Commercial/Healthcare Exchange PA Criteria

Effective: August 14th, 2019

Prior Authorization: Vyndaqel

Products Affected: Vyndaqel (tafamidis)

Medication Description: Vyndaqel (tafamidis) is a selective stabilizer of transthyretin(TTR). Vyndaqel (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: 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); 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.

References:

1. 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