

AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed.**

For Medicare Members: 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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Yartemlea[®] (narsoplimab-wuug) (J3590) (MEDICAL)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage

- 370 mg (or 4 mg/kg if less than 50 kg) once weekly; increase frequency to twice weekly if needed
- Initiating therapy: 2 vials once weekly

Maximum Units:

- Yartemlea 370 mg/2 mL (185 mg/mL) single-dose vial in a carton: 62225-0300-xx
- Maximum Units: 370 mg twice weekly (740 mg every 7 days)

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 8 weeks

- Member is 2 years of age or older
 - Provider is a specialist in hematology or stem cell transplant, or in consultation with a multidisciplinary team trained in handling complications of stem cell transplants
 - Member is post-hematopoietic stem cell transplant (HSCT) (**submit chart notes with documented history of procedure**)
 - Member is experiencing Transplant Associated-Thrombotic Microangiopathy (TA-TMA) meeting **ALL** the following:
 - Platelet count less than 150,000/ μ L
 - 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])
 - Renal dysfunction defined as doubling of serum creatinine from pretransplant, or requiring dialysis
 - Member does **NOT** have an active infection, including clinically important localized infections
 - Member does **NOT** have a positive direct Coombs test
 - Member does **NOT** have Shiga Toxin-Producing Escherichia coli Hemolytic Uremic Syndrome (STEC-HUS)
 - Member does **NOT** have a hereditary condition resulting in a deficiency of a disintegrin and metalloproteinase with thrombospondin type 1 motif, member13 (ADAMTS13)
 - Provider will **NOT** attempt to use Yartemlea[®] (narsoplimab-wuug) concurrently with eculizumab (e.g., Soliris[®], Bkmv[™], Epsyqli[®]) or ravulizumab [Ultomiris[®]]
 - The initiating dose will **NOT** exceed the following
 - Weight \geq 50 kg: 370 mg once weekly
- OR**
- Weight < 50 kg: 4 mg/kg once weekly

Reauthorization: 8 weeks. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- Member continues to meet the indication-specific, safety, and therapeutic preclusion relevant criteria identified in the section above
- Member has **NOT** received Yartemlea[®] (narsoplimab-wuug) for > 16 weeks

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- Member is **NOT** experiencing unacceptable toxicity from drug therapy (i.e. serious and/or life-threatening infections such as including sepsis, viral infections, pneumonia, bacteremia, fungal infection, gastroenteritis, respiratory tract infection, and urosepsis)
 - Member has an improvement in clinical status evidenced by **ONE** of the following (**submit chart notes obtained from the time since the previous approval and/or recent progress notes required**):
 - Improvement in clinical status in at least one organ system (e.g., blood, kidney, pulmonary, gastrointestinal, neurological, etc.)
 - Reduction in, or independence from, RBC and/or platelet transfusions
 - Laboratory documentation has been submitted demonstrating disease stability in **ALL** the following:
 - Platelet count response based on **ONE** of the following:
 - For baseline platelet count $\leq 20,000/\mu\text{L}$: improvement of 3-fold or more increase in platelet count, a post-baseline platelet count measuring $> 30,000/\mu\text{L}$, or no platelet transfusions received within 2 days prior to the platelet count assessment
 - For baseline platelet count $> 20,000/\mu\text{L}$: improvement $\geq 50\%$ increase in platelet count, a post-baseline platelet count measuring $> 75,000/\mu\text{L}$, no platelet transfusions received within 2 days prior to the platelet count assessment
 - Response in lactate dehydrogenase (LDH) level measuring less than 1.5 x ULN
 - Member has had an inadequate improvement in TA-TMA signs and symptoms and requires an escalation in dosing frequency to twice weekly to maximize effectiveness with **ONE** of the following weight-based dosing regimens:
 - Weight ≥ 50 kg: 370 mg twice weekly
- OR**
- Weight < 50 kg: 4 mg/kg twice weekly

Medication being provided by: Please check applicable box below.

- Location/site of drug administration:** _____
NPI or DEA # of administering location: _____

OR

- Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****