Neighborhood Health Plan OF RHODE ISLAND™
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Yartemlea® (narsoplimab-wuug)
(Intravenous)

Effective Date: 11/01/2026
Dates Reviewed: 08/17/2026
Scope: Medicaid, Commercial, Medicare

I. Length of Authorization

- Initial: Prior authorization coverage will be provided initially for 8 doses (eight weeks dosed once-weekly, or four weeks dosed twice-weekly).
- Renewal: Prior authorization coverage may be renewed for an additional 8 doses.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 370 billable units twice-weekly (740 mg every 7 days)

III. Summary of Evidence

Yartemlea (narsoplimab-wuug) is a mannan-binding lectin-associated serine protease-2 (MASP-2) inhibitor indicated for the treatment of adults and pediatric patients ≥2 years of age with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA). Yartemlea is the first therapy approved for TA-TMA, a serious and often fatal complication of hematopoietic stem cell transplantation characterized by endothelial injury, thrombocytopenia, hemolytic anemia, and organ dysfunction. The safety and efficacy of Yartemlea were evaluated in a Phase 2 single-arm study of 28 adults with TA-TMA and an expanded access program (EAP) that included 19 pediatric and adult patients. In the Phase 2 study, 61% of patients achieved a TMA response, defined as improvement in laboratory markers of TMA (LDH and platelet counts) along with either improvement in organ function or transfusion independence. The 100-day survival rate from time of TA-TMA diagnosis was 73.4% (95% CI: 52.2, 86.4) in the Phase 2 study and 73.7% (95% CI: 47.9, 88.1) in the EAP. Response rates were 67% in pediatric patients and 69% in adults treated through the EAP. Yartemlea was studied in a medically fragile population with severe disease and multiple risk factors for poor outcomes. The most common adverse reactions (≥20%) were viral infections, sepsis, hemorrhage, diarrhea, vomiting, nausea, neutropenia, pyrexia, fatigue, and hypokalemia. Serious adverse reactions occurred in 61% of patients and fatal adverse reactions occurred in 7%, including neutropenic sepsis and septic shock.

IV. Initial Approval Criteria

Coverage is provided in the following conditions:

- Member is at least 2 years of age; **AND**

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Universal Criteria [1]

- Member does not have an active infection, including clinically important localized infections (Note: If member has active infections, monitor closely for signs and symptoms of worsening infection during therapy with narsoplimab and treat promptly); **AND**
- Documentation that member does not have a positive direct Coombs test**; AND**
- Documentation that member does not have Shiga Toxin-Producing Escherichia coli Hemolytic Uremic Syndrome (STEC-HUS); **AND**

Transplant Associated-Thrombotic Microangiopathy (TA-TMA) † Φ [1,4]

- Yartemlea is prescribed by, or in consultation with, a hematologist or transplant specialist; **AND**
- Member is post-hematopoietic stem cell transplant (HSCT); **AND**
- Documentation that the member has a confirmed diagnosis of TA-TMA based on all of the following:
  - Platelet count less than 150,000/μL; **AND**
  - Evidence of microangiopathic hemolysis (i.e., presence of schistocytes, serum lactate dehydrogenase [LDH] greater than the upper limit of normal [ULN] and/or haptoglobin less than the lower limit of normal [LLN]); **AND**
  - Renal dysfunction (i.e., doubling of serum creatinine from pretransplant)
- The dose does not exceed one of the following:
  - Documented weight ≥50 kg: 370 mg once weekly; **OR**
  - Documented weight <50 kg: 4 mg/kg once weekly; **AND**
- Yartemlea will not be used in combination with another complement inhibitor (e.g., Soliris (eculizumab), Ultomiris (ravulizumab)); **AND**
- Medicare members who have previously received this medication within the past 365 days are not subject to step therapy requirements

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

V. Renewal Criteria [1,4]

Prior authorization validity can be renewed based upon meeting the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria identified in section IV; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious and/or life-threatening infections, etc.; **AND**
- Documentation that member has had a positive response to therapy defined as at least one of the following:
  - Improvement in platelet levels; **OR**
  - Normalization of LDH and/or haptoglobin; **OR**
  - Improvement in renal function and/or reduced need for dialysis; **AND**
- Member has not received treatment with Yartemlea for greater than 16 weeks

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VI. Dosage/Administration [1]

Indication	Dose
Transplant Associated-Thrombotic Microangiopathy (TA-TMA)	Weight ≥ 50 kg: – 370 mg given as an intravenous infusion over 30 minutes once weekly. Increase frequency to twice weekly if there is inadequate improvement in TA-TMA signs and symptoms. Weight < 50 kg: – 4 mg/kg given as an intravenous infusion over 30 minutes once weekly. Increase frequency to twice weekly if there is inadequate improvement in TA-TMA signs and symptoms.

VII. Billing Code/Availability Information

HCPCS Code(s):

- J1289 – Injection, narsoplimab-wuug, 1 mg

NDC(s):

- Yartemlea 370 mg/2 mL (185 mg/mL) single-dose vial in a carton: 62225-0300-xx

VIII. References

1. Yartemlea [package insert]. Seattle, WA; Omeros Corporation, December 2025. Accessed January 2026.
2. Stavrou E, Lazarus HM. Thrombotic microangiopathy in haematopoietic cell transplantation: an update. Mediterr J Hematol Infect Dis. 2010;2(3):e2010033. doi: 10.4084/MJHID.2010.033. Epub 2010 Nov 3. PMID: 21776339; PMCID: PMC3134219.
3. Carreras E, Diaz-Ricart M, Jodele S, et al. Early Complications of Endothelial Origin. 2024 Apr 11. In: Sureda A, Corbacioglu S, Greco R, et al., editors. The EBMT Handbook: Hematopoietic Cell Transplantation and Cellular Therapies [Internet]. 8th edition. Cham (CH): Springer; 2024. Chapter 42. Available from: https://www.ncbi.nlm.nih.gov/books/NBK608292/ doi: 10.1007/978-3-031-44080-9_42
4. Khaled SK, Claes K, Goh YT, et al; OMS721-TMA-001 Study Group Members. 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 Aug 1;40(22):2447-2457. doi: 10.1200/JCO.21.02389. Epub 2022 Apr 19.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M31.10	Thrombotic microangiopathy, unspecified
M31.11	Hematopoietic stem cell transplantation-associated thrombotic microangiopathy [HSCT-TMA]

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims

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payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:

Yartemlea was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Yartemlea according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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