Commercial/Healthcare Exchange PA Criteria

Effective: August 14th, 2019

Prior Authorization: Tafamidis

Products Affected: Vyndaqel (tafamidis meglumine) oral capsule, Vyndamax (tafamidis meglumine) oral capsule

Medication Description: Tafamidis is a selective stabilizer of TTR. Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, the rate-limiting step in the amyloidogenic process.

Covered Uses: Vyndaqel and Vyndamax are indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis (documentation required)
2. Medical history

Age Restrictions: Patient is 18 years of age or older

Prescriber Restrictions: Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.

Coverage Duration: 12 Months

Other Criteria:

1. Patient has a diagnosis of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) confirmed by one of the following:
    a. Technetium pyrophosphate scan (for example, nuclear scintigraphy):
        i. Both SPECT and planar images have been obtained during ^{99m}Tc-PYP testing to confirm diagnosis; OR
    b. Biopsy of tissue of affected organ(s) (cardiac and possibly non-cardiac sites) to confirm amyloid presence; AND
2. Genetic testing identified a transthyretin (TTR) mutation (pathogenic or likely pathogenic variant in TTR; for example, Val122Ile mutation, Thr60Ala mutation) or wild-type amyloidosis in this patient; AND
3. Patient has a confirmed diagnosis of New York Heart Association (NYHA) class I, II or III heart failure; AND
4. Patient-specific documentation showing clinical signs and symptoms of cardiomyopathy (e.g., heart failure, dyspnea, edema, hepatomegaly, ascites, etc.) has been provided; AND
5. Light chain (AL) amyloidosis has been ruled out with monoclonal protein testing:
    a. Required ALL three:
        i. Serum protein immunofixation
        ii. Urine protein immunofixation
        iii. Serum kappa/lambda free light chain ratio analysis; AND
6. Baseline 6-minute walk test (6MWT) results have been provided.

Renewal Criteria:
Clinical documentation showing patient's improvement of signs and symptoms of disease (e.g., distance walked on 6-minute walk improved, reduced the decline in functional capacity and quality of life, cardiovascular-related hospitalizations decreased).

References:
Vyndaqel® capsules and Vyndamax™ capsules [prescribing information]. New York, NY: Pfizer; May 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/12/2019
2	Update	Updated criteria (new requirements): • Both SPECT and planar images required • Documentation showing clinical signs and symptoms of cardiomyopathy • Light chain (AL) amyloidosis has been ruled out (3 tests required) • Baseline 6-minute walk test (6MWT) results Renewal Criteria added	Other Criteria Renewal Criteria	2/2/2021