Onpattro

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the member 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*

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

Note: This fax may contain medical information that is privileged and confidential and is solely for the use of individuals named above. If you are not the intended recipient you hereby are advised that any dissemination, distribution, or copying of this communication is prohibited. If you have received the fax in error, please immediately notify the sender by telephone and destroy the original fax message. Onpattro SGM - 10/2020.

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

Site of Service Questions (SOS):

A. Indicate the site of service requested:
- ❑ On Campus Outpatient Hospital
- ❑ Home infusion, *skip to Clinical Questions*
- ❑ Ambulatory surgical, *skip to Clinical Questions*
- ❑ Off Campus Outpatient Hospital
- ❑ Physician office, *skip to Clinical Questions*
- ❑ Pharmacy, *skip to Clinical Questions*
- ❑ Inpatient hospital, *skip to Clinical Questions*

B. Is the patient less than 21 years old or 65 years of age or older?
- ❑ Yes – less than 21 years old, *skip to Clinical Criteria Questions*
- ❑ Yes – age 65 years or older, *skip to Clinical Criteria Questions*
- ❑ No

C. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes - This is a continuation of an existing treatment.
- ❑ No - This is a new therapy request (patient has not received requested medication in the last 6 months). *skip to Clinical Criteria Questions*

D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids other pre- medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

E. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

F. Does the patient have severe venous access issues that require the use of special interventions only available in the outpatient hospital setting? ***ACTION REQUIRED: Attach supporting clinical documentation.***
❑ Yes, *skip to Clinical Criteria Questions* ❑ No

G. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? ***ACTION REQUIRED: Attach supporting clinical documentation.*** ❑ Yes ❑ No

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Criteria Questions:

1. What is the diagnosis?
   ❑ Polyneuropathy of hereditary transthyretin-mediated amyloidosis ❑ Other _____
2. What is the ICD-10 code? _____
3. Was the diagnosis confirmed by detection of a mutation in the TTR gene? ***ACTION REQUIRED: If Yes, attach a copy of the TTR gene test result.*** ❑ Yes ❑ No ❑ Unknown
4. Does the patient exhibit clinical manifestations of polyneuropathy of hereditary transthyretin-mediated amyloidosis (ATTR-FAP) (e.g., amyloid deposition in biopsy specimens, TTR protein variants in serum, progressive peripheral sensory-motor polyneuropathy)? ***ACTION REQUIRED: If Yes, attach medical record documentation confirming clinical manifestations of the condition.*** ❑ Yes ❑ No
5. Is the patient a liver transplant recipient? ❑ Yes ❑ No
6. Will the requested medication be used in combination with either inotersen (Tegsedi) or tafamidis (Vyndaqel, Vyndamax)? ❑ Yes ❑ No
7. Is the requested medication prescribed by or in consultation with any of the following: a) neurologist, b) geneticist, or c) physician specializing in the treatment of amyloidosis? ❑ Yes ❑ No
8. Is the request for a continuation of therapy with Onpattro? ❑ Yes ❑ No *If No, no further questions.*
9. Has the patient demonstrated a beneficial response to Onpattro therapy compared to baseline (e.g., improvement of neuropathy severity and rate of disease progression as demonstrated by the modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, manual grip strength)? ***ACTION REQUIRED: If Yes, attach medical record documentation confirming improvement of the condition.*** ❑ 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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