

Prior Authorization Criteria  
**Onpattro (patisiran) and Tegsedi (inotersen)**

All requests for Onpattro (patisiran) and Tegsedi (inotersen) 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  $\leq$  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  $\leq$  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.



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Updated: 08/2021  
PARP Approved: 10/2021

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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