# SENTARA COMMUNITY PLAN
# (MEDICAID)

## 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 1-844-305-2331**. 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**.

**Drug Requested: Tegsedi™** (inotersen) **Subcutaneous Injection (J3490) (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:** _____

**DEA OR NPI #:** _____

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

**Drug Form/Strength:** _____

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

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

**Weight:** _____ **Date:** _____

**RECOMMENDED PRIOR TO THERAPY:** Patients should receive vitamin A supplementation.

- ❑ 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.

**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 Approval Length – 6 months**

- ❑ Medication must be prescribed by or in consultation with a neurologist; **AND**
- ❑ Member must be 18 years of age or older; **AND**
- ❑ Member must have a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis polyneuropathy or familial amyloid polyneuropathy (FAP) confirmed by **BOTH** of the following:

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- ❑ Documented genetic mutation of a pathogenic TTR variant; **AND**
- ❑ Confirmation of amyloid deposits on tissue biopsy; **AND**

❑ Attestation the member is enrolled in the Tegsedi™ Risk Evaluation and Mitigation Strategy (REMS) program; **AND**

❑ Member must have documentation for all of the following:

- ❑ Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.); **AND**
- ❑ Member has a baseline polyneuropathy disability (PND) score ≤ IIIb; **OR**
- ❑ Member has a baseline FAP Stage 1 or 2 **(stage 1=ambulatory, stage 2=ambulatory with assistance)**; **AND**
- ❑ Member has not received a liver transplant; **AND**
- ❑ Platelet count is above 100 x $10^9$/L; **AND**
- ❑ Urinary protein to creatinine ratio (UPCR) is below 1000 mg/g; **AND**
- ❑ The estimated glomerular filtration rate (eGFR) above 45 mL/minute/1.73 $m^2$

**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; **OR**

❑ History of acute glomerulonephritis caused by Tegsedi; **OR**

❑ Severe renal impairment or end-stage renal disease; **OR**

❑ Moderate or severe hepatic impairment; **OR**

❑ New York Heart Association (NYHA) class III or IV heart failure; **OR**

❑ Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis **(monoclonal gammopathy, autoimmune disease, etc.)**, **OR**

❑ Concurrent use of Onpattro® (patisiran), tafamidis or diflunisal

**REAUTHORIZATION APPROVAL- 6 months.** All criteria 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 Tegsedi™; **AND**

❑ Prescribed by or in consultation with a neurologist; **AND**

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- ❑ Documentation of **ONE** of the following:
  - ❑ Member continues to have a polyneuropathy disability (PND) score ≤ IIIb; **OR**
  - ❑ Member continues to have a FAP Stage 1 or 2; **AND**
- ❑ Documentation that the patient has experienced a positive clinical response to Tegsedi™ **(e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)**; **AND**
- ❑ Absence of drug toxicity

## Medication being provided by a Specialty Pharmacy - PropriumRx

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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:**
**REVISED/UPDATED:** ~~6/7/2019~~7/25/2019; ~~10/27/2019~~**(Reformatted) 10/16/2020**