

Clinical Policy Title:	TTR stabilizers
Policy Number:	RxA.886
Drug(s) Applied:	Attruby, Vyndamax, Vyndaquel
Original Policy Date:	6/19/2025
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Cardiomyopathy of Transthyretin-Mediated Amyloidosis (ATTR-CM) (must meet all):

1. Diagnosis of ATTR-CM confirmed by one of the following (a, b, or c):
 - a) Genetic testing confirming TTR gene mutation for variant ATTR-CM;
 - b) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of ATTR amyloid deposits;
 - c) ECG or cardiac MRI suggestive of amyloidosis and both of the following (i and ii):
 - i) Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake;
 - ii) Systemic light chain amyloidosis ruled out by a urine or blood test showing absence of monoclonal proteins;
 - iii) Member has symptomatic heart failure classified as NYHA class I, II, or III;
2. Member has not received a liver transplant.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Cardiomyopathy of Transthyretin-Mediated Amyloidosis (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. Fontana, Marianna, et al. "Changing Treatment Landscape in Transthyretin Cardiac Amyloidosis." *Circulation Heart Failure*, 31 Mar. 2025, <https://doi.org/10.1161/circheartfailure.124.012112>.
2. Schwarting, Stéphanie Kristina, et al. "Guideline-Directed Medical Therapy for Heart Failure in Transthyretin Amyloid Cardiomyopathy." *Circulation. Heart Failure*, vol. 18, no. 4, Apr. 2025, p. e011796, pubmed.ncbi.nlm.nih.gov/39963776/, <https://doi.org/10.1161/CIRCHEARTFAILURE.124.011796>.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	6/19/25	6/19/25
Policy reviewed	12/11/2025	12/11/2025

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.