



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Wainua (eplontersen)

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Effective Date: 11/1/2024

Last Review Date: 10/4/2024

Applies to:	<input type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> New Jersey
	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Michigan	<input checked="" type="checkbox"/> Virginia	<input checked="" type="checkbox"/> Kentucky PRMD

### Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Wainua under the patient's prescription drug benefit.

### Description:

#### FDA-Approved Indication

Wainua is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

All other indications are considered experimental/investigational and not medically necessary.

### Applicable Drug List:

Wainua

### Policy/Guideline:

#### Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:

1. Testing or analysis confirming a mutation in the TTR gene.
2. Medical record documentation confirming the member demonstrates signs and symptoms of polyneuropathy.

B. Continuation of therapy requests:

1. Chart notes or medical record documentation supporting clinical benefit of therapy compared to baseline.

### Prescriber Specialties

This medication must be prescribed by or in consultation with a neurologist, geneticist, or physician specializing in the treatment of amyloidosis.

### Criteria for Initial Approval

#### **Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis**

Authorization may be granted for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (also called transthyretin-type familial amyloid polyneuropathy [ATTR-FAP]) when ALL the following criteria are met:

- A. The diagnosis is confirmed by detection of a mutation in the TTR gene.



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- B. Member exhibits clinical manifestations of ATTR-FAP (e.g., amyloid deposition in biopsy specimens, TTR protein variants in serum, progressive peripheral sensory-motor polyneuropathy).
- C. Member is not a liver transplant recipient.
- D. The requested medication will not be used in combination with any other medication approved for the treatment of hereditary transthyretin-mediated amyloidosis (e.g., Amvuttra, Onpattro, Tegsedi, Vyndaqel, Vyndamax).

### **Criteria for Continuation of Therapy**

**Authorization may be granted for continued treatment when ALL the following criteria are met:**

- A. Member must have met all initial authorization criteria.
- B. Member must have demonstrated a beneficial response to treatment with the requested medication compared to baseline (e.g., improvement of neuropathy severity and rate of disease progression as demonstrated by the modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, manual grip strength).

### **Approval Duration and Quantity Restrictions:**

**Approval Duration:** 12 months

**Quantity Level Limit:**

Medication	Standard Limit	FDA-recommended dosing
Wainua (eplontersen) 45 mg/0.8 mL single-dose autoinjector	1 autoinjector per 28 days	45 mg administered by subcutaneous injection once monthly.

### **References:**

- Wainua [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2023.
- Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013; 8:31.
- Sekijima Y. Hereditary Transthyretin Amyloidosis. 2001 Nov 5 [Updated 2021 June 17]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1194/>. Accessed March 1, 2024.