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| **Clinical Policy Title:** | tafamidis |
| **Policy Number:** | RxA.618 |
| **Drug(s) Applied:** | Vyndaqel®, Vyndamax® |
| **Original Policy Date:** | 03/06/2020 |
| **Last Review Date:** | 8/28/2024 |
| **Line of Business Policy Applies to:** | All lines of business (except Medicare) |

## Criteria

**I. Initial Approval Criteria**

**A. Transthyretin Amyloid Cardiomyopathy** (must meet all)**:**

1. Diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis;
2. Cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 mm);
3. One of the following (a or b):
   a. Biopsy is positive for amyloid deposits; or
   b. Technetium-labelled bone scintigraphy tracing results confirm presence of amyloid deposits;
4. One of the following (a or b):
   a. For members with wild type ATTR-CM, presence of TTR precursor protein confirmed by immunohistochemistry, scintigraphy, or mass spectrometry); or
   b. For members with hereditary ATTR-CM, presence of a TTR mutation confirmed by genetic testing;
5. Negative serum or urine test for amyloid light chains;
6. Member has not had a liver transplant;
7. Vyndaqel®/Vyndamax® is not prescribed concurrently with Onpattro® and Tegsedi®.

**Approval Duration**

**All Lines of Business (except Medicare):** 6 months

**II. Continued Therapy Approval**

**A. Transthyretin Amyloid Cardiomyopathy** (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. Lin H, Merkel M, Hale C, Marantz JL. Experience of patisiran with transthyretin stabilizers in patients with hereditary transthyretin-mediated amyloidosis. Neurodegener Dis Manag. 2020;10(5):289-300. Available: https://pubmed.ncbi.nlm.nih.gov/32519928/. Accessed August 28, 2024.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
|---|---|---|
| Policy established. | 01/01/2020 | 03/06/2020 |
| Policy was reviewed<br>1. Policy formatting updated.<br>2. Policy applies to all lines of business.<br>3. Criteria for approval updated.<br>4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…".<br>5. References were reviewed and updated. | 12/03/2020 | 12/07/2020 |
| Policy was reviewed<br>1. References were reviewed and updated. | 10/18/2021 | 12/07/2021 |
| Policy was reviewed:<br>1. Initial Approval Criteria, I.A.9: Updated to include new prescribing criteria Vyndaqel®/Vyndamax® is not prescribed concurrently with Onpattro® and Tegsedi®.<br>2. Continued Therapy Approval, II.A.3: Updated to include new prescribing criteria Vyndaqel®/Vyndamax® is not prescribed concurrently with Onpattro® and Tegsedi®.<br>3. References were reviewed and updated. | 10/18/2022 | 01/17/2023 |
| Policy was reviewed. | 10/19/2023 | 10/19/2023 |
| Policy was reviewed:<br>1. Removed age restrictions.<br>2. Removed prescriber restrictions.<br>3. Removed dose restrictions.<br>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.<br>5. Removed other reauthorization requirements including positive response to therapy.<br>6. Updated approval duration verbiage.<br>7. Reference was reviewed and updated. | 8/28/2024 | 9/13/2024 |