HIGHMARK HEALTH OPTIONS

Updated: 07/2025
Approved: 07/2025

Request for Prior Authorization for Onpattro (patisiran) and Amvuttra (vutrisiran)
Website Form – www.wv.highmarkhealthoptions.com
Submit request via: Fax - 1-833-547-2030

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

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)]
- 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 with a diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) and the following criteria is met (Amvuttra only):

- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- The diagnosis is confirmed by presence of amyloid deposits on biopsy analysis from cardiac or non-cardiac sites (e.g., fat aspirate, gastrointestinal sites, salivary glands, bone marrow) or by technetium-labeled bone scintigraphy tracing
- Cardiac involvement was confirmed by echocardiography or cardiac magnetic resonance imaging (MRI) (e.g., end-diastolic interventricular septal wall thickness exceeding 12 mm)
- For members with hereditary ATTR-CM, presence of a mutation of the TTR gene was confirmed
- For members with wild type ATTR-CM, presence of transthyretin precursor proteins was confirmed by immunohistochemical analysis, scintigraphy, or mass spectrometry
- The member exhibits clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema)
- Member has a New York Heart Association Class I, II or III heart failure
- The requested medication will not be used in combination with tetramer stabilizers (e.g. diflunisal)
- Must be prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis
- Member does not have a history of liver or heart transplantation
- 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 confirming the member demonstrates a beneficial response to treatment (e.g., improvement 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, NT-proBNP level)
- **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.

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ONPATTRO (PATISIRAN) 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: (833)-547-2030.**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: 1-844-325-6251 Mon – Fri 8 am to 7 pm

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 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

Cardiomyopathy ATTR-CM:
Has the diagnosis been confirmed by presence of amyloid deposits on biopsy analysis from cardiac or non-cardiac sites (e.g., fat aspirate, gastrointestinal sites, salivary glands, bone marrow) or by technetium-labeled bone scintigraphy tracing? ☐ Yes ☐ No
Has cardiac involvement been confirmed by echocardiography or cardiac magnetic resonance imaging? ☐ Yes ☐ No
For members with hereditary ATTR-CM, has the presence of a TTR gene mutation been confirmed? ☐ Yes ☐ No
For members with wild type ATTR-CM, has the presence of transthyretin precursor proteins been confirmed by immunohistochemical analysis, scintigraphy, or mass spectrometry? ☐ Yes ☐ No
Does the member exhibit clinical symptoms of cardiomyopathy and heart failure (e.g., dyspnea, fatigue, orthostatic hypotension, syncope, peripheral edema)? ☐ Yes ☐ No
Does the member have a New York Heart Association Class I, II or III heart failure? ☐ Yes ☐ No
Will the member be using the requested medication in combination with tetramer stabilizers (e.g. diflunisal)? ☐ Yes ☐ No
Does the member have a history of liver or heart transplantation? ☐ Yes ☐ No
Is the medication being prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis? ☐ Yes ☐ No

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PRIOR AUTHORIZATION FORM – Page 2 of 2

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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:

CURRENT or PREVIOUS THERAPY

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

REAUTHORIZATION

Has there been 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