Utilization Review Policy 388

POLICY: Transplantation – Yartemlea UM Medical Policy
- Yartemlea® (narsoplimab-wuug intravenous infusion – Omeros)

EFFECTIVE DATE: 05/15/2026
LAST REVISION DATE: 01/14/2026

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Yartemlea, a mannan-binding lectin-associated serine protease-2 inhibitor, is indicated for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy in adults and pediatric patients ≥ 2 years of age.[1]

Disease Overview

Transplant-associated thrombotic microangiopathy is a recognized complication of hematopoietic stem cell transplantation that can be severe and have life threatening consequences; non-relapse mortality may be adversely impacted as well.[2] This systemic condition is linked to endothelial injury and activation of the terminal complement pathway. Transplant-associated thrombotic microangiopathy is characterized by the development of microangiopathic hemolytic anemia, thrombocytopenia, and end-organ damage. The kidneys, gastrointestinal tract, central nervous system, heart, and lungs can be impacted. The gold standard for diagnosis is based on characteristic histologic findings and patients also have bleeding issues. Mortality rates among patients who develop multi-organ dysfunction, approximately one-half of the patients, range between 50% to 80%. Current management relies on supportive measures such as plasma exchange, dialysis, and transfusions. Some medications have been used off-label, such as complement inhibitors.

Dosing Information

For a patient ≥ 50 kg, the recommended dose is 370 mg given as an intravenous (IV) infusion over 30 minutes once weekly.[1] For a patient < 50 kg, the recommended dose is 4 mg/kg given as an IV infusion over 30 minutes once weekly. For both dosage regimens, the administration frequency can be increased to twice weekly if there is inadequate improvement in transplant-associated thrombotic microangiopathy symptoms.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Yartemlea. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Yartemlea as well as the monitoring required for adverse events and long-term efficacy, approval requires Yartemlea to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Yartemlea is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Transplant-Associated Thrombotic Microangiopathy.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 2 years of age; AND
   - **B)** Patient has undergone hematopoietic stem cell transplantation; AND
   - **C)** The medication is prescribed by or in consultation with a hematologist, oncologist, transplant specialist physician, or a physician associated with a transplant center.

   Dosing. Approve one of the following dosage regimens of Yartemlea given by intravenous infusion (A or B).
   - **A)** ≥ 50 kg: 370 mg no more than twice weekly; OR
   - **B)** < 50 kg: 4 mg/kg no more frequently than twice weekly.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Yartemlea is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Yartemlea® intravenous infusion [prescribing information]. Seattle, WA: Omeros; December 2025.
2. Schoettler ML, Gavriilaki E, Carreras E, et al, on behalf of the American Society for Transplantation and Cellular Therapy. An ASTCT, CIBMTR, EBMT and APBMT consensus statement defining response criteria for hematopoietic cell transplantation associated thrombotic microangiopathy (TA-TMA) directed therapy. *Transplant Cell Ther*. 2025;31(9):610-623.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/14/2026
UCare P&T Review	New policy reviewed and approved by UCare P&T committee.	03/16/2026