SENTARA HEALTH PLANS

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Onpattro® (patisiran lipid complex) **IV (J0222) MEDICAL**

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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

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

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage:

- 10 mg vial = 100 billable units; 300 billable units every 3 weeks
  - ❑ Weight < 100 kg – 0.3 mg/kg intravenous infusion every 3 weeks
  - ❑ Weight ≥ 100kg – 30 mg intravenous infusion every 3 weeks

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Recommended Prior to Therapy:

- Dosing is based on actual body weight
- Members should be pre-medicated with corticosteroid, acetaminophen and antihistamines
- Infusion should be filtered, diluted, and infused, via a pump, over at least 80 minutes
- Members should receive vitamin A supplementation

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
- ❑ 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 has submitted documentation to support of **ONE** of the following:
  - ❑ Member continues to have a polyneuropathy disability (PND) score ≤ IIIb
  - ❑ Member continues to have a FAP Stage 1 or 2
- ❑ Member has experienced a positive clinical response to the medication confirmed via chart notes (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression)

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

- Onpattro is 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 Amvuttra, Vyndamax® (tafamidis), Vyndaqel® (tafamidis meglumine), Attruby™ (acoramidis), Wainua™ (eplontersen), or diflunisal

Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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.****

***Approved by Pharmacy and Therapeutics Committee: 9/16/2022**
REVISED/UPDATED: ~~6/7/2019; (Reformatted) 7/7/2019; 9/24/2019; 10/4/2022;~~ **6/9/2025**