



Pharmacy Drug Policy & Procedure

Policy Name:	Wainua (eplontersen)	Policy#:	2774P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Wainua (eplontersen)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Wainua (eplontersen) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN)
- 1.2 Documentation that the patient has a pathogenic TTR gene mutation
- 1.3 Age 18 years or older
- 1.4 Presence of clinical signs and symptoms of the disease of polyneuropathy, including peripheral or autonomic, that are determined to be mild to moderate
- 1.5 Documentation to support all of the following:
 - Neuropathy impairment scale score between 10-130
 - Stage 1 or 2 familial amyloidotic polyneuropathy (FAP) or Coutinho stage
- 1.6 Prescribed by or in consultation with a neurologist (nervous system doctor)

2. Exclusion Criteria

- 2.1 Concurrent coverage with other treatments for hATTR (such as Amvuttra or Onpattro)
- 2.2 Wainua is not supported to treat hATTR associated cardiomyopathy

3. Managed Dose Limit

- 3.1 Maximum 0.8 mL per 28 days

4. Approval Period

- 4.1 Initial: 12 months
- 4.2 Reauthorization: 12 months with documentation that the patient has experienced a positive clinical response to therapy (e.g., improved neuropathy impairment, motor function, quality of life assessment, serum TTR levels, etc.)

CPT Codes

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HCPCS Codes

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References

1. Wainua (eplontersen) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP: December 2023.
2. Coelho T, Marques W Jr, Dasgupta NR, et al; NEURO-TTRansform Investigators. Eplontersen for Hereditary Transthyretin Amyloidosis With Polyneuropathy. JAMA. 2023 Oct 17;330(15):1448-1458

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.