

PA Criteria	Criteria Details	
Description	YARTEMLEA is a mannan-binding lectin-associated serine protease 2 (MASP-2) inhibitor.	
Covered Uses (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).	
Dosing and Administration	Weight (kg)	Recommended Dosage
	≥ 50 kg	370 mg IV infusion over 30 minutes once weekly. Increase frequency to twice weekly if there is inadequate improvement in TA-TMA signs and symptoms.
	< 50 kg	4 mg/kg IV infusion over 30 minutes once weekly. Increase frequency to twice weekly if there is inadequate improvement in TA-TMA signs and symptoms.
	Continue therapy until complete resolution of TA-TMA signs and symptoms. PLEASE NOTE: The median duration of treatment with YARTEMLEA in clinical trials was eight weeks .	
Billing and Coding Information	10-digit NDC	11-digit NDC
	62225-300-00	62225-0300-00
	HCPCS Code	Description
	J3590	Unclassified biologics
	C9399	Unclassified drugs or biologicals
	CPT Procedural Codes	Description
96395	Ther/proph/diag IV infusion, initial	
96413	Chemotherapy IV infusion, up to one hour	
Product Availability	<i>Single-dose vial: 370 mg/2 mL (185 mg/mL)</i>	
Contraindications	None.	
Recommended Medical Monitoring	YARTEMLEA may be associated with serious infections; monitor patients for signs/symptoms and treat appropriately.	

Approval Criteria	<p>A. Physician administered IV infusion; in-office or HOPD</p> <ol style="list-style-type: none"> 1. Cannot be self-administered <p>B. Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy (must meet ALL):</p> <ol style="list-style-type: none"> 1. Diagnosis of hematopoietic stem cell TA-TMA; 2. Prescribed by or in consultation with a hematologist or transplant specialist; 3. Age \geq 2 years; 4. Member has signs of persistent TMA as evidenced by presence of ALL of the following for at least two weeks after modification or discontinuation of calcineurin inhibitor therapy (e.g., cyclosporine, tacrolimus) (a, b, and c): <ol style="list-style-type: none"> a. Platelet count $<$ 150 x 10⁹ /L; b. Evidence of hemolysis (e.g., serum lactate dehydrogenase [LDH] above the upper limit of normal, presence of schistocytes); c. Serum creatinine \geq 2X pre-transplantation baseline or member requires dialysis; 5. Documentation that member does NOT have any of the following (a, b, and c): <ol style="list-style-type: none"> a. A disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13 (ADAMTS13) deficiency; b. Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS); c. Atypical hemolytic uremic syndrome (aHUS); 6. Yartemlea is not prescribed concurrently with Soliris®/Bkern™/Epysqli® or Ultomiris®; 7. Dose does not exceed one of the following (a or b): <ol style="list-style-type: none"> a. Weight \geq 50 kg: 370 mg twice weekly; OR b. Weight $<$ 50 kg: 4 mg/kg twice weekly. 8. If request is for reauthorization of therapy, member must meet all criteria above AND must NOT have received Yartemlea for $>$ 16 weeks.
Age Restriction	Age \geq 2 years old.
Coverage Duration	<p>Initial/Reauthorization: 8 weeks.</p> <p>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.</p>
Other Criteria (LCD, NCD, etc.)	None.
Misc Info, Appendix Etc.	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	4/22/26	4/22/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	5/14/26	Pharmacy & Therapeutics (P&T) Committee	5/14/26