SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Wainua™ (eplontersen)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosage: 45 mg administered by subcutaneous injection once monthly

Quantity Limit: 1 single-dose auto-injector per 28 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Medication is prescribed by or in consultation with a neurologist
- ❑ Member is 18 years of age or older
- ❑ Member must have a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis polyneuropathy or familial amyloid polyneuropathy (FAP) confirmed by **BOTH** of the following:
  - ❑ Documented genetic mutation of a pathogenic *TTR* variant
  - ❑ Confirmation of amyloid deposits on tissue biopsy

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- ❑ Member must have documentation of the following:
  - ❑ Presence of clinical signs and symptoms of the disease **(e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability)**
  - ❑ Clinical exam findings of abnormal nerve conduction study or neurological examination results
- ❑ Member has **ONE** of the following:
  - ❑ A baseline polyneuropathy disability (PND) score ≤ IIIb
  - ❑ A baseline FAP Stage 1 or 2 **(stage 1=ambulatory, stage 2=ambulatory with assistance)**
- ❑ Member has **NOT** received a liver transplant

Reauthorization: 6 months. All criteria that apply must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member has previously received treatment with requested medication
- ❑ Provider attests to an absence of unacceptable toxicity from the drug (e.g., ocular symptoms related to hypovitaminosis A)
- ❑ Member has experienced a positive clinical response to therapy confirmed via chart notes (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression)
- ❑ Member has documented disease response compared to pre-treatment baseline as evidenced by stabilization or improvement in at least **ONE** of the following **(submit documentation)**:
  - ❑ Signs and symptoms of neuropathy
  - ❑ MRC muscle strength

EXCLUSIONS – Therapy will NOT be approved if member has history of any of the following:

- Hereditary transthyretin amyloidosis agents are considered experimental, investigational, or unproven for **ANY** other use including the following:
  - History of liver transplant
  - Treatment of cardiomyopathy hATTR in absence of polyneuropathy symptoms
  - Severe renal impairment or end-stage renal disease
  - Moderate or severe hepatic impairment
  - New York Heart Association (NYHA) class III or IV heart failure
  - Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis **(e.g., monoclonal gammopathy, autoimmune disease)**
  - Concurrent use of Tegsedi® (inotersen), Amvuttra® (vutrisiran), Onpattro® (patisiran), Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), or diflunisal

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Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****