UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2326-2
Program	Prior Authorization/Medical Necessity
Medication	Wainua™ (eplontersen)
P&T Approval Date	2/2024, 2/2025
Effective Date	5/1/2025

1. Background:

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

2. Coverage Criteria [a]:

A. Initial Authorization

1. **Wainua** will be approved based on **all** of the following criteria:

   a. **Both** of the following:

      (1) Diagnosis of hATTR amyloidosis with polyneuropathy

      -AND-

      (2) Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)

      -AND-

   b. Prescribed by or in consultation with a neurologist

      -AND-

   c. Documentation of **one** of the following:

      (1) Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb

      -OR-

      (2) Patient has a baseline FAP Stage 1 or 2

      -OR-

      (3) Patient has a baseline neuropathy impairment (NIS) score ≥ 10 and ≤ 130

      -AND-

   d. Patient has not had a liver transplant

-AND-

e. Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

-AND-

f. Patient is not receiving Wainua in combination with **either** of the following:

(1) Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]

-OR-

(2) Transthyretin stabilizer [e.g., Vyndaqel/Vyndamax (tafamadis), Attruby (acoramidis)]

Authorization will be issued for 12 months.

B. Reauthorization

1. **Wainua** will be approved based on **both** of the following criteria:

a. Documentation that the patient has experienced a positive clinical response to Wainua therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

-AND-

b. Patient is not receiving Wainua in combination with **either** of the following:

(1) Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran), Tegsedi (inotersen)]

-OR-

(2) Transthyretin stabilizer [e.g., Vyndaqel/Vyndamax (tafamadis), Attruby (acoramidis)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Wainua [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.

Program	Prior Authorization/Medical Necessity - Wainua™ (eplontersen)
Change Control	
2/2024	New program.
2/2025	Added Attruby to Vyndaqel/Vyndamax and relabeled as transthyretin stabilizer agents not to be used in combination. Updated reference.