 45 or higher
    c. Moulin FCS Score of at least 10 or higher

AND

2. The patient is at least 18 years of age or older

AND

3. Prescribed by cardiologist, endocrinologist, gastroenterologist, or lipidologist

AND

4. Documentation of baseline fasting triglyceride level that is greater than or equal to 880 mg/dL prior to treatment with a triglyceride-lowering medication

AND

5. Documentation of inadequate response or clinical inappropriateness to traditional triglyceride lowering therapies (for example, statin, omega-3 fatty acid, icosapent ethyl, fibrate)

AND

6. Documentation the patient will be maintained on low-fat diet (less than or equal to 20 grams of fat per day)

AND

7. Documentation the requested medication will not be used in combination with Tryngolza (olezarsen)

Reauthorization Criteria

1. Documented diagnosis of familial chylomicronemia syndrome (FCS) confirmed by ONE (1) of the following:
    a. Genetic testing results demonstrating biallelic pathogenetic variants in at least one gene known to cause FCS [for example, lipoprotein lipase (LPL), glycosylphosphatidylinositol-anchored HDL-binding protein 1 (GPIHBP1), apolipoprotein (apo) C-II (APOC2), apo A-V (APOA5), lipase maturation factor 1 (LMF1)]
    b. North American FCS (NAFCS) Score of at least 45 or higher
    c. Moulin FCS Score of at least 10 or higher

AND

2. The patient is at least 18 years of age or older

AND

3. Prescribed by cardiologist, endocrinologist, gastroenterologist, or lipidologist

AND

4. Documentation of baseline fasting triglyceride level that is greater than or equal to 880 mg/dL prior to treatment with a triglyceride-lowering medication

AND

5. Documentation the patient will be maintained on low-fat diet (less than or equal to 20 grams of fat per day)

AND

6. Documentation the requested medication will not be used in combination with Tryngolza (olezarsen)

AND

7. Documentation the patient has experienced a therapeutic response as defined by ONE (1) of the following:

    a. Reduction in fasting triglyceride level from baseline
    b. Reduction in incidence of acute pancreatitis

LIMITATIONS

- Initial and reauthorization approval of Redemplo will be authorized for 12 months.
- Members new to the plan stable on Redemplo should be reviewed against Reauthorization Criteria.
- Redemplo will be limited to a quantity of 1 syringe per 84 days.

CODES

None

REFERENCES

1. 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
2. Moulin P, Dufour R, Averna M, et al. Identification and diagnosis of patients with familial chylomicronaemia syndrome (FCS): expert panel recommendations and proposal of an "FCS score". *Atherosclerosis*. 2018;275:265-272.
3. Redemplo (plozasiran) [package insert]. Pasadena, CA: Arrowhead Pharmaceuticals, Inc.; November 2025.
4. Watts GF, Rosenson RS, Hegele RA, et al. Plozasiran for managing persistent chylomicronemia and pancreatitis risk. *New Engl J Med*. 2025;392(2):127-137.

APPROVAL HISTORY

May 12, 2026: Reviewed by Pharmacy & Therapeutics Committee.

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BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated.

Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic. Provider Services