AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Wainua (eplontersen)	Page:	1 of 2
Effective Date:	4/25/2024	Last Review Date:	03/26/2024

Applies to:	☐Illinois	☐Florida	☒New Jersey
	☒Maryland	☒Florida Kids	☒Pennsylvania Kids
	☐Michigan	☒ Virginia	☒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.

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:

1. Wainua [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2023.
2. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, Lewis WD, Obici L, Planté-Bordeneuve V, Rapezzi C, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013; 8:31.
3. Sekijima Y. Hereditary Transthyretin Amyloidosis. 2001 Nov 5 [Updated 2021 June 17]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2023. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1194/. Accessed January 2, 2024.