Medical Policy:

Tegsedi® (inotersen) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.309	January 2, 2024	2019

Definitions

Tegsedi, an antisense oligonucleotide, is indicated for treatment of adults with polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR). Tegsedi has not been studied in patients with a history of liver transplantation. hATTR is a progressive disease caused by mutations in the transthyretin (TTR) gene leading to multisystem organ dysfunction. Common neurologic manifestations include sensiomotor polyneuropathy, autonomic neuropathy, small-fiber polyneuropathy, and carpal tunnel syndrome.

Length of Authorization

12 months

Dosing Limits [Medical Benefit]

Approve 284 mg subcutaneously once weekly.

Guideline

1. **Polyneuropathy of Hereditary Transthyretin–Mediated Amyloidosis (hATTR).** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A.** Patient is ≥ 18 years of age; **AND**
   - **B.** Patient has a transthyretin mutation as confirmed by genetic testing; **AND**
   - **C.** Patient has symptomatic polyneuropathy; **AND**
     Note: Examples of polyneuropathy include reduced motor strength/coordination, and impaired sensation (e.g., pain, temperature, vibration, touch). Examples of assessments for symptomatic disease include history and clinical exam, electromyography, or nerve conduction velocity testing.
   - **D.** Patient does not have a history of liver transplantation; **AND**
   - **E.** The medication is prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.

Applicable Procedure Codes

Code	Description
J3490	Tegsedi 284mg/1.5mL; unclassified drugs

Applicable NDCs

Code	Description
72126-0007-02	Tegsedi 284mg/1.5mL prefilled syringe
72126-0007-01	Tegsedi 284mg/1.5mL prefilled syringe

ICD-10 Diagnoses

Code	Description
E85.82	Wildtype transthyretin-related (ATTR) amyloidosis
E85.1	Neuropathic heredofamilial amyloidosis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/23/2023	Transfer policy from CCUM template to EH template; Added code: J3490 Tegsedi 284mg/1.5mL - Retired MG.MM.PH.183

References

1. Tegsedi® injection [prescribing information]. Waltham, MA: Sobi/Akcea; June 2022.