MEDICAL MUTUAL®

Drug Policy

Policy:	**Vyndaqel (tafamidis meglumine) and Vynadamax (tafamidis) Prior Authorization**	**Annual Review Date: 05/16/2024** **Last Revised Date: 05/16/2024**

OVERVIEW

POLICY STATEMENT

This policy involves the use of Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis). Prior authorization is recommended for pharmacy benefit coverage of Vyndaqel and Vyndamax. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Vyndaqel and Vyndamax as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Vyndaqel and Vyndamax be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) is recommended in those who meet the following criteria:

1. <u>Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis</u>
Criteria. *Patient must meet the following criteria*

Initial Therapy, *Patient must meet all of the following* (A, B, C, D, E, F, G, H, <u>AND</u> I):

A. Patient is 18 years of age or older; AND
B. Diagnosed with wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM); AND
C. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction); AND
D. Patient has a diagnosis of heart failure (NHYA functional Class I-III); AND
E. Patient has a medical history of either of the following (I <u>OR</u> II); AND
  I. At least one prior hospitalization for heart failure; OR

II. Clinical evidence of heart failure manifested by signs or symptoms of volume overload or elevated intracardiac pressures (e.g. elevated jugular venous pressure, shortness of breath or sings of pulmonary congestion on x-ray or auscultation, peripheral edema) requiring treatment with a diuretic for improvement

F. Patient must have evidence of cardiac involvement by echocardiography OR MRI with an end-diastolic interventricular septal wall thickness >12 mm; AND

G. Patient must have presence of amyloid deposits in biopsy tissue or presence of a variant TTR genotype and/or TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry; AND

H. Patient will not receive Vyndaqel or Vyndamax in combination with either of the following (I or II);
I. Oligonucleotide agents (e.g., patisiran, inotersen); OR
II. Tetramer stabilizers (e.g., diflunisal); AND

I. Vyndaqel/Vyndamax is prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.

***Continuation of therapy**, Patient must meet all the following:*

A. Patient has previously received treatment with Vyndaqel or Vyndamax; AND

B. Patient has experienced a positive clinical response to Vydaqel/Vyndamax (e.g. cardiac function, quality of life assessment, serum TTR levels, etc.); AND

C. Patient will not receive Vyndaqel or Vyndamax in combination with the following agents (I or II); AND
I. Oligonucleotide agents (e.g., patisiran, inotersen)
II. Tetramer stabilizers (e.g., diflunisal)

D. Vyndaqel/Vyndamax is prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Vyndaqel or Vyndamax has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Concomitant Use With Amvuttra (vutrisiran subcutaneous injection), Onpattro (patisiran lipid complex intravenous infusion), or Tegsedi (inotersen subcutaneous injection). There are no data supporting the safety and efficacy of concurrent use with Vyndaqel/Vyndamax. The Vyndaqel/Vyndamax pivotal trial, which took place prior when Onpattro and Tegsedi were under investigation for amyloidosis, did not include patients who were taking investigational drugs. The pivotal trials for Amvuttra, Onpattro, and Tegsedi did not allow concurrent use of tetramer stabilizers (e.g., tafamidis, diflunisal). A Phase II open-label extension study, included 13 patients who were treated with concomitantly with Onpattro and tafamidis.[7] Following 24 months of treatment, there was not significant difference in the median serum TTR percent change from baseline with concomitant Onpattro and tafamidis (-80%) vs. Onpattro monotherapy

(-88%). A scientific statement from the American Heart Association notes that there is little data to support combination therapy for these products.[8]

2. Concurrent use of Vyndaqel and Vyndamax**.** There are no data available to support concomitant use.
3. Polyneuropathy due to hereditary transthyretin amyloidosis
4. Patients with NYHA functional Class IV
5. Patients with the presence of primary (light chain) amyloidosis
6. Patients with a prior liver or heart transplantation or implanted cardiac mechanical assist device
7. Patients with an estimated glomerular filtration rate (eGFR) less than 25 mL per minute per 1.73 m^2 of body-surface area
8. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Vyndaqel and Vyndamax prescribing information. Pfizer labs. New York, New York. May 2019.
2. Vyndaqel (tafamidis). IPD analytics. May 2019.
3. Maurer MS, Schwartz JH, Gundepaneni B, et al. Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med 2018; 379:1007-1016. Sept 13, 2018.