Louisiana Medicaid
Tafamidis (Vyndamax™) / Tafmidis Meglumine (Vyndaqel®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for tafamidis (Vyndamax™) and tafmidis meglumine (Vyndaqel®).

Approval Criteria

- Recipient is 18 years of age or older on the date of the request; **AND**
- Recipient has a diagnosis of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) confirmed by definitive tests [dates, type of testing, and results are **stated on the reques**t]; **AND**
- Recipient exhibits clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction); **AND**
- Recipient has a medical history of heart failure with at least one prior hospitalization for heart failure within 12 months prior to the date of the request [**List most recent date of hospitalization**]; **AND**
- Recipient does **NOT** have a diagnosis of New York Heart Association (NYHA) class IV heart failure; **AND**
- Tafamidis (Vyndamax™) / tafmidis meglumine (Vyndaqel®) is prescribed by, or the request states that the medication is being prescribed in consultation with, a cardiologist or physician who specializes in the treatment of amyloidosis; **AND**
- By submitting the authorization request, the prescriber attests to the following;
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of tafamidis (Vyndamax™) / tafmidis meglumine (Vyndaqel®); **AND**
    - Tafamidis (Vyndamax™) / tafmidis meglumine (Vyndaqel®) will not be used in combination with any medication that is contraindicated or not recommended per FDA labeling.

NOTE: Vyndaqel® and Vyndamax™ are not substitutable on a per mg basis.

Reauthorization Criteria

- The recipient continues to meet initial diagnosis, age, and heart failure classification approval criteria; **AND**

- The prescriber states on the request that there is evidence of a positive response to therapy as indicated by either maintenance of the current condition or improvement in signs and symptoms compared to baseline (e.g. improved cardiac function, quality of life, slowing of disease progression, decreased hospitalizations).

Duration of initial and reauthorization approval: 12 months

Point-of-Sale Quantity Limits

- Vyndaqel®: 120 capsules per 30 days
- Vyndamax ™: 30 capsules per 30 days

Additional edits may apply at Point-of-Sale (POS). Override options may be available. For more information, refer to the Louisiana Department of Health Pharmacy Benefits Management Services Manual at www.lamedicaid.com/provweb1/Providermanuals/manuals/PHARMACY/PHARMACY.pdf

References

Donnelly JP, Hanna M. cardiac amyloidosis: an update on diagnosis and treatment. Cleve Clin J Med. 2017;84(12 Suppl 3):12-26. Retrieved from https://mdedge-files-live.s3.us-east-2.amazonaws.com/files/s3fs-public/issues/articles/hanna_.cardiacamyloidosis.pdf

Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018 Sep 13; 379(11): 1007-1016. Retrieved from https://www.nejm.org/doi/10.1056/NEJMoa1805689?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dwww.ncbi.nlm.nih.gov

Siddiqi OK, Ruberg FL. Cardiac amyloidosis: an update on pathophysiology, diagnosis, ant treatment. Trends Cardiovasc Med. 2018;28(1):10-21. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741539/

Vyndaqel® (tafamidis meglumine), Vyndamax ™ (tafamidis) [package insert]. New York, NY: Pfizer Labs; 2019. Retrieved from https://www.fda.gov/media/126283/download

Revision	Date
Policy created	October 2019