

Policy Name:	Tegsedi (inotersen)	Policy #:	2707P
---------------------	----------------------------	------------------	--------------

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Tegsedi (inotersen).

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Tegsedi (inotersen) under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis
- 1.2 Documentation that the patient has a pathogenic TTR gene mutation (e.g., V30M)
- 1.3 Age 18 years or older
- 1.4 Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic nerve pain, motor disability, heart dysfunction, kidney dysfunction)
- 1.5 One of the following:
 - Patient has a baseline polyneuropathy disability (PND) score IIIb
 - Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2
- 1.6 Prescribed by or in consultation with a neurologist (nervous system doctor)

2. Exclusion Criteria

- 2.1 Members also taking Onpattro (patisiran) or Amvuttra

3. Approval Period

- 3.1 Initial Approval: 12 months
- 3.2 Reapproval: 12 months with documentation that the patient has experienced a positive clinical response to Tegsedi (e.g., improved neurologic impairment, motor function, heart function, quality of life assessment, serum TTR levels, etc.)

CPT Codes

--	--

HCPCS Codes

--	--

References

1. Tegsedi (inotersen) [prescribing information]. Waltham, MA: Sobi Inc; June 2022.
2. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen Treatment for Patients with Hereditary Transthyretin Amyloidosis. N Engl J Med 2018; 379:22.

3. Brannagan TH, Wang AK, Coelho T, et al. Early data on long-term efficacy and safety of inotersen in patients with hereditary transthyretin amyloidosis: a 2-year update from the open-label extension of the NEURO-TTR trial. *Eur J Neurol* 2020; 27:1374.

Created Date: 10/02/19

Effective Date: 10/02/19

Posted to Website: 01/01/2022

Revision Date: 10/05/2023

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.