Medical Drug Clinical Criteria

Subject:	Yartemlea (narsoplimab-wuug)		
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Overview

This document addresses the use of Yartemlea (narsoplimab-wuug) for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). Yartemlea is a fully human immunoglobulin G4 monoclonal antibody that binds to and inhibits MAST-2. Via this inhibition, Yartemlea blocks lectin pathway activation while leaving the adaptive immune response intact and fully functional. In clinical trials, patients received Yartemlea for 4-8 weeks with a median of 8 doses.

HSCT-TMA is a rare, but severe, and often fatal, complication of stem cell transplants caused by endothelial cell damage triggered by therapies, infection, graft vs. host disease, and other factors associated with stem cell transplants. HSCT occurs in mostly allogeneic transplantations, but can exist in both autologous and allogeneic transplants. Currently, there is no approved therapy or standard of care for HSCT-TMA.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Yartemlea (narsoplimab-wuug)

Requests for Yartemlea (narsoplimab-wuug) may be approved if the following criteria are met:

I. Individual has a diagnosis of persistent hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA); **AND**
II. Individual is 2 years of age and older; **AND**
III. Individual meets all of the following (Khaled 2022):
   A. Platelet count of less than 150 x 10^9/L; **AND**
   B. Evidence of microangiopathic hemolysis; **AND**
   C. Evidence of renal dysfunction defined as a doubling of serum creatinine from pretransplant; **AND**
   D. Alternative etiologies for thrombocytopenia and anemia have been ruled out.

Yartemlea (narsoplimab-wuug) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J1289	Injection, narsoplimab-wuug, 1 mg [Yartemlea]

ICD-10 Diagnosis

M31.11	Hematopoietic stem cell transplantation-associated thrombotic microangiopathy [HSCT-TMA]

Document History

Revised: 08/14/2026
Document History:

- 08/14/2026 – Annual Review: Update may not be approved criteria. Coding Reviewed: No changes.
- 06/12/2026 – Coding Update: Removed HCPCS NOC C9399 and J3590 effective 6/30/26 and added J1289 effective 7/1/26.
- 02/20/2026 – New Drug Review: Added new clinical criteria for Yartemlea.

References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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