eplontersen (Wainua)

Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Wainua (C9399 / J3490) Prefilled Syringe (given by a healthcare provider subcutaneously) is managed under the Medical Benefit policy. Wainua (C9399 / J3490) autoinjector (given by subcutaneous injection) can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

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