

TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Eplontersen (Wainua)	CRITERIA ID: TX.CC.PHAR.64
BUSINESS UNIT: Superior HealthPlan	FUNCTIONAL AREA: Pharmacy
EFFECTIVE DATE: 10/01/2026	PRODUCT(S): STAR, STAR+PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	REGULATOR MOST RECENT APPROVAL DATE(S): N/A

CRITERIA STATEMENT:

The purpose of this clinical criteria is to provide a guide to medical necessity reviews for eplontersen (Wainua).

PURPOSE:

Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

SCOPE:

Superior HealthPlan (SHP) Pharmacy team, Centene Pharmacy Services (CPS)

DEFINITIONS:

CPS = Centene Pharmacy Services

MCO = Managed Care Organization

SHP = Superior HealthPlan

UM = Utilization Management

POLICY:

It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of eplontersen (Wainua); procedure code: C9311.

Description/Mechanism of Action:

Wainua is a subcutaneous, transthyretin-directed antisense oligonucleotide.

FDA Approved Indications:

Wainua is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults.

Formulations:

Wainua is available as:

- 45 mg/0.8 mL in a single-dose autoinjector.
- 45 mg/0.8 mL in a single-dose prefilled syringe.

PROCEDURE:

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Polyneuropathy of hereditary transthyretin-mediated (hATTR) (must meet all):

1. The client is 18 years or older.
2. The client has a diagnosis of hereditary transthyretin (hATTR) amyloidosis (diagnosis code: E85.1), supported by:
 - a. Transthyretin (TTR) mutation proven by genetic testing
 - b. Clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability)
3. Provider attestation client will not receive Wainua therapy in combination with other polyneuropathy hATTR amyloidosis therapies (e.g., inotersen, patisiran, vutrisiran, or tafamidis meglumine).
4. Provider attestation client has not had a liver transplant.

Approval duration: 12 months

II. Continued Therapy:

A. Polyneuropathy of hereditary transthyretin-mediated (hATTR) (must meet all):

1. The client has previously received treatment with Wainua without an adverse reaction.
2. The client has a positive clinical response to Wainua (e.g., improved neurologic impairment, improved motor function, slowing of disease progression)

Approval duration: 12 months

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	10/01/2026

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