TAFAMIDIS

Generic	Brand	HICL	GCN	Exception/Other
TAFAMIDIS MEGLUMINE	VYNDAQEL	41631		
TAFAMIDIS	VYNDAMAX	45729		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a documented diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) as confirmed by **ONE** of the following?
   - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD *(**Note:** Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)*
   - Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or given in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
   - The patient has New York Heart Association (NYHA) class I, II, or III heart failure

   If yes, **approve for 12 months for both of the following drugs:**
   - **Vyndaqel (tafamidis meglumine): Approve by HICL (41631) with a quantity limit of #4 per day.**
   - **Vyndamax (tafamidis): Approve by HICL (45729) with a quantity limit of #1 per day.**

   APPROVAL TEXT: Renewal requires the physician attestation that the patient has not progressed to New York Heart Association (NYHA) Class IV heart failure.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TAFAMIDIS

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: The guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires a documented diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM). In addition, the following criteria must be met.

- Diagnosis confirmed by ONE of the following:
  - Bone scan (scintigraphy) strongly positive for myocardial uptake of 99mTcPYP/DPD *(**Note:** Strongly positive defined as heart to contralateral lung [H/CL] ratio of at least 1.5 or Grade 2 or greater localization to the heart using the Perugini Grade 1-3 scoring system)*
  - Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence **AND** chemical typing to confirm presence of transthyretin (TTR) protein
- The patient is 18 years of age or older
- Therapy is prescribed by or given in consultation with a cardiologist, transthyretin amyloidosis (ATTR) specialist, or medical geneticist
- The patient has New York Heart Association (NYHA) class I, II or III heart failure

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) **AND** meet the following criterion?
   - Physician attestation that the patient has not progressed to New York Heart Association (NYHA) Class IV heart failure

   If yes, **approve for 12 months for both of the following drugs:**
   - **Vyndaqel (tafamidis meglumine): Approve by HICL (41631) with a quantity limit of #4 per day.**
   - **Vyndamax (tafamidis): Approve by HICL (45729) with a quantity limit of #1 per day.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **TAFAMIDIS (Vyndaqel, Vyndamax)** requires a diagnosis of cardiomyopathy associated with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM). In addition, the following must be met.
   - Physician attestation that the patient has not progressed to New York Heart Association (NYHA) Class IV heart failure

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TAFAMIDIS

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Vyndaqel and Vyndamax.

REFERENCES

- Vyndaqel [Prescribing Information]. New York, NY: Pfizer Inc.; May 2019.
- Vyndamax [Prescribing Information]. New York, NY: Pfizer Inc.; August 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/19
Created: 05/19
Client Approval: 09/19
P&T Approval: 04/19