

# PHARMACY POLICY STATEMENT

## Marketplace

<b>DRUG NAME</b>	<b>Tegsedi (inotersen)</b>
BENEFIT TYPE STATUS	Pharmacy

**CareSource considers Tegsedi (inotersen) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

DATE	ACTION/DESCRIPTION
08/07/2019	New policy for Tegsedi created.
07/06/2020	physicians who specialize in treating amyloidosis. Simplified diagnostic requirement of hATTR to just any method of confirmation by chart notes. Separated genetic testing and FAP staging into their own mandatory requirements. Removed the following exclusions: type 1 or type 2 DM, sensorimotor or autonomic neuropathy, Acute Coronary Syndrome or major surgery, HF Class III, anticipated survival less than 2 years.
08/03/2022	Transferred to new template. Updated and added references. Removed other specialists except neurology. Removed exclusions except liver transplant. Added baseline monitoring (platelets, UPCR, GFR). Simplified FAP stage descriptions. Increased initial auth duration from 6 mo to 9 mo. Edited renewal criteria.
02/22/2024	Simplify reauth criteria and allow stabilization as well as improvement. Added Wainua to list of drugs not to be used in combination with.

References:

1. Tegsedi [prescribing information]. Akcea Therapeutics, Inc.; 2024.
2. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. *Orphanet J Rare Dis*. 2013;8:31.
3. National Institutes of Health (NIH). Transthyretin amyloidosis. Available at: <https://ghr.nlm.nih.gov/condition/transthyretin-amyloidosis>.
4. Amyloid transthyretin (ATTR) Amyloidosis: Signs, symptoms, and diagnostic workup. 2018 Akcea Therapeutics, Inc. Available at: <https://www.hattrguide.com/wp-content/uploads/2018/04/Diagnostic-Card.pdf>
5. BioNews Services, LLC. Stages of familial amyloid polyneuropathy. Available at: <https://fapnewstoday.com/stages-of-familial-amyloid-polyneuropathy/>
6. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen Treatment for Patients with Hereditary Transthyretin Amyloidosis. *N Engl J Med*. 2018;379(1):22-31. doi:10.1056/NEJMoa1716793
7. Ando Y, Adams D, Benson MD, et al. Guidelines and new directions in the therapy and monitoring of ATTRv amyloidosis [published online ahead of print, 2022 Jun 2]. *Amyloid*. 2022;1-13. doi:10.1080/13506129.2022.2052838
8. Sekijima Y. Hereditary Transthyretin Amyloidosis. 2001 Nov 5 [Updated 2021 Jun 17]. In: Adam MP, Mirzaa GM, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1194/>
9. Dyck PJB, González-Duarte A, Obici L, et al. Development of measures of polyneuropathy impairment in hATTR *J Neurol Sci*. 2019;405:116424. doi:10.1016/j.jns.2019.116424
10. Adams D, Ando Y, Beirão JM, et al. Expert consensus recommendations to improve diagnosis of ATTR amyloidosis with polyneuropathy. *J Neurol*. 2021;268(6):2109-2122. doi:10.1007/s00415-019-09688-0
11. Magrinelli F, Fabrizi GM, Santoro L, et al. Pharmacological treatment for familial amyloid polyneuropathy. *Cochrane Database Syst Rev*