Sample Letter of Medical Necessity

This letter is provided as an example that a prescriber's office can use to create an independent Letter of Medical Necessity, on your own office letterhead, to be sent to a patient's health plan to obtain a prior authorization decision from a health plan and/or in the event that there is a denial of coverage for Redemplo® (plozasiran) 25 mg. All bracketed pink content needs to be filled out based on the details of each specific patient. Be sure to review and understand specific health plan requirements for your patient, including checking to see if the patient's health insurance has their own template for you to follow when submitting a Letter of Medical Necessity. It is also important to understand each plan's submission process (online vs fax).

This sample letter is for informational purposes only. It is not intended to be construed as providing medical, legal or reimbursement advice. In no way does the provision of this sample letter provide any promise or guarantee of coverage or payment. It is strictly your responsibility to complete your letter of medical necessity in accordance with your best medical judgment.

INDICATION

REDEMPLO® (plozasiran) is indicated as an adjunct to diet to reduce triglycerides in adult patients with familial chylomicronemia syndrome (FCS).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: None.

ADVERSE REACTIONS: Most common adverse reactions in REDEMPLO treated patients (incidence ≥10% of patients treated with REDEMPLO and > 5% more frequently than with placebo) are hyperglycemia, headache, nausea, and injection site reaction.

Please see full Prescribing Information for REDEMPLO.

[Date]

Attention:
[Name of health insurance company]
[PO Box or street address]
[City], [State] [Zip code]
[Phone]
[Fax]

Regarding:
[Patient Name]
[Patient DOB]
Policy number: [Number]
Group number: [Number]
[Medicaid number:] [Number]
[Medicare Beneficiary Identifier:] [Number]

RE: Authorization for treatment with Redemplo® (plozasiran)

Dear [Medical Director/Contact Name],

I am writing on behalf of my patient, [patient name], to request authorization for treatment with Redemplo® (plozasiran) 25 mg. Redemplo is indicated as an adjunct to diet to reduce triglycerides in adult patients with Familial Chylomicronemia Syndrome (FCS)[1] and I strongly believe treatment with this product is medically necessary for my patient. The recommended dosage of Redemplo is 25 mg administered as a single subcutaneous injection every 3 months by the patient.[1]

[Patient name] was diagnosed with FCS on [MM/DD/YYYY]. This letter outlines [patient name]'s medical history, treatment rationale, and documentation to support the use of Redemplo for the treatment of FCS. This request is supported by the following information:

Summary of patient's relevant medical and treatment history:

- [Basis of diagnosis of FCS[1]]
- [Fasting triglyceride levels of ≥880 mg/dL[2]:
  – XXX mg/dL on DD/MM/YY
  – XXX mg/dL on DD/MM/YY
  – XXX mg/dL on DD/MM/YY]

- [Acute pancreatitis episodes (not caused by alcohol or cholelithiasis)[1] on:
  – DD/MM/YYYY
  – DD/MM/YYYY
  – DD/MM/YYYY]
- [Hospitalized or received emergency department care for severe abdominal pain without other explainable cause[1] on:
  – DD/MM/YYYY
  – DD/MM/YYYY
  – DD/MM/YYYY]
- [History of childhood pancreatitis[1]]
- [Family history of hypertriglyceridemia-induced acute pancreatitis[1]]
- [Brief description of the patient's current medical condition]
- [Patient's previous and current treatments specific to lowering triglycerides (ie, statin, fibrate)]
- [Include information on lack of response and/or tolerability on previous treatments (if applicable)]
- [Additional relevant laboratory results and dates]

Rationale for treatment:
Considering the patient's medical and treatment history, current medical condition [(including prior admissions and/or emergency department care for abdominal pain and/or acute pancreatitis)], lack of significant response to other therapies, and the indicated use of Redemplo, I believe treatment with Redemplo at this time is warranted, appropriate, and medically necessary for [patient name]. This is based on their medical and treatment history and current condition, and on the full Prescribing Information and published data for Redemplo.

Please promptly review the information provided [and enclosed documentation] to authorize treatment and approve [patient name]'s coverage for Redemplo. If you have any questions or require additional information to approve this request, please contact [me/my office] immediately using the information below.

Thank you for your attention on this matter. I look forward to hearing from you.

Sincerely,

[Physician name] [Credentials]

[Office address]

[Physician/office phone number]

[Physician/office email address]

Suggested links and materials for inclusion with this letter:

- [Redemplo Prescribing Information]
- [Redemplo FDA Approval Letter/Official press release]
- [Medical literature regarding the use of Redemplo for FCS]
- [Professional guidelines recommending the reduction of triglyceride levels to <500 mg/dL to lower the risk of acute pancreatitis (eg recommendations from American Association of Clinical Endocrinologists, American College of Endocrinology, American College of Cardiology, American Heart Association, National Lipid Association)]
- [Relevant clinical documentation, progress notes, treatment history, and outcomes]

References: 1. Redemplo. Prescribing Information. Arrowhead Pharmaceuticals, Inc.; 2025. **2.** Watts GF, Rosenson RS, Hegele RA, et al. Plozasiran for managing persistent chylomicronemia and pancreatitis risk. *N Engl J Med*. 2025;392(2)127-137.

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