

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

All requests for Amvuttra (vutrisiran) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

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:

- 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:
 - o modified Neuropathy Impairment Scale +7 (mNIS+7) composite score
 - o polyneuropathy disability (PND) score of \leq IIIb
 - o 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:
 - o 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
- Prescribed by or in consultation with a neurologist or a specialist in the treatment of amyloidosis
- **Initial Duration of Approval:** 12 months
- Reauthorization criteria
 - O 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 \leq IIIb
 - familial amyloid polyneuropathy (FAP) Stage 1 or 2
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a <u>diagnosis</u> of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) and the following criteria is met:

- 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 noncardiac sites (e.g., fat aspirate, gastrointestinal sites, salivary glands, bone marrow) or by technetiumlabeled 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.



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.

			rvices. FAX: (833)- 547-2030. 844) 325-6251 Mon-Fri 8:00am to 7:00pm	
if fleeded, you may can to speak to		NEORMATION	844) 323-0231 Mon-Fit 8:00ani to 7:00pin	
Requesting Provider:	I KO VIDEK II	NPI:		
Provider Specialty:		Office Co	ntact·	
Office Address:	1 7		Office Phone:	
Office Address.		Office Fax		
	MEMBER IN	FORMATION	. .	
Member Name:	NICK INC.	DOB:		
Member ID:		Member weight:	Height:	
Member 12.	REQUESTED DRI	G INFORMATION	5	
Medication:	REQUESTED DRU	Strength:		
Directions:		Quantity:	Refills:	
Is the member currently receiving r	requested medication?		Medication Initiated:	
			lication may be necessary for the life of	
the patient? Yes No	emonie of long term conditi	ion for which the filee	inearion may be necessary for the me of	
the patient.	Rilling In	formation		
This medication will be billed:	at a pharmacy OR medi			
Place of Service: Hospital		mber's home Othe	r	
Trace of Service. [] Hospital		ce Information		
Name:		NPI:		
Address:		Phone:		
riddioss.	MEDICAL HISTORY (C		quests)	
Diagnosis:		<u> </u>	ICD-10 Code:	
Polyneuropathy hATTR: Document	nted TTR mutation:			
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Does the member have one of the follow:	ing baseline testing performed?			
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Is there documentation of a therapeutic response as evidenced by stabilization or improveme				
function, quality of life, slowing of disease progression, etc.) from baseline in one of the following? \square mNIS+7 score \square polyneuropathy disability				
(PND) score of \leq IIIb \square familial amyloid polyneuropathy (FAP) Stage 1 or 2				
SUPPORTING INFORMATION or CLINICA	L RATIONALE			
Prescribing Provider Signature	Date			

