Commercial PA Criteria

Effective: February 8, 2024

Prior Authorization: Wainua

Products Affected: Wainua (eplontersen) subcutaneous injection

Medication Description: Wainua is a TTR-directed ASO, covalently linked to a ligand containing three N-acetyl galactosamine (GalNAc) residues to enable delivery of the ASO to hepatocytes. As an ASO-GalNAc conjugate, Wainua causes 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.

Covered Uses:

1. Treatment of Polyneuropathy of Hereditary Transthyretin–Mediated Amyloidosis (hATTR)

Exclusion Criteria:

1. Concomitant Use With Amvuttra**,** Onpattro, Tegsedi, or a Tafamidis Product.

Required Medical Information:

1. Diagnosis
2. Documented transthyretin (TTR) mutation verified by genetic testing
3. Medical history

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.

Coverage Duration: 12 months

Other Criteria:

Initial

1. Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR)

Approve for if the patient meets ALL of the following:

A. Patient has a transthyretin mutation as confirmed by genetic testing; **AND**

B. Patient has symptomatic polyneuropathy; **AND**

Note: Examples of symptomatic polyneuropathy include reduced motor strength/coordination, and impaired sensation (e.g., pain, temperature, vibration, touch). Examples of assessments for symptomatic disease include history and clinical exam, electromyography, or nerve conduction velocity testing.

C. Patient does not have a history of liver transplantation

References:

1. Wainua™ subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; December 2023.

Policy Revision history

January 2024

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/08/2024