

## Inotersen (Tegsedi™)

**Place of Service**  
**Self-Administration**  
*Pharmacy Benefit*

**HCPs:** J3490

### **NDCs:**

- 72126-007-03: 284 mg/ 1.5 mL single-dose prefilled syringe (pack of 1 syringe)
- 72126-007-01: 284 mg/ 1.5 mL single-dose prefilled syringe (pack of 4 syringes)

### **Condition listed in policy (see criteria for details)**

- [Hereditary transthyretin amyloidosis \(hATTR\) with polyneuropathy](#)

**AHFS therapeutic class:** Amyloidosis agent, transthyretin (TTR) suppression

**Mechanism of action:** Transthyretin-directed antisense oligonucleotide

### **(1) Special Instructions and pertinent Information**

**This drug is managed under the outpatient Pharmacy Benefit for self-administration.** Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

**To submit a request to the Medical Benefit,** please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

**For plans with self-injectables only covered under the Medical Benefit,** please submit clinical information for prior authorization review.

### **(2) Prior Authorization/Medical Review is required for the following condition(s)**

**All requests for inotersen (Tegsedi™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

### **Hereditary transthyretin amyloidosis (hATTR) with polyneuropathy**

1. Age 18 years or older, **AND**
2. Prescribed by or in consultation with a neurologist, **AND**
3. Documented diagnosis of hATTR with polyneuropathy confirmed by documentation of a pathogenic TTR mutation, **AND**
4. Patient has a baseline platelet count above  $100 \times 10^9/L$ , **AND**

5. Patient has a baseline urine protein to creatinine ratio (UPCR) below 1000 mg/g, **AND**
6. Not being used in combination with Onpattro or tafamidis

**Covered Doses**

284 mg SC once weekly

**Coverage Period**

Indefinite

**ICD-10:**

E85.1

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

**All requests for inotersen (Tegsedi™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s)**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

**(5) Additional Information**

How supplied:

- 284 mg/ 1.5 mL (single-dose prefilled syringe)

**(6) References**

- Adams D, Gonzalez-Duarte A, O’Riordan WD, et al. Patisiran, an RNAi therapeutic, for hereditary transthyretin amyloidosis. N Engl J Med 2018;379:11-21.
- Adams D, Suhr OB, Hund E, et al. First European consensus for diagnosis, management, and treatment of transthyretin familial amyloid polyneuropathy. Curr Opin Neurol. 2016;29(Suppl 1):S14-26.
- AHFS®. Available by subscription at <http://www.lexi.com>
- Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. N Engl J Med 2018; 379: 22-31.
- Buxbaum JN. Oligonucleotide drugs for transthyretin amyloidosis. N Engl J Med 2018; 379:1.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med 2018; 379(11):1007-1016.
- Tegsedi® (patisiran) [Prescribing Information]. Waltham, MA: Akcea Therapeutics; 5/2021.

**(7) Policy Update**

Date of last review: 3Q2022

Date of next review: 3Q2023

Changes from previous policy version:

- No clinical change to policy following routine annual review.

*BSC Drug Coverage Criteria to Determine Medical Necessity*  
*Reviewed by P&T Committee*

Commercial

inotersen (Tegsedi™)

Effective: 08/03/2022

Page 2 of 3

