Mass General Brigham
Health Plan

Wainua (eplontersen)
Effective 07/01/2025

Plan	☐ MassHealth UPPL ☒ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Wainua (eplontersen) is a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Coverage Guidelines
Authorization may be reviewed for members new to the plan within the last 90 days who are currently receiving treatment with the requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met:

1. Member has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hAATR-PN)
2. Diagnosis is confirmed by documentation of presence of a transthyretin (TTR) mutation (e.g., V30M)
3. Member is 18 years of age or older
4. Member is experiencing clinical signs and symptoms of polyneuropathy, defined as ONE of the following:
    a. Polyneuropathy disability (PND) score ≤ IIIb
    b. Stage 1 or 2 familial amyloidotic polyneuropathy (FAP) or Coutinho stage
    c. Neuropathy Impairment Scale score ≥ 10 and ≤ 130
5. Prescribed by or in consultation with a neurologist
6. Requested medication will not be used in combination with a TTR silencer (e.g., Amvuttra) or a TTR stabilizer (e.g., diflunisal, Attruby, Vyndamax, or Vyndaqel)

<u>Continuation of Therapy</u>
Requestions for reauthorization will be approved when the following criteria are met:

1. Documentation member has had a positive clinical response to therapy (e.g., improved quality of life, improved or stable motor function, decreased serum TTR level)

Limitations

1. Initial and reauthorization approvals will be authorized for 12 months.
2. The following quantity limitations apply:

Drug Name and Dosage Form	Quantity Limit
Wainua injection	1 injection per 28 days

References

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14. Coelho T, Maurer MS, Suhr OB. THAOS - The Transthyretin Amyloidosis Outcomes Survey: initial report on clinical manifestations in patients with hereditary and wild type transthyretin amyloidosis. *Curr Med Res Opin.* 2013[b];29(1):63-76.
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Review History

09/11/2024 – Reviewed for September P&T. Effective 11/1/2024.

04/09/2025 – Reviewed at April P&T. Updated initial criteria to: provide an example of a TTR mutation; clarify that member must be experiencing clinical signs and symptoms of polyneuropathy; require that Wainua is prescribed by or in consultation with a neurologist; include Attruby as an example of a TTR stabilizer that should

not be co-prescribed with Wainua. Updated reauthorization criteria to include examples of positive clinical response to therapy. Effective 07/01/2025.