Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Tegsedi (inotersen)**

Effective: July 14, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Tegsedi (inotersen) is a transthyretin-directed antisense oligonucleotide indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Tegsedi for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy

AND

2. Documentation in the Member's medical record of transthyretin (TTR) genetic mutation

AND

3. The patient is at least 18 years of age or older

AND

4. Prescribed by or in consultation with a neurologist or a provider who specializes in amyloidosis

AND

5. Documentation of baseline polyneuropathy disability (PND) score ≤IIIb

AND

6. Documentation the patient has not had a prior liver transplant

AND

7. Documentation the requested medication will not be used concomitantly with another medication indicated for the management of cardiomyopathy or neuropathy of transthyretin-mediated amyloidosis (e.g., Amvuttra, Onpattro, Vyndamax)

Reauthorization Criteria

1. Documented diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy

AND

2. Documentation in the Member's medical record of transthyretin (TTR) genetic mutation

AND

3. The patient is at least 18 years of age or older

AND

4. Prescribed by or in consultation with a neurologist or a provider who specializes in amyloidosis

AND

5. Documentation the requested medication will not be used concomitantly with another medication indicated for the management of cardiomyopathy or neuropathy of transthyretin-mediated amyloidosis (e.g., Amvuttra, Onpattro, Vyndamax)

AND

6. Documentation of both of the following:
    a. Polyneuropathy disability (PND) score has remained ≤IIIb
    b. Positive clinical response as evidenced by improved or stable motor function, neurologic impairment, and quality of life

Limitations

1. Initial coverage of Tegsedi will be authorized for 12 months. Reauthorization of Tegsedi will be provided in 12-month intervals.
2. Members new to the plan stable on Tegsedi should be reviewed against Reauthorization criteria.
3. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi therapeutic, for hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):11-21.
2. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases. 2013;8(31):1-18.
3. Benson MD, Waddington-Cruz M, Berk J, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):22-31.
4. Brannagan T, Wang AK, Coelho T, et al. Open label extension of the phase 3 study NEURO-TTR to assess the long-term efficacy and safety of inotersen in patients with hereditary transthyretin amyloidosis. Neurology. 2018;90(15 Suppl). Abstract P1.324.
5. Lasser KE, Mickle K, Chapman R, et al. Inotersen and patisiran for hereditary transthyretin amyloidosis: effectiveness and value. Evidence report. 2018 August 29. Available from Internet. Accessed 2018 September 12.
6. Tegsedi (inotersen) [package insert]. Boston, MA: Akcea Therapeutics, Inc.; Jan 2024.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- June 13, 2023: Added documentation the requested medication will not be concomitantly with another medication indicated for the management cardiomyopathy or neuropathy of transthyretin-mediated amyloidosis (effective September 1, 2023).
- May 14, 2024: No changes.
- July 8, 2025: No changes.(eff 7/8/25)
- July 14, 2026: Administrative update to remove CareLink from the Medical Necessity Guideline template. (eff 7/14/26)

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.