CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Yartemlea (narsoplimab-wuug)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Yartemlea, initially approved by the FDA in 2025, is a MASP-2 inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA).
TA-TMA is a multifactorial disorder characterized by endothelial damage from conditioning regimens, infections including graft-versus-host disease, immunosuppressive therapies and other transplant complications. It is marked by microvascular hemolysis, endothelial injury/activation and complement dysregulation. It is difficult to diagnosis given that cytopenias can be expected in hematopoietic stem cell transplant (HSCT) patients and lack of standardized diagnosis criteria. Clinical presentation can range from mild to severe with severe being rapidly progressive that can lead to end-organ dysfunction, including multiple organ dysfunction syndrome, and death.

Yartemlea (narsoplimab-wuug) will be considered for coverage when the following criteria are met:

Hematopoietic Stem Cell Transplant-associated Thrombotic Microangiopathy (TA-TMA)

For **initial** authorization:
1. Member is at least 2 years of age; AND
2. Medication must be prescribed by or in consultation with a hematologist or transplant specialist; AND
3. Member is post-hematopoietic stem cell transplant (HSCT); AND
4. Member has a diagnosis of TA-TMA confirmed by renal or intestinal biopsy (documentation must be included in chart notes); OR
5. Member has a diagnosis of TA-TMA confirmed by **ALL** of the following:
   a) Platelet count < 150,000/µL;
   b) Evidence of microangiopathic hemolysis (presence of schistocytes, serum LDH greater than the upper limit of normal [ULN] and/or haptoglobin less than the lower limit of normal [LLN]);
   c) Renal dysfunction; AND
6. Provider attests member does **NOT** have any of the following:
   a) Active infection;
   b) Positive direct Coombs test;
   c) Shiga Toxin-Producing Escherichia coli Hemolytic Uremic Syndrome (STEC-HUS); AND
7. Provider attests Yartemlea will not be used in combination with another complement inhibitor.
8. **Dosage allowed/Quantity limit:** Quantity limit: 4 vials per 28 days.
   a) Greater than or equal to 50 kg: administer 370 mg as an intravenous infusion once weekly.
   b) Less than 50 kg: administer 4 mg/kg as an intravenous infusion once weekly.

Of note: frequency can be increased to twice weekly if there is inadequate improvement in signs and symptoms (see reauthorization criteria).

If all the above requirements are met, the medication will be approved for 8 weeks.

For **reauthorization**:
1. Chart notes must show improvement in platelet count and LDH levels; AND
2. Chart notes must show improvement in organ function OR independence from transfusions; OR
3. If request is for dose escalation, chart notes must document inadequate improvement in signs and symptoms (platelet count, LDH level, organ function etc.).

If all the above requirements are met, the medication will be approved for an additional 8 weeks (total treatment duration cannot exceed 16 weeks).

CareSource considers Yartemlea (narsoplimab-wuug) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
03/13/2026	New policy for Yartemlea created.

References:

1. Yartemlea [prescribing information]. Omeros Corporation; 2025.
2. Schoettler ML, Gavriilaki E, Carreras E, et al. 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. doi:10.1016/j.jtct.2025.05.028
3. Khaled SK, Claes K, Goh YT, et al. Narsoplimab, a Mannan-Binding Lectin-Associated Serine Protease-2 Inhibitor, for the Treatment of Adult Hematopoietic Stem-Cell Transplantation-Associated Thrombotic Microangiopathy. *J Clin Oncol*. 2022;40(22):2447-2457. doi:10.1200/JCO.21.02389
4. Schoettler ML, Carreras E, Cho B, et al. Harmonizing Definitions for Diagnostic Criteria and Prognostic Assessment of Transplantation-Associated Thrombotic Microangiopathy: A Report on Behalf of the European Society for Blood and Marrow Transplantation, American Society for Transplantation and Cellular Therapy, Asia-Pacific Blood and Marrow Transplantation Group, and Center for International Blood and Marrow Transplant Research. *Transplant Cell Ther*. 2023;29(3):151-163. doi:10.1016/j.jtct.2022.11.015
5. Li A, Sartain SE. Transplant-associated TMA: the conundrum of diagnosis and treatment. *Hematology Am Soc Hematol Educ Program*. 2024;2024(1):206-213. doi:10.1182/hematology.2024000545
6. Matsui H, Arai Y, Kanda J, et al. Survival in adults with high-risk TA-TMA: a comparative analysis of narsoplimab vs supportive care. *Blood Adv*. 2026;10(1):111-120. doi:10.1182/bloodadvances.2025017540
7. Schoettler ML, Pusarla SK, Nangia N, et al. Narsoplimab Results in Excellent Survival in Adults and Children With Hematopoietic Cell Transplant Associated Thrombotic Microangiopathy (TA-TMA). *Am J Hematol*. 2025;100(11):2040-2051. doi:10.1002/ajh.70044

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