

WAINUA (eplontersen)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis

AND ALL of the following:

- Diagnosis of hATTR confirmed by a genetic test OR a tissue biopsy showing amyloid deposition
- 2. Patient must have **ONE** of the following baseline scores:
 - a. Polyneuropathy disability (PND) score ≤ IIIb (see Appendix 1)
 - b. FAP Stage 1 or 2 (see Appendix 2)
- Prescriber agrees to supplement the patient with the recommended daily allowance of Vitamin A if indicated
- 4. Patient has **NONE** of the following:
 - a. New York Heart Association (NYHA) class III or IV heart failure
 - b. Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis (monoclonal gammopathy, autoimmune disease, etc.)
 - c. Prior liver transplantation
- 5. Prescribed by or in consultation with a neurologist, or a specialist in the treatment of the patient's diagnosis
- 6. **NO** dual therapy with another Prior Authorization (PA) medication for polyneuropathy caused by hATTR amyloidosis (see Appendix 3)

Prior - Approval Limits

Quantity 3 single-dose autoinjectors per 90 days

Duration 12 months

Prior – Approval Renewal Requirements

Age 18 years of age and older



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Diagnosis

Patient must have the following:

Polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis

AND ALL of the following:

- 1. Patient condition has improved or stabilized
- 2. Prescriber agrees to supplement the patient with the recommended daily allowance of Vitamin A if indicated
- 3. **NO** dual therapy with another Prior Authorization (PA) medication for polyneuropathy caused by hATTR amyloidosis (see Appendix 3)

Prior - Approval Renewal Limits

Same as above



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Appendix 1 - Polyneuropathy Disability (PND) Severity Scoring System

Polyneuropathy Disability (PND) Score		
Stage 0	No impairment	
Stage I	Sensory disturbances but preserved walking capability	
Stage II	Impaired walking capability but ability to walk without a stick or crutches	
Stage IIIA	Walking only with the help of one stick or crutches	
Stage IIIB	Walking only with the help of two sticks or crutches	
Stage IV	Confined to a wheelchair or bedridden	

Appendix 2 - FAP Stage Severity Scoring System

FAP Stage		
Stage 0	No symptoms	
Stage I	Unimpaired ambulation; mostly mild sensory, motor, and autonomic neuropathy in the lower limbs	
Stage II	Assistance with ambulation required; mostly moderate impairment progression to the lower limbs, upper limbs, and trunk	
Stage III	Wheelchair bound or bedridden; severe sensory, motor, and autonomic involvement of all limbs	

Appendix 3 - List of PA Medications for Polyneuropathy caused by hATTR Amyloidosis

Generic Name	Brand Name
eplontersen	Wainua
inotersen	Tegsedi
patisiran	Onpattro
vutrisiran	Amvuttra