



**Vyndaqel Vyndamax
CareFirst 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 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. 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:** _____

Referring Provider Info: Same as Requesting Provider
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: Same as Referring Provider Same as Requesting Provider
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____ kg
Patient Height: _____ cm

Please indicate the place of service for the requested drug:

- Ambulatory Surgical Home Off Campus Outpatient Hospital
- On Campus Outpatient Hospital Office Pharmacy

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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**CVS Caremark Specialty Pharmacy • 2211 Sanders Road NBT-6 • Northbrook, IL 60062
Phone: 1-888-877-0518 • Fax: 1-855-330-1720 • www.caremark.com**

Exception Criteria Questions:

A. Is the member using Vyndamax, Vyndaqel, or Attruby concomitantly with Amvuttra to treat cardiomyopathy associated with wild-type or hereditary transthyretin-mediated amyloidosis?

- Yes, *Skip to Criteria Questions*
- No, *Continue to Question B*

B. The preferred products for your patient's health plan are Amvuttra and Onpattro. Can the patient's treatment be switched to one of the preferred products?

- Yes, Amvuttra, *Please obtain Form for preferred product and submit for corresponding PA*
- Yes, Onpattro, *Please obtain Form for preferred product and submit for corresponding PA*
- No, *Continue to Question C*

C. Did the patient have a documented inadequate response, intolerable adverse event, or contraindication to both preferred products (Amvuttra and Onpattro)? ***ACTION REQUIRED: If 'Yes', attach supporting chart note(s)***

- Yes, *Continue to Criteria Questions*
- No, *Continue to Criteria Questions*

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Criteria Questions:

1. What is the diagnosis?

- Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM), *Continue to 2*
 Other, please specify. _____, *Continue to 2*

2. Is the patient an adult (18 years of age or older)?

- Yes, *Continue to 3*
 No, *Continue to 3*

3. Is the requested drug being prescribed by or in consultation with a geneticist, cardiologist, or a physician specializing in the treatment of amyloidosis?

- Yes, *Continue to 4*
 No, *Continue to 4*

4. Does the patient exhibit clinical symptoms of heart failure (e.g., volume overload, dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema) at baseline (prior to treatment with the requested drug)? ***ACTION REQUIRED:***

If Yes, attach chart notes or medical record documentation demonstrating the patient exhibits clinical symptoms of heart failure. ***ACTION REQUIRED:*** Submit supporting documentation

- Yes, *Continue to 6*
 No, *Continue to 5*

5. Does the patient have medical history of heart failure with at least one prior hospitalization for heart failure (not due to arrhythmia or conduction system disturbance treated with permanent pacemaker)? ***ACTION REQUIRED:*** If Yes,

attach chart notes or medical record documentation of prior hospitalization of heart failure. ***ACTION REQUIRED:*** Submit supporting documentation

- Yes, *Continue to 6*
 No, *Continue to 6*

6. Has the diagnosis been confirmed by the presence of transthyretin amyloid deposits on analysis of biopsy from cardiac or noncardiac sites? ***ACTION REQUIRED:*** If Yes, attach tissue biopsy results from cardiac or noncardiac sites

confirming the presence of the transthyretin amyloid deposition. ***ACTION REQUIRED:*** Submit supporting documentation

- Yes, *Continue to 7*
 No, *Continue to 8*

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. ***ACTION REQUIRED:*** Submit supporting documentation

- Yes, *Continue to 10*
 No, *Continue to 8*

8. Has the presence of amyloid deposits been confirmed by technetium-labeled bone scintigraphy tracing? ***ACTION REQUIRED:*** If Yes, attach technetium-labeled bone scintigraphy tracing results confirming the presence of amyloid

deposits. ***ACTION REQUIRED:*** Submit supporting documentation

- Yes, *Continue to 9*
 No, *Continue to 9*

9. Has systemic light chain amyloidosis been ruled out by showing the absence of monoclonal proteins by all of the following tests: A) serum kappa/lambda free light chain ratio, B) serum protein immunofixation, and C) urine protein

