COMMON GROUND
HEALTHCARE COOPERATIVE

PHARMACY POLICY STATEMENT
Common Ground Healthcare Cooperative (CGHC)

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.

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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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