

Updated: 07/2025 PARP Approved: 09/2025

Prior Authorization Criteria Onpattro (patisiran) and Amvuttra (vutrisiran)

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.

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:
 - 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)]
- 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.



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Onpattro (patisiran) and Amvuttra (vutrisiran) PRIOR AUTHORIZATION FORM

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				(800) 392-1147 Mon – Fri 8:30am to 5:00pm	
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Onpattro (patisiran) 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 If needed, you may call to speak to a Pharmacy Services Representative. PHONE: (800) 392-1147 Mon – Fri 8:30am to 5:00pm MEMBER INFORMATION Member Name: DOB: Member ID: Member weight: Height: SUPPORTING INFORMATION or CLINICAL RATIONALE Prescribing Provider Signature Date