UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tegsedi

Program	Prior Authorization
Medication	Tegsedi™ (inotersen)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	11/2018
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

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

2. Coverage Criteria:

A. <u>Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy</u>

1. <u>Initial Authorization</u>

a. **Tegsedi** will be approved based on **<u>all</u>** of the following criteria:

(1) **<u>Both</u>** of the following:

(a) Diagnosis of hATTR amyloidosis with polyneuropathy
(b) Documentation that the patient has a pathogenic TTR mutation (e.g., V30M)

-AND-

(2) Prescribed by or in consultation with a neurologist

-AND-

(3) Documentation of **<u>one</u>** of the following:

(a) Patient has a baseline polyneuropathy disability (PND) score ≤ IIIb
(b) Patient has a baseline FAP Stage 1 or 2

(c) Patient has a baseline neuropathy impairment (NIS) score ≥ 10 and ≤ 130

-AND-

(4) Patient has not had a liver transplant

-AND-

(5) Presence of clinical signs and symptoms of the disease (e.g., peripheral sensorimotor polyneuropathy, autonomic neuropathy, motor disability, etc.)

-AND-

(6) Patient is not receiving Tegsedi in combination with **either** of the following:

(a) Oligonucleotide agents [e.g., Onpattro (patisiran)]
(b) Tafamidis (e.g. Vyndaqel, Vyndamax)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tegsedi** will be approved based on **all** of the following criteria:

(1) Patient has previously received treatment with Tegsedi

-AND-

(2) Prescribed by or in consultation with a neurologist

-AND-

(3) Documentation of **one** of the following:

(a) Patient continues to have a polyneuropathy disability (PND) score ≤ IIIb
(b) Patient continues to have a FAP Stage 1 or 2
(c) Patient continues to have a NIS score ≥ 10 and ≤ 130

-AND-

(4) Documentation that the patient has experienced a positive clinical response to Tegsedi therapy (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.)

-AND-

(5) Patient is not receiving Tegsedi in combination with **either** of the following:

(a) Oligonucleotide agents [e.g., Onpattro (patisiran)]
(b) Tafamidis (e.g. Vyndaqel, Vyndamax)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Tegsedi [package insert]. Boston MA: Akcea Therapeutics, Inc.; September 2020.
2. Coutinho P, Martins da Silva A, Lopes Lima J, Resende Barbosa A. (1980) Forty years of experience with type I amyloid neuropathy. Review of 483 cases. In: Glenner G., Costa P., de Freitas A., editors (eds.), Amyloid and Amyloidosis. Amsterdam: Execerpta Medica, pp. 88–98.
3. Yamamoto S, Wilczek H, Nowak G, et al. Liver transplantation for familial amyloidotic polyneuropathy (FAP): a single-center experience over 16 years. Am J Transplant. 2007 Nov;7(11):2597-604. https://clinicaltrials.gov/ct2/show/NCT02586805. Accessed October 8, 2018.
4. Koike H, Misu K, Ikeda S, et al. Type I (transthyretin Met30) familial amyloid polyneuropathy in Japan: early- vs late-onset form. Arch Neurol. 2002 Nov;59(11):1771-6.
5. Koike H, Tanaka F, Hashimoto R, et al. Natural history of transthyretin Val30Met familial amyloid polyneuropathy: analysis of late-onset cases from non-endemic areas. J Neurol Neurosurg Psychiatry. 2012 Feb;83(2):152-8.
6. Institute for Clinical and Economic Review: Draft Evidence Report - Inotersen and Patisiran for Hereditary Transthyretin Amyloidosis: Effectiveness and Value. July 20, 2018.
7. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen Treatment for Patients with Hereditary Transthyretin Amyloidosis. N Engl J Med. 2018 Jul 5;379(1):22-31.

8. Ionis Pharmaceuticals. Efficacy and Safety of Inotersen in Familial Amyloid Polyneuropathy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2018 October 8]. Available from: https://clinicaltrials.gov/show/NCT01737398. NLM Identifier: NCT01737398.

Program	Prior Authorization
Change Control	
Date	Change
11/2018	New program
11/2019	Annual review. Updated references.
11/2020	Annual review. Added examples of tafamidis products but no change to clinical intent. Added Additional Clinical Rules section. Updated references.