

## Medical Policy:

### Tegsedi® (inotersen) subcutaneous injection

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## 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 sensimotor 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  $\geq 18$  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.