OPTIMA HEALTH PLAN

MEDICAL/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 1-844-723-2094**. 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 will 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)**

❑ **URGENT REVIEW. In checking this box, prescriber attests to the fact that by applying the standard review timeframe may seriously jeopardize the member's life, health, or ability to regain maximum function.**

❑ **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.

DRUG INFORMATION: Complete **all** information below or authorization will be delayed.

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:** _____

RECOMMENDED PRIOR TO THERAPY: Member should receive vitamin A supplementation.

CLINICAL CRITERIA: Check below **ALL** that apply. **ALL** criteria **must** be met for approval. To support each lined checked, **ALL** documentation, including lab results, diagnostics, and/or chart notes, **must** be provided or request will 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:
  - ❑ Documented genetic mutation of a pathogenic TTR variant); **AND**

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- ❑ 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**
  - ❑ Clinical exam findings of abnormal nerve conduction study or neurological examination results; **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. 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 will 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 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

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.*

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:**
REVISED/UPDATED: ~~5/10/2019,~~ **(Reformatted) 7/8/2019**;