Medical Policy:
Hereditary transthyretin amyloidosis (hATTR)

Last review date: 3/24/2025

Applicable Products:
Amvuttra (vutrisiran) Onpattro (patisiran)

Initial Approval Criteria:
Coverage may be approved if all of the following are met:

- Disease-specific criteria; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (Amvuttra)

- Patient is > 18 years old; **AND**
- Confirmed diagnosis of ATTR-CM by the presence of amyloid deposits on biopsy analysis from cardiac or non-cardiac sites and one of the following:
    - For patients with hereditary ATTR-CM, documentation of a mutation in the TTR gene; **OR**
    - For patients with wild-type ATTR-CM, documentation of the presence of transthyretin precursor proteins was confirmed by immunohistochemical analysis, scintigraphy, or mass spectrometry; **AND**
- Patient exhibits symptoms of cardiomyopathy and heart failure such as dyspnea, fatigue, syncope, peripheral edema, orthostatic hypotension, etc.; **AND**
- Patient is not concomitantly using other gene targeted therapy for ATTR-CM; **AND**
- Patient has no prior or planned liver transplantation

Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN) (Amvuttra, Onpattro)

- Patient is > 18 years old; **AND**
- Confirmed diagnosis of hATTR-PN with documentation of a mutation in the TTR gene; **AND**
- Currently experiencing signs and symptoms of polyneuropathy such as tingling or pain in the hands, orthostatic hypotension, etc.; **AND**
- Prescribed by or in consultation with a neurologist or physician who specializes in the treatment of amyloidosis; **AND**
- Patient is not concomitantly using other gene targeted therapy for ATTR-PN; **AND**
- Patient has no prior or planned liver transplantation

Renewal Criteria:
Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Documentation of clinical response to therapy, such as an improvement, stabilization, or slowing of progression of hATTR manifestations; **AND**
- Absence of unacceptable toxicity

Length of Authorization:
12 months

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.