Policy Name:	Vyndaqel/Vyndamax (tafamidis meglumine)	Policy#:	2714P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Vyndaqel or Vyndamax.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Vyndaqel (tafamidis meglumine) or Vyndamax (tafarnidis meglumine) under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of transthyretin (ATIR) - mediated amyloidosis with cardiomyopathy (ATIR-CM)

1.2 One of the following:
- Documentation that the patient has a pathogenic TIR mutation (e.g., V30M), or
- Cardiac or non-cardiac tissue biopsy demonstrating histologic confirmation of ATIR amyloid deposits, or
- ALL of the following:
  - Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, and
  - Radionuclide imaging (99mTc-DPD, 99mTc-PYP, or 99m Tc-HMDP) showing grade 2 or 3 cardiac uptake, and
  - Absence of monoclonal protein identified in serum, urine immunofixation (JFE), serum free light chain (sFLC) assay

1.3 Prescribed by or in consultation with a cardiologist (heart doctor)

1.4 Presence of clinical signs and symptoms of cardiomyopathy (e.g., heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)

1.5 Documentation of BOTH of the following:
- One of the following:
  - Patient has New York Heart Association (NYHA) Functional Class I or II heart failure, or
  - Patient has New York Heart Association (NYHA) Functional Class III heart failure, and patient's cardiopulmonary functional status allows patient to ambulate I00 meters or greater in 6 minutes or less
- Patient has an N-terminal pro-B-type naturetic peptide (NT-proBNP) level greater than or equal to 600 pg/mL

1.6 Documentation of previous trial and failure or contraindication to Attruby (acoramidis)

2. Exclusion Criteria

2.1 Concomitant use with any other disedase modifying therapy for ATIR-CM

3. Approval Period

3.1 Initial Approval: 12 months

3.2 Reapproval: 12 months with documentation that the patient has experienced a positive clinical response to VyndaqeWyndamax (e.g., improved symptoms, quality of life, slowing of disease progression, decreased hospitalizations, etc.)

References

1. Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) [prescribing information]. New York, NY: Pfizer Labs; October 2023.
2. Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med 2018; 379:1007.
3. Bulawa CE, Connelly S, Devit M, et al. Tafamidis, a potent and selective transthyretin kinetic stabilizer that

inhibits the amyloid cascade. Proc Natl Acad Sci US A 2012; 109:9629.
4. Kittleson MM, Maurer MS, Ambardekar AV, et al; American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology. Cardiac Amyloidosis: Evolving Diagnosis and Management: A Scientific Statement From the American Heart Association. Circulation. 2020 Jul 7;142(1):e7-e22.

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