

Attruby (acoramidis)
Effective 07/01/2025

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Attruby (acoramidis) is a transthyretin stabilizer indicated for the treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.

Coverage Guidelines

Authorization may be granted for members new to the plan within the past 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance program

OR

Authorization may be granted when all of the following criteria are met:

1. Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM)
2. Member is 18 years of age or older
3. Diagnosis is confirmed by at least ONE of the following:
 - a. Presence of transthyretin (TTR) mutation (e.g., V122I)
 - b. Presence of TTR amyloid deposits in biopsy tissue
 - c. Cardiac magnetic resonance imaging or scintigraphy scan suggestive of amyloidosis and light chain testing has ruled out light chain amyloidosis (AL amyloidosis)
4. Member has New York Heart Association (NYHA) Functional Class I, II, or III heart failure
5. Requested medication is not used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., diflunisal, Vyndamyax, Vyndaqel)
6. Requested medication is prescribed by or in consultation with a cardiologist.

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Documentation is submitted demonstrating member has had a positive clinical response to therapy (e.g., improvement in 6-minut walk test [6MWT] compared to baselined, decreased number of cardiovascular-related hospitalizations, improvement in Kansas City Cardiomyopathy Questionnaire, improvement in signs and symptoms, slowing of disease progression)

Limitations

1. Initial and reauthorization requests will be approved for 12 months.

References

1. Attruby (acoramidis) [prescribing information]. Palo Alto, CA: BridgeBio Pharma, Inc; November 2024.
2. Buxbaum JN, Ruberg FL. Transthyretin V122I (pV142I)* cardiac amyloidosis: an age dependent autosomal dominant cardiomyopathy too common to be overlooked as a cause of significant heart disease in elderly African Americans. *Genet Med.* 2017;19(7):733-742.
3. Buxbaum JN. Oligonucleotide drugs for transthyretin amyloidosis. *N Engl J Med.* 2018;379-381.
4. Carroll A, Dyck PJ, de Carvalho M, et al. Novel approaches to diagnosis and management of hereditary transthyretin amyloidosis. *J Neurol Neurosurg Psychiatry.* 2022;93:668-678. doi: 10.1136/jnnp-2021-327909.
5. Coelho T, Conceicao I, Waddington-Cruz M, et al on behalf of the THAOS investigators. A natural history analysis of asymptomatic TTR gene carriers as they develop symptomatic transthyretin amyloidosis in the Transthyretin Amyloidosis Outcomes Survey (THAOS). *Amyloid.* 2022. doi: 10.1080/13506129.2022.2070470
6. Coelho T, Maurer MS, Suhr OB. THAOS - The Transthyretin Amyloidosis Outcomes Survey: initial report on clinical manifestations in patients with hereditary and wild type transthyretin amyloidosis. *Curr Med Res Opin.* 2013[b];29(1):63-76.
7. Dispenzieri A, Coelho T, Conceicao I, et al on behalf of the THAOS investigators. Clinical and genetic profile of patients enrolled in the Transthyretin Amyloidosis Outcomes Survey (THAOS): 14-year updated. *Orphanet J Rare Dis.* 2022;17:236.
8. Dorbala S, Ando Y, Bokhari et al. ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMMI expert consensus recommendations for multimodality imaging in cardiac amyloidosis. Part 1 of 2 – evidence base and standardized methods of imaging. *Circ Cardiovasc Imaging.* 2021[a];14:e000029. doi: 10.1161/HCI.0000000000000029.
9. Dorbala S, Ando Y, Bokhari et al. ASNC/AHA/ASE/EANM/HFSA/ISA/SCMR/SNMMI expert consensus recommendations for multimodality imaging in cardiac amyloidosis. Part 2 of 2 – diagnostic criteria and appropriate utilization. *Circ Cardiovasc Imaging.* 2021[b];14:e000030. doi: 10.1161/HCI.0000000000000030.
10. Dyck PJB, González-Duarte A, Obici L, et al. Development of measures of polyneuropathy impairment in hATTR amyloidosis: from NIS to mNIS+7. *J Neurol Sci.* 2019;405:116424.
11. Gillmore JD, Judge DP, Cappelli F, et al. Efficacy and safety of acoramidis in transthyretin amyloid cardiomyopathy. *N Engl J Med.* 2024;390(2):132-142.
12. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol.* 2022;79:e263-e421.
13. Ibrahim M, Saint Croix GR, Lacy S, et al. The use of diflunisal for transthyretin cardiac amyloidosis: a review. *Heart Failure Rev.* 2022;27:517-524.
14. Kittleson MK, Maurer MS, Ambardekar AV, et al. Cardiac amyloidosis: evolving diagnosis and management: a scientific statement from the American Heart Association. *Circ.* 2020;142:e7-e22. doi: 10.1161/CIR.0000000000000792.
15. Kittleson MM, Ruberg FL, et al. 2023 ACC expert consensus decision pathway on comprehensive multidisciplinary care for the patient with cardiac amyloidosis: a report of the american college of cardiology solution set oversight committee. *J Am Coll Cardiol.* 2023;81(11):1076-1126.



16. Maurer MS, Hanna M, Grogan M, et al. Genotype and phenotype of transthyretin cardiac amyloidosis: THAOS (Transthyretin Amyloid Outcome Survey). *J Am Coll Cardiol.* 2016;68(2):161-172.
17. Midwest Comparative Effectiveness Public Advisory Council (CEPAC) for the Institute for Clinical and Economic Review (ICER). Disease modifying therapies for the treatment of transthyretin amyloid cardiomyopathy. Final Evidence Report. October 21, 2024. https://icer.org/wp-content/uploads/2024/03/ICER_ATTR-CM_Final-Report_For-Publication_10212024.pdf. Accessed January 16, 2025.
18. Parcha V, Malla G, Ivin MR, et al. Association of transthyretin Val122Ile variant with incident heart failure among Black individuals. *JAMA.* 2022;327(14):1368-1378.
19. Pocock SJ, Gregson J, Collier TJ, Ferreira JP, Stone GW. The win ratio in cardiology trials: lessons learnt, new developments, and wise future use. *Eur Heart J.* 2024;45(44):4684-4699.

Review History

04/09/2025 – Reviewed at April P&T. Effective 07/01/2025.

