MEDICAL MUTUAL®

Drug Policy

Policy:	Transthyretin (TTR) dissociation inhibitors • Attruby (acoramidis tablets – Bridgebio) • Vyndaqel (tafamidis meglumine capsules – Pfizer) • Vyndamax (tafamidis capsules – Pfizer)	**Annual Review Date: 02/20/2025** **Last Revised Date: 02/20/2025**

OVERVIEW

Attruby, Vyndamax, and Vyndaqel are transthyretin (TTR) stabilizers that are indicated for the treatment of the **cardiomyopathy of wild-type or variant TRR-mediated amyloidosis (ATTR-CM)** to reduce cardiovascular death and cardiovascular-related hospitalization in adults.[1] Studies excluded patients with New York Heart Association class IV disease.[2]

POLICY STATEMENT

This policy involves the use of Attruby, Vyndamax, and Vyndaqel. Prior authorization is recommended for pharmacy benefit coverage of Attruby, Vyndamax, and Vyndaqel. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Attruby, Vyndamax, and Vyndaqel as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Attruby, Vyndamax, and Vyndaqel be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Attruby, Vyndamax, and Vyndaqel is recommended in those who meet the following criteria:

1. <u>Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis</u>
Criteria. *Patient must meet the following criteria*

Initial Therapy, *Patient must meet all of the following* (A, B, C, D, E, F, *<u>and</u>* G):

A. Patient is 18 years of age or older; AND
B. The diagnosis was confirmed by ONE of the following* (i, ii, <u>or</u> iii):
- i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy); OR
- ii. A tissue biopsy with confirmatory transthyretin (TTR) amyloid typing by mass spectrometry, immunoelectron microscopy or immunohistochemistry; OR
- iii. Patient had genetic testing which, according to the prescriber, identified a transthyretin (TTR) pathogenic variant; AND
  <u>Note</u>: Examples of TTR variants include Val122Ile variant and Thr60Ala variant. If the patient has wild-type amyloidosis, this is **<u>not</u>** a TTR pathogenic variant.

C. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction); AND
D. The patient has both of the following* (i AND ii):
  i. Patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level greater than or equal to 600 pg/mL; AND
  ii. One of the following (I or II):
    I. Patient has New York Heart Association (NHYA) Functional Class I or II; OR
    II. Patient has both of the following:
      1. Patient has New York Heart Association (NYHA) Functional Class III; AND
      2. Patient's cardiopulmonary functional status allows patient to ambulate 100 meters or greater in 6 minutes or less; AND
E. Patient has a medical history of either of the following (I OR II); AND
  i. At least one prior hospitalization for heart failure; OR
  ii. Clinical evidence of heart failure manifested by signs or symptoms of volume overload or elevated intracardiac pressures (e.g. elevated jugular venous pressure, shortness of breath or sings of pulmonary congestion on x-ray or auscultation, peripheral edema) requiring treatment with a diuretic for improvement
F. Patient must have evidence of cardiac involvement by echocardiography OR MRI with an end-diastolic interventricular septal wall thickness >12 mm; AND
G. The medication is prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis; AND

***Continuation of therapy**, Patient must meet all the following:*

A. Patient has previously received treatment with the medication; AND
B. Patient has demonstrated a beneficial response to treatment with the medication* (e.g. reduction in hospitalizations, improvement or stabilization in 6-Minute Walk Test, improvement in symptom burden or frequency); AND
C. The patient continues to have New York Heart Association (NYHA) Functional Class I, II, or II heart failure*; AND
D. The medication is prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Attruby, Vyndamax, and Vyndaqel has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concurrent use with other medications indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., Amvuttra [vutrisiran subcutaneous injection], Onpattro [patisiran intravenous infusion], Tegsedi [inotersen subcutaneous injection], Wainua [eplontersen subcutaneous injection], or a tafamidis product).**
   The requested medication should not be administered in combination with other medications indicated for polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy. Combination therapy is generally not recommended due to a lack of controlled clinical trial data supporting additive efficacy.

2. **Concurrent Use of Vyndaqel and Vyndamax.** There are no data available to support concomitant use.

3. **Polyneuropathy of Hereditary Transthyretin–Mediated Amyloidosis (hATTR).** Attruby is not indicated for treatment of symptoms of polyneuropathy associated with hATTR.[1]
   Note: For patients with hATTR and cardiomyopathy or mixed phenotype (concurrent cardiomyopathy and polyneuropathy), refer to FDA-Approved Indication, above.

2. **Patients with NYHA functional Class IV**

3. **Patients with the presence of primary (light chain) amyloidosis**

4. **Patients with a prior liver or heart transplantation or implanted cardiac mechanical assist device**

5. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available

***Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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