

eplontersen (Wainua)

Medical Benefit Drug Policy

Place of Service

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

Drug Details

USP Category: MISCELLANEOUS THERAPEUTIC AGENTS

Mechanism of Action: transthyretin-directed antisense oligonucleotide

HCPCS:

C9399:Unclassified drugs or biologicals

J3490:Unclassified drugs

How Supplied:

45 mg/0.8 mL in a single-dose prefilled syringe

Condition(s) listed in policy *(see coverage criteria for details)*

- Hereditary Transthyretin Amyloidosis (hATTR) with Polyneuropathy

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

Hereditary Transthyretin Amyloidosis (hATTR) with Polyneuropathy

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication(Patient is at least 18 years old)
2. Prescribed by or in consultation with all relevant specialists or physicians experienced in the treatment of ATTR amyloidosis
3. Documented diagnosis of hATTR with polyneuropathy confirmed by documentation of a pathogenic transthyretin (TTR) mutation
4. Not being used in combination with other TTR-silencer or TTR stabilizers
5. Dose does not exceed FDA-approved maximum

Covered Doses:

45 mg SC monthly

Coverage Period:

yearly, based on continued response to therapy

ICD-10:

E85.1

References

1. Wainua (eplontersen) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; April 2026.

Review History

Date of Last Annual Review: 2Q2026

Changes from previous policy version:

- New policy for physician administered pre-filled syringe.

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*