AvMed

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 1-877-535-1391**. 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: Tegsedi™ (inotersen) **Subcutaneous Injection (J3490) (Medical)**

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: **284mg subcutaneous once weekly**

Length of Therapy: (check box that applies) ❑ **Initial - 6 months** ❑ **Renewal - 6 months**

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

Weight: _____ **Date:** _____

RECOMMENDED PRIOR TO THERAPY: Member 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

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- ❑ 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:
  - ❑ 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

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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**
- ❑ 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 member 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 AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed'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: ~~5/10/2019;~~ **(Reformatted)** ~~7/8/2019;~~ **9/25/2019**;