UnitedHealthcare

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1434-3
Program	Prior Authorization/Notification
Medication	Wainua™ (eplontersen)
P&T Approval Date	2/2024, 2/2025, 2/2026
Effective Date	5/1/2026

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. Diagnosis of hATTR amyloidosis with polyneuropathy

   -AND-

   b. Patient has a pathogenic TTR mutation (e.g., V30M)

   -AND-

   c. 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 of positive clinical response to Wainua therapy

   -AND-

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

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(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 Rules:

- 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/Notification – 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.
2/2026	Annual review. No changes to coverage criteria.

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