

AvMed

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 1-305-671-0200**. 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 AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Recommended Dosage: 45 mg administered by subcutaneous injection once monthly

Quantity Limit: 1 injection (0.8 mL) 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 $\leq$ 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.