**Generic Name:** Eplontersen

**Therapeutic Class or Brand Name:** Wainua

**Applicable Drugs:** N/A

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** 8/26/2024

**Date Last Reviewed / Revised:** N/A

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IX are met)

I. Documented diagnosis of polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR-PN)

II. Documentation of biopsy and transthyretin mutation as confirmed by genetic testing.

III. Stage 1 (independent ambulation) or Stage 2 (requires ambulatory support) per Coutinho's system. See appendix, table 1.

IV. Neuropathy Impairment Score ≥ 10 and ≤ 130.

V. Documented treatment failure or contraindication to at least ONE medication from the following pharmacologic classes for symptoms of polyneuropathy:

   A. Anticonvulsant (gabapentin, or pregabalin)

   B. Tricyclic antidepressant (nortriptyline, amitriptyline)

   C. Serotonin/norepinephrine reuptake inhibitor (duloxetine or venlafaxine)

VI. Age >18 years of age.

VII. Medication has been prescribed by or in consultation with a neurologist.

VIII. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IX. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

## EXCLUSION CRITERIA

- History of liver transplantation
- Neuropathy not related to Hereditary Transthyretin-Medicated Amyloidosis
- In combination with Tegsedi (inosetron), Onpattro (patisiran), Vyndaqel (tafamidis), or Diflunisal
- Advanced disease (stage 3 hATTR-PN)

## Other Criteria

- NA

## Quantity / Days Supply Restrictions

- One 40 mg autoinjector per 30 days

## Approval Length

- **Authorization:** 1 year
- **Re-Authorization:** 1 year with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication

## Appendix

| Table 1: Coutinho's System | |
|---|---|
| Stage 1 | Does not require assistance with ambulation<br>Disease is limited to lower limbs; slight weakness of the extensors of the big toes |
| Stage 2 | Requires assistance with ambulation<br>Motor signs progress in lower limbs with steppage and distal amyotrophies; the muscles of the hands begin to be wasted and weak |
| Stage 3 | Confined to a wheelchair or bedridden<br>Generalized weakness and areflexia |

Neuropathy Impairment Score (NIS)

- Cranial nerves (range: 0 to 40)
- Muscle weakness (range: 0 to 152)
- Sensation loss (finger and toe) (range: 0 to 32)
- Decreased muscle stretch reflexes (range: 0 to 20)

## References

1. Wainua [Package insert]. Wilmington, DE: Astrazeneca Pharmaceuticals LP: December 2023.

2. Coelho T, Marques W, Dasgupta NR, et al. Eplontersen for Hereditary Transthyretin Amyloidosis With Polyneuropathy. *JAMA*. 2023;330(15):1448–1458.
3. Ando Y, Adams D, Benson MD, et al. Guidelines and new directions in the therapy and monitoring of ATTRv amyloidosis. *Amyloid*. 2022;29(3):143-155.
4. Kittleson, M, Ruberg, F. et al. 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis: A Report of the American College of Cardiology Solution Set Oversight Committee. *JACC*. 2023 Mar, 81 (11) 1076–1126.
5. Clinical Review Report: Inotersen (Tegsedi): (Akcea Therapeutics, Inc.): Indication: Stage I or II polyneuropathy in adults with hereditary transthyretin-mediated amyloidosis (hATTR) [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2020 Jan. Table 31, Comparison of Disease Staging Systems. Available from: https://www.ncbi.nlm.nih.gov/books/NBK558478/table/cl.app5.tab3/
6. Dyck PJ, Kratz KM, Lehman KA, Karnes JL, Melton LJ, O'Brien PC, et al. The Rochester diabetic neuropathy study: design, criteria for types of neuropathy, selection bias, and reproducibility of neuropathic tests. *Neurology*. 1991;41(6):799–807.