Vyndaqel Vyndamax

Description

Vyndaqel (tafamidis meglumine), Vyndamax* (tafamidis)

*This medication is included in this policy but is not available in the market as of yet

Background

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are selective stabilizers of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, which is the rate-limiting step in the amyloidogenic process (1).

Regulatory Status

FDA-approved indication: 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 (1).

Vyndaqel and Vyndamax are not substitutable on a per mg basis (1).

Vyndaqel and Vyndamax have not been studied in: New York Heart Association (NYHA) class IV, primary light chain amyloidosis, prior liver or heart transplantation, or implanted cardiac mechanical assist device (1).

The safety and effectiveness of Vyndaqel and Vyndamax in pediatric patients less than 18 years old have not been established (1).
 Vyndaqel and Vyndamax may be considered **medically necessary** in patients 18 years of age and older with cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) and if the conditions indicated below are met.

Vyndaqel and Vyndamax are considered **investigational** in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age and older

**Diagnosis**

The patient must have the following:

Cardiomyopathy

**AND ALL** of the following:

1. Genetic confirmation of wild type or hereditary transthyretin-mediated amyloidosis (ATTR)
2. Confirmation of amyloid deposits showing cardiac involvement by **ONE** of the following:
   a. Biopsy
   b. Nuclear imaging
   c. Diagnostic cardiac imaging
3. Prescribed by a cardiologist or the prescriber has consulted with a cardiologist
4. Prescriber will monitor patients taking NSAIDs, calcium channel blockers (CCBs), or digoxin for toxicity

**AND NONE** of the following:

1. Heart failure due to causes other than ATTR
2. Light-chain amyloidosis
3. History of heart or liver transplantation
Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnosis

The patient must have the following:

Cardiomyopathy

AND ALL of the following:
1. Genetic confirmation of wild type or hereditary transthyretin-mediated amyloidosis (ATTR)
2. Patient has been assessed for improvement and has experienced a clinical benefit from therapy
3. Prescribed by a cardiologist or the prescriber has consulted with a cardiologist
4. Prescriber will monitor patients taking NSAIDs, calcium channel blockers (CCBs), or digoxin for toxicity

AND NONE of the following:
1. Heart failure due to causes other than ATTR
2. Light-chain amyloidosis
3. History of heart or liver transplantation
4. Implanted cardiac device
5. Severe malnutrition

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Quantity

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>Vyndaqel 20 mg capsules</td>
<td>360 capsules per 90 days</td>
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<tr>
<td>Vyndamax 61 mg capsules</td>
<td>90 capsules per 90 days</td>
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Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are selective stabilizers of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, which is the rate-limiting step in the amyloidogenic process. The safety and effectiveness of Vyndaqel and Vyndamax in pediatric patients less than 18 years old have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Vyndaqel and Vyndamax while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>May 2019</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>September 2019</td>
<td>Annual review. Addition of requirement for prescriber to monitor for NSAID, CCB, or digoxin toxicity and no heart failure not due to ATTR, light-chain amyloidosis, transplant, severe malnutrition per SME</td>
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</tbody>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 13, 2019 and is effective on October 1, 2019.