Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Redemplo under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Redemplo is indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

Applicable Drug List:

Redemplo

Policy/Guideline:

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests:
- Genetic test(s) confirming diagnosis of FCS.
- Chart notes or medical record documentation indicating North American familial syndrome (NAFCS) score or Moulin score (if applicable).
- Laboratory tests or medical record documentation of fasting triglycerides (TG) level.

Continuation requests:
- Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

This medication must be prescribed by or in consultation with a cardiologist, endocrinologist, lipid specialist, geneticist, or a prescriber specialized in the treatment of FCS.

Criteria for Initial Approval:

Familial chylomicronemia syndrome (FCS)
Authorization of 12 months may be granted for treatment of familial chylomicronemia syndrome (FCS) (type 1 hyperlipoproteinemia) in adult members when ALL of the following criteria are met:
- Member meets EITHER of the following:
  - Member has a confirmed FCS diagnosis by genetic testing (i.e., biallelic pathogenic variants in FCS-causing genes [e.g., LPL, GPIHBP1, APOA5, APO2, LMF1, GPD1, CREB3L3]).
  - Genetic testing was inconclusive, and the member has confirmed FCS diagnosis by either of the following:

  - North American familial chylomicronemia syndrome (NAFCS) score greater than or equal to 45.
  - Moulin score greater than or equal to 10.
- Member has a fasting triglycerides (TG) level of more than or equal to 880 mg/dL.
- Member is currently receiving a very-low fat diet (e.g., less than 20 to 30 g of total fat per day, 10% to 15% of calories of fat).
- Member will not use the requested medication concomitantly with Tryngolza.

Criteria for Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in adult members requesting reauthorization for FCS when the following criteria are met:

- Member has demonstrated a positive clinical response with the requested medication (e.g., reduction in TG level from baseline, reduction in episodes of acute pancreatitis).
- Member is currently receiving a very-low fat diet (e.g., less than 20 to 30 g of total fat per day, 10% to 15% of calories per day of fat).
- Member will not use the requested medication concomitantly with Tryngolza.

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: One prefilled syringe per 90 days

References:

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3. Falko JM. Familial chylomicronemia syndrome: a clinical guide for endocrinologists. *Endocr Pract*. 2018;24(8):756-763.
4. Hegele RA, Boren J, Ginsberg HN, et al. Rare dyslipidaemias, from phenotype to genotype to management: a European Atherosclerosis Society task force consensus statement. *Lancet Diabetes Endocrinol*. 2020;8(1):50-67.
5. Spagnuolo CM, Hegele RA. Etiology and emerging treatments for familial chylomicronemia syndrome. Expert Rev Endocrinol Metab. 2024;19(4):299-306.
6. Javed F, Hegele RA, Garg A et al. Familial chylomicronemia syndrome: An expert clinical review from the National Lipid Association. *J Clin Lipidol*.2025; 19:382-403.
7. 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.
8. 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.
9. Brown AS, Moulin P, Dibble A et al. Brief communication: Strong concordance of the North American Familial Chylomicronemia Syndrome Score with a positive genetic diagnosis in patients from the Balance study. *J Clin Lipidol*. 2025; 11(16): 1-6.