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immunofixation? **ACTION REQUIRED:** If Yes, attach serum kappa/lambda free light chain ratio, serum protein immunofixation, and urine protein immunofixation test results showing the absence of monoclonal proteins. **ACTION REQUIRED:** Submit supporting documentation

- Yes, *Continue to 10*
- No, *Continue to 10*

10. What is the patient's diagnosis?

- Cardiomyopathy of hereditary transthyretin-mediated amyloidosis, *Continue to 11*
- Cardiomyopathy of wild-type transthyretin-mediated amyloidosis, *Continue to 12*

11. Does the patient have a confirmed detection of a pathogenic or likely pathogenic variant in the transthyretin (TTR) gene? **ACTION REQUIRED:** If Yes, attach results confirming pathogenic or likely pathogenic variant in the TTR gene. **ACTION REQUIRED:** Submit supporting documentation

- Yes, *Continue to 12*
- No, *Continue to 12*

12. Is the patient a liver or heart transplant recipient?

- Yes, *Continue to 13*
- No, *Continue to 13*

13. Does the patient have an implanted left-ventricular assist device (LVAD)?

- Yes, *Continue to 14*
- No, *Continue to 14*

14. Will the requested drug be used in combination with inotersen (Tegsedi), patisiran (Onpattro), vutrisiran (Amvuttra), eplontersen (Wainua), or acoramidis (Attruby)?

- Yes, *Continue to 15*
- No, *Continue to 15*

15. Is this a request for continuation of therapy with the requested drug?

- Yes, *Continue to 16*
- No, *No Further Questions*

16. 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, New York Heart Association [NYHA] classification of heart failure, left ventricular stroke volume, N-terminal B-type natriuretic peptide [NT-proBNP] level)? **ACTION REQUIRED:** If Yes, attach chart notes or medical record documentation confirming the patient demonstrates a beneficial response to treatment. **ACTION REQUIRED:** Submit supporting documentation

- Yes, *No Further Questions*
- No, *No Further Questions*

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Step Therapy Override 2197-D: Complete if Applicable for the state of Maryland.	Please Circle	
1. Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
2. Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
3. Is the alternate drug FDA-approved for the medical condition being treated? <i>If No, No Further Questions</i>	Yes	No
4. Has the prescriber documented in the patient's chart that the requested drug was ordered for the patient in the past 180 days? <i>If No, Skip to 6</i>	Yes	No
5. Has the prescriber documented in the patient's chart that in their opinion the requested drug is effective for the patient's condition? <i>If Yes or No, No Further Questions</i>	Yes	No
6. Is the alternate drug contraindicated or will likely cause an adverse reaction to the patient? <i>If Yes, No Further Questions</i>	Yes	No
7. Is the alternate drug expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen? <i>If Yes, No Further Questions</i>	Yes	No
8. Is the patient stable on the requested drug for the medical condition under consideration? <i>If Yes, No Further Questions</i>	Yes	No
9. Has the patient tried a prescription drug while covered under their current policy or a previous source of coverage, that is in the same pharmacologic class or has the same mechanism of action as the alternate drug and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? <i>No Further Questions</i>	Yes	No

Step Therapy Override 3145-D: Complete if Applicable for the state of Virginia.	Please Circle	
1. Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)?	Yes	No
2. Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature?	Yes	No
3. Is the alternate drug contraindicated? <i>If Yes, No Further Questions</i>	Yes	No
4. Is the alternate drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen? <i>If Yes, No Further Questions</i>	Yes	No
5. Has the patient tried the alternate drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? NOTE: Pharmaceutical drug samples are not considered trial and failure of a preferred drug. <i>If Yes, No Further Questions</i>	Yes	No
6. Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition? <i>No Further Questions</i>	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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