Pharmacy Medical Necessity Guidelines: Vyndaqel® (tafamidis meglumine) and Vyndamax® (tafamidis)

Effective: September 15, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are transthyretin stabilizers indicated for the treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalizations.

Vyndaqel (tafamidis meglumine) is dosed 80 mg orally once daily and Vyndamax (tafamidis) is dosed 61 mg orally once daily. Vyndaqel (tafamidis meglumine) and Vyndamax (tafadidis) are not substitutable on a per mg basis.

COVERAGE GUIDELINES

The plan may authorize coverage of Vyndagel (tafamidis meglumine) and Vyndamax (tafamidis) for Members when all of the following criteria are met:

1. Documented diagnosis of wild type or hereditary transthyretin amyloid cardiomyopathy

AND

2. Documentation in the Member's medical record of transthyretin (TTR) mutation

AND

3. Prescribed by, or in consultation with, a cardiologist

AND

4. Member is at least 18 years of age

AND

5. Documentation the Member has not had a prior cardiac or liver transplant or there is evidence of amyloid deposits post transplantation

LIMITATIONS

- Members new to the plan stable on Vyndagel (tafamidis meglumine) or Vyndamax (tafamidis) are required to meet coverage guidelines as outlined above.
- Treatment for heart failure not related to hereditary transthyretin-mediated amyloidosis will not be approved.
- Treatment for light chain amyloidosis will not be approved.
- A quantity limit of 120 capsules per month and 30 capsules per month for Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) apply.

CODES

None

REFERENCES

1. Mauer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018;379(11):1007-16.
2. National Institute of Health and Care Excellence. Tafamidis for treating transthyretin amyloid cardiomyopathy [ID1531]. Available on the Internet. URL: http://www.nice.org.uk. Accessed 2019 June 11.
3. Ruberg FL, Grogan M, Hanna M, et al. Transthyretin amyloid cardiomyopathy. J Amer Coll Cardiology. 2019;73(22):2872-91.
4. Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) [prescribing information]. New York, NY: Pfizer; 2020 April.

APPROVAL HISTORY

November 12, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. September 15, 2020: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.