Drug Coverage Policy

Effective Date.....7/1/2026
Coverage Policy Number.....IP0789
Policy Title.....Yartemlea

Transplantation - Yartemlea

- Yartemlea® (narsoplimab-wuug intravenous infusion – Omeros)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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.

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POLICY STATEMENT
Prior Authorization is required for medical benefit coverage of Yartemlea. Approval is required 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.

Yartemlea is considered medically necessary when the following are met:

FDA-Approved Indication

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 Covered

Yartemlea for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals (Code effective until 6/30/2026)
J1289	Injection, narsoplimab-wuug, 1 mg (Code effective 7/1/2026)
J3490	Unclassified drugs (Code effective until 6/30/2026)
J3590	Unclassified biologics (Code effective until 6/30/2026)

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.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy.	4/1/2026
Selected Revision	**Coding Information:** **Added HCPCS** J1289 with a note "Code effective 7/1/2026" **Updated** the description for C9399, J3490 & J3590 to include the note "Code effective until 6/30/2026"	7/1/2026

The policy effective date is in force until updated or retired.

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