JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS121
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	Subject **Vyndamax and Vyndaqel**	*Revision Date*	12/08/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Vyndamax, Vyndaqel

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I. POLICY

Vyndamax (tafamidis) and Vyndaqel (tafamidis meglumine) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Vyndamax or Vyndaqel may be approved when the following criteria have been met:
   1. Patient is 18 years of age or older
   2. Documented diagnosis of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) supported by ONE of the following:
      1. Documentation of tissue biopsy supporting histologic confirmation of ATTR amyloid deposits
      2. Documentation of genetic testing that shows the patient has a hereditary variant in the TTR mutation (such as Val122lle, or Val30Met mutations)
      3. Documentation of ALL the following:
         1. Grade 2 or 3 cardiac retention of radionuclide-tagged bisphosphonate on bone scintigraphy (^{99m}Tc-DPD/^{99m}Tc-PYP/^{99m}Tc-HMDP)
         2. Absence of a detectable monoclonal protein in serum and urine immunofixation electrophoresis (IFE) and serum free light chain (sFLC) assay
         3. Echocardiogram, Electrocardiogram, or cardiac magnetic resonance imaging that suggest cardiac amyloidosis
   3. Documentation that the patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure symptoms
   4. Documented clinical signs and symptoms of cardiomyopathy (such as dyspnea, peripheral edema, hepatomegaly, ascites, etc.)

5. Prescriber is, or has consulted with, a cardiologist

III. AUTHORIZATION PERIOD/LIMITATIONS

1. Initial approval will be restricted to 6 months of therapy
2. Approval for continuation of therapy may be extended in 12-month intervals with documentation showing the patient continues to have NYHA Functional Class I, II, or III heart failure, but has experienced clinical improvement from treatment. Clinical improvement may be evidenced by at least one of the following:
    1. Improvement of clinical signs and symptoms
    2. Slowing of cardiomyopathy disease progression
    3. Increased quality of life activities
    4. Reduced hospital admissions related to the condition

IV. EXCLUSIONS

A. Vyndamax and Vyndaqel will not be approved for the following:
    1. Patient with NYHA Functional Class IV heart failure symptoms
    2. Patients with a history of liver or heart transplant
    3. Any indications that are not FDA-approved, or guideline-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

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6. Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE

10/16/2019	Policy Creation
12/08/2021	Updated Exclusions section regarding physician samples

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