Updated: 09/2023
PARP Approved: 10/2023

Prior Authorization Criteria

Onpattro (patisiran), Tegsedi (inotersen) and Amvuttra (vutrisiran)

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.

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 the following:
    - 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

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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

HIGHMARK WHOLECARE

Updated: 09/2023
PARP Approved: 10/2023

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 Wholecare Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
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:	

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 Code:

Documented TTR mutation: _____

Does the member have a baseline polyneuropathy disability (PND) score ≤ IIIb, OR a baseline familial amyloid polyneuropathy (FAP) Stage 1 or 2 OR a 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 have been assessed and ruled out? ☐ Yes ☐ No

Will the member be receiving the requested medication in combination with a oligonucleotide agent? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced an improvement with treatment? ☐ Yes ☐ No

Has the member had 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

Please describe:

continued on next page

Onpattro (patisiran), Tegsedi (inotersen) and Amvuttra (vutrisiran)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Wholecare Pharmacy Services. **FAX:** (888) 245-2049
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MEMBER INFORMATION		
Member Name:	DOB:	
Member ID:	Member weight:	Height:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date