CareSource Rx Innovations

# PHARMACY POLICY STATEMENT
## Marketplace

| DRUG NAME | Wainua (eplontersen) |
|---|---|
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Wainua is a ligand-conjugated antisense oligonucleotide (LICA) indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. It inhibits hepatic synthesis of human transthyretin (TTR) protein by causing degradation of mutant and wild-type TTR mRNA through binding to the TTR mRNA, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Efficacy was demonstrated in the NEURO-TTRansform clinical trial. hATTR is a rare and progressive inherited disorder where misfolded TTR accumulates as amyloid fibrils in the body. In polyneuropathy of hATTR (hATTR-PN), these fibrils deposit in the peripheral nerves which leads to pain, muscle weakness, and autonomic dysfunction. It is a monthly self-administered subcutaneous injection.

Wainua (eplontersen) will be considered for coverage when the following criteria are met:

### Hereditary Transthyretin Amyloidosis (hATTR Amyloidosis): Polyneuropathy

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of hATTR amyloidosis with documentation of a transthyretin (TTR) mutation confirmed by genetic testing; AND
4. Member has signs/symptoms of polyneuropathy; AND
5. Member must have documentation of familiar amyloid polyneuropathy (FAP) Cutinho stage 1 (ambulatory without assistance) or stage 2 (ambulatory with assistance); AND
6. Member has NOT had a liver transplant; AND
7. Wainiua is NOT being used in combination with another hATTR drug (e.g., Amvuttra, Onpattro, Tegsedi, Vyndaqel, Vyndamax).
8. **Dosage allowed/Quantity limit:** 45 mg injected subQ once monthly. (1 syringes per 28 days)

***If all the above requirements are met, the medication will be approved for 9 months.***

For **reauthorization**:

1. Chart notes must include documentation of positive clinical response to therapy such as improvement or stabilization of neuropathy impairment.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Wainua (eplontersen) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

| DATE | ACTION/DESCRIPTION |
|---|---|
| **1/26/2024** | New policy for Wainua created. |

References:


1. Wainua [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023.
2. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013;8:31
3. National Institutes of Health (NIH). Transthyretin amyloidosis. Available at: https://ghr.nlm.nih.gov/condition/transthyretin-amyloidosis.
4. Amyloid transthyretin (ATTR) Amyloidosis: Signs, symptoms, and diagnostic workup. 2018 Akcea Therapeutics, Inc. Available at: https://www.hattrguide.com/wp-content/uploads/2018/04/Diagnostic-Card.pd
5. BioNews Services, LLC. Stages of familial amyloid polyneuropathy. Available at: https://fapnewstoday.com/stages-of-familial-amyloid-polyneuropathy/
6. Coelho T, Marques Jr W, Dasgupta NR, et al. Eplontersen for Hereditary Transthyretin Amyloidosis With Polyneuropathy. JAMA. 2023;330(15):1448-1458. doi:10.1001/jama.2023.18688
7. Coelho T, et al. Characteristics of Patients with Hereditary Transthyretin Amyloidosis-Polyneuropathy (ATTRv-PN) in NEURO-TTRansform, an Open-label Phase 3 Study of Eplontersen. Neurol Ther. 2023;12:267–287
8. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen Treatment for Patients with Hereditary Transthyretin Amyloidosis. N Engl J Med. 2018;379(1):22-31. doi:10.1056/NEJMoa1716793
9. Stages of FAP. FAP News Today. Accessed February 1, 2024. https://fapnewstoday.com/stages-of-familial-amyloid-polyneuropathy/


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