Vyndaqel, Vyndamax

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-249-6155**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____
Request Initiated For: _____

1. What is the prescribed drug? ❑ Vyndaqel ❑ Vyndamax
2. What is the diagnosis?
   ❑ Cardiomyopathy of ***wild type*** transthyretin-mediated amyloidosis
   ❑ Cardiomyopathy of ***hereditary*** transthyretin-mediated amyloidosis
   ❑ Other _____
3. What is the ICD-10 code? _____
4. Has the diagnosis been confirmed by positive technetium-labeled bone scintigraphy tracing? ***ACTION REQUIRED: If Yes, attach technetium labeled bone scintigraphy tracing results confirming the presence of amyloid deposits.*** ❑ Yes ❑ No *If No, skip to #6*
5. Has systemic light chain amyloidosis been ruled out by the absence of monoclonal proteins using one of the following tests: A) serum kappa/lambda free light chain ratio, B) serum protein immunofixation, or C) urine protein immunofixation? ***ACTION REQUIRED: If Yes, attach serum kappa/lambda free light chain ratio, serum protein immunofixation, or urine protein immunofixation test results and skip to #8.*** ❑ Yes ❑ No
6. Has the diagnosis been confirmed by presence of transthyretin amyloid deposits on analysis of biopsy from cardiac or noncardiac sites? ***ACTION REQUIRED: If Yes, attach biopsy results.*** ❑ Yes ❑ No
7. Has the presence of transthyretin precursor proteins been confirmed by immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy? ***ACTION REQUIRED: If Yes, attach immunohistochemical analysis, mass spectrometry, tissue staining, or polarized light microscopy results confirming transthyretin precursor proteins.*** ❑ Yes ❑ No
8. Has cardiac involvement been confirmed by echocardiography or cardiac magnetic resonance imaging (e.g., end-diastolic interventricular septal wall thickness exceeding 12 mm)? ***ACTION REQUIRED: If Yes, attach echocardiography or cardiac magnetic resonance imaging results.*** ❑ Yes ❑ No
9. Does the patient exhibit clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema)? ❑ Yes ❑ No

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10. Is the patient a liver transplant recipient? ❑ Yes ❑ No

11. Will the requested medication be used in combination with inotersen (Tegsedi), patisiran (Onpattro), or vutrisiran (Amvuttra)? ❑ Yes ❑ No

12. Is this a request for continuation of therapy with the requested drug?
❑ Yes ❑ No *If No and diagnosis is "wild type", no further questions OR "hereditary", skip to #14*

13. Has the patient demonstrated a beneficial response to treatment with the requested drug [e.g., improvement in rate of disease progression as demonstrated by distance walked on the 6-minute walk test, the Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score, cardiovascular-related hospitalizations, NYHA classification of heart failure, left ventricular stroke volume, N-terminal B-type natriuretic peptide (NT-proBNP) level]? ***ACTION REQUIRED: If Yes, attach medical record documentation confirming the member demonstrates a beneficial response to treatment.*** ❑ Yes ❑ No

Complete the following question if patient has Cardiomyopathy of Hereditary Transthyretin-Mediated Amyloidosis.

14. Does the patient have a confirmed transthyretin (TTR) gene mutation? ***ACTION REQUIRED: If Yes, attach results confirming a mutation of the transthyretin (TTR) gene.*** ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

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