Yartemlea® (narsoplimab-wuug)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter.

II. Dosing Limits

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

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

III. Initial Approval Criteria

Prior authorization validity is provided based upon meeting the following criteria:

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

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**
- Member does not have a positive direct Coombs test**; AND**
- Member does not have Shiga Toxin-Producing Escherichia coli Hemolytic Uremic Syndrome (STEC-HUS); **AND**

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

- Member is post-hematopoietic stem cell transplant (HSCT); **AND**
- 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)*

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

IV. 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 III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: serious and/or life-threatening infections, etc.; **AND**
    - Member has an improvement in clinical status in at least one organ system (e.g., blood, kidney, pulmonary, gastrointestinal, neurological, etc.) OR as evidenced by independence from RBC and/or platelet transfusions; **AND**
        - Response to therapy defined as BOTH of the following changes in TMA markers:
            - LDH levels less than 1.5x ULN; **AND**
            - Improvement in platelet count; **AND**
                - For baseline platelet count ≤ 20,000/µL:
                    - ≥ 3-fold increase in platelet count; **AND**
                    - Post-baseline platelet count > 30,000/µL; **AND**
                    - Receipt of no platelet transfusions within 2 days prior to the platelet count assessment; **OR**
                - For baseline platelet count > 20,000/µL:
                    - ≥ 50% increase in platelet count; **AND**
                    - Platelet count > 75,000/µL; **AND**
                    - Receipt of no platelet transfusions within 2 days prior to the platelet count assessment; **OR**
    - Member has had an inadequate improvement in TA-TMA signs and symptoms**; AND**
        - Member requires an escalation in dosing frequency to twice weekly to maximize effectiveness

V. 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.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3590 – Unclassified biologics

NDC(s):

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

VII. 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 A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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 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