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Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	July 1, 2026
Subject:	Yartemlea	**Page:**	1 of 5

Last Review Date: June 11, 2026

Yartemlea

Description

Yartemlea (narsoplimab-wuug)

Background
Yartemlea (narsoplimab-wuug) inhibits MASP-2, the effector enzyme of the lectin pathway of the complement system, blocking lectin-dependent activation of complement component 3 (C3) and C4 without affecting the classical and alternative pathways of complement. In hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA), MASP-2 inhibition is thought to prevent lectin pathway-mediated cellular injury, including endothelial cell injury in small blood vessels (1).

Regulatory Status
FDA-approved indication: Yartemlea 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) (1).

Yartemlea has been associated with serious and life-threatening infections. If Yartemlea is administered to patients with active infections, monitor closely for signs and symptoms of worsening infection and treat promptly (1).

The safety and effectiveness of Yartemlea in pediatric patients less than 2 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Yartemlea may be considered **medically necessary** if the conditions indicated below are met.

Yartemlea may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

1. Hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA)

AND ALL of the following:

a. Diagnosis confirmed by **ALL** of the following:
   i. Platelets < 150,000 µL
   ii. Evidence of microangiopathic hemolysis (presence of schistocytes, serum LDH greater than the upper limit of normal, and/or haptoglobin less than the lower limit of normal)
   iii. Anemia (failure to achieve red cell transfusion independence, new transfusion dependence, or hemoglobin decline by ≥1 g/dL)
   iv. Proteinuria ≥ 1 mg/mg
b. Patient has an ADAMTS13 activity level ≥ 10%
c. **NO** dual therapy with another Prior Authorization (PA) complement inhibitor (see Appendix 1)

Prior–Approval *Renewal* Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

1. Hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. **NO** dual therapy with another Prior Authorization (PA) complement inhibitor (see Appendix 1)

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity 24 vials per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Yartemlea (narsoplimab-wuug) is a MASP-2 inhibitor indicated for the treatment of patients with hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA). Yartemlea has been associated with serious and life-threatening infections. The safety and effectiveness of Yartemlea in pediatric patients less than 2 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Yartemlea while maintaining optimal therapeutic outcomes.

References

1. Yartemlea [package insert]. Seattle, WA: Omeros Corporation; December 2025.
2. 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.

Policy History

Date	Action
July 2026	Addition to PA. Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.

Appendix 1 - List of PA complement inhibitors

Generic Name	Brand Name
crovalimab-akkz	Piasky
eculizumab	Soliris
pozelimab-bbfg	Veopoz
ravulizumab-cwvz	Ultomiris
zilucoplan	Zilbrysq