Pharmacy Drug Policy & Procedure

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