

ALASKA MEDICAID
Prior Authorization Criteria

**Vyndaqel®, Vyndamax™
(tafamidis meglumine, tafamidis)**

FDA INDICATIONS AND USAGE¹

Vyndaqel® and Vyndamax™ are transthyretin (TTR) stabilizers. Tafamidis meglumine and tafamidis are indicated for the treatment of the cardiomyopathy of the wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce the cardiovascular mortality and cardiovascular-related hospitalization.

APPROVAL CRITERIA^{1,2,3}

1. Patient is 18 years of age or older **AND**;
2. Prescribed by or in consultation with a cardiologist **AND**;
3. Patient has a diagnosis of transthyretin (ATTR)- mediated amyloidosis with cardiomyopathy confirmed by:
 - a. Presence of amyloid deposits identified on a cardiac biopsy **OR**;
 - b. Confirmation of a TTR mutation by genetic testing or wild type amyloidosis **AND**;
4. Patient has clinical symptoms of cardiomyopathy and heart failure **AND**;
5. Patient has not had a liver or heart transplant.

DENIAL CRITERIA^{1,2,3}

1. Patient is less than 18 years of age **OR**;
2. Has not been prescribed by or in consultation with a cardiologist **OR**;
3. Patient does not have a diagnosis of transthyretin (ATTR)- mediated amyloidosis with cardiomyopathy confirmed by:
 - a. Presence of amyloid deposits identified on a cardiac biopsy **OR**;
 - b. Confirmation of a TTR mutation by genetic testing or wild type amyloidosis **OR**;
4. Patient does not have clinical symptoms of cardiomyopathy and heart failure **OR**;
5. Patient has had a liver or heart transplant **OR**;
6. Patient has New York Heart Association class IV heart failure.

CAUTIONS¹

- Tafamidis may cause fetal harm, therefore it is recommend that females use some form of contraception.
- Breastfeeding is not recommended during treatment due to potential serious adverse reactions in a breastfed infant.
- Drugs are not equivalent on a per mg to mg basis.

DURATION OF APPROVAL

- Initial Approval: up to 3 months

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- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 120 - 20mg capsules (80mg per day) Vyndaqel
- 30 – 61mg capsules Vyndamax

REFERENCES / FOOTNOTES:

1. Vyndaqel® and Vyndamax™ capsules [prescribing information]. New York, NY: Pfizer; May 2019.
2. Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.
3. Siddiqi OK, Ruberg FL. Cardiac amyloidosis: an update on pathophysiology, diagnosis, and treatment. Trends Cardiovasc Med. 2018;28(1):10-21.