Draft New Policy: Do Not Implement

Narsoplimab-wuug (Yartemlea®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Yartemlea is 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).

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- For initial requests:
  - Chart notes or medical record documentation confirming the diagnosis of TA-TMA
  - Laboratory report confirming ADAMTS13 activity
- For continuation requests: Chart notes or medical record documentation supporting positive clinical response to therapy

COVERAGE CRITERIA

Transplant-Associated Thrombotic Microangiopathy (TA-TMA)

Authorization of 6 months may be granted for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) when all of the following criteria are met:

- The member is 2 years of age or older
- Diagnosis has been confirmed by all of the following:
  - Platelet count < 150,000/µL
  - 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])
- The member has an ADAMTS13 activity level ≥10%
- The requested medication will not be used in combination with another complement inhibitor (e.g., Soliris, Ultomiris) or Defitelio (defibrotide)

CONTINUATION OF THERAPY

Authorization of 12 months (including new members) may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no unacceptable toxicity while on the current regimen, the member demonstrates a positive response to therapy (e.g., improvement in platelet levels, normalization of lactate dehydrogenase [LDH] and haptoglobin levels), and the requested medication will not be used in combination with another complement inhibitor (e.g., Soliris, Ultomiris) or Defitelio (defibrotide).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

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

EFFECTIVE DATE

ID_CHS_2026