Updated: 06/2024
DMMA Approved: 06/2024

Request for Prior Authorization for Onpattro (patisiran) and Tegsedi (inotersen) and Amvuttra (vutrisiran)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Onpattro (patisiran), Tegsedi (inotersen) and Amvuttra (vutrisiran) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Onpattro (patisiran), Tegsedi (inotersen) and Amvuttra (vutrisiran) Prior Authorization Criteria:

Coverage may be provided with a diagnosis of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis and the following criteria is met:

- Member must be 18 years of age and older
- Prescribed by or in consultation with a neurologist or a specialist in the treatment of amyloidosis
- Diagnosis of hATTR amyloidosis with polyneuropathy confirmed by the presence of a transthyretin (TTR) gene mutation (e.g., V30M, A97S, T60A, E89Q, S50R)
- Documentation of one of the following baseline tests:
  - modified Neuropathy Impairment Scale +7 (mNIS+7) composite score
  - polyneuropathy disability (PND) score of ≤ IIIb
  - familial amyloid polyneuropathy (FAP) Stage 1 or 2
- Member has clinical signs and symptoms of polyneuropathy (i.e. weakness, sensory loss, decreased motor strength, decreased gait speed)
- Other causes of peripheral neuropathy have been assessed and ruled out
- Member will not be receiving the requested medication in combination with either of the following:
  - A TTR stabilizer [Vyndamax (tafamidis), Vyndaqel (tafamidis meglumine, Dolobid (diflunisal)]
  - oligonucleotide agents [Onpattro (patisiran), Tegsedi (inotersen)]
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months

Reauthorization criteria

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - mNIS+7 score
  - polyneuropathy disability (PND) score of ≤ IIIb
  - familial amyloid polyneuropathy (FAP) Stage 1 or 2
- **Reauthorization Duration of Approval:** 12 months

HIGHMARK HEALTH OPTIONS

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Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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ONPATTRO (PATISIRAN), TEGSEDI (INOTERSEN) AND AMVUTTRA (VUTRISIRAN)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: ICD-10 Code: _____
Documented TTR mutation: _____
Does the member have one of the following baseline testing performed?

- polyneuropathy disability (PND) score ≤ IIIb ☐ Yes ☐ No
- familial amyloid polyneuropathy (FAP) Stage 1 or 2 ☐ Yes ☐ No
- modified Neuropathy Impairment Scale +7 (mNIS+7) composite score ☐ Yes ☐ No

Does the member have clinical signs and symptoms of polyneuropathy? ☐ Yes ☐ No
Have other causes of peripheral neuropathy been assessed and ruled out? ☐ Yes ☐ No
Is the member going to be receiving the requested medication in combination with another TTR stabilizer or oligonucleotide agent? ☐ Yes ☐ No

REAUTHORIZATION

Is there documentation the member has had a therapeutic response to the requested medication as evidenced by stabilization or improvement from baseline in the previous baseline testing performed for initial authorization? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

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