CareSource

PHARMACY POLICY STATEMENT
Arkansas PASSE

DRUG NAME	Tegsedi (inotersen)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 4 prefilled syringes per month
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Tegsedi (inotersen) will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED (hATTR) AMYLOIDOSIS

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Member has diagnosis of hATTR Amyloidosis with polyneuropathy confirmed by chart notes; AND
3. Member has documented transthyretin (TTR) gene mutation as confirmed through genetic testing (documentation required); AND
4. Member must have documentation of familial amyloid polyneuropathy (FAP) stage 1 (unimpaired ambulation; mostly mild sensory, motor, and autonomic neuropathy in the lower limbs) or stage 2 (assistance with ambulation required; mostly moderate impairment progression to the lower limbs, upper limbs, and trunk); AND
5. Member does **not** have ANY of the following:
   a) Prior liver transplant;
   b) Known Primary or Leptomeningeal Amyloidosis;
   c) Platelet count < 100 x 10^9/L; AND
6. Member is **not** using Tegsedi concomitantly with Onpattro, Vyndaqel, or Vyndamax.
7. **Dosage allowed:** 284 mg SQ injection once weekly.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member continues to have FAP stage 1 or stage 2; AND
2. Chart notes have been provided that show the member has positive response to Tegsedi (e.g., quality of life and motor function improved, disease progression slowed down, serum TTR levels reduced); AND
3. Member did not have acute glomerulonephritis caused by Tegsedi; AND
4. Member's platelet count is no less than 100 x 10^9/L; AND
5. Member is not using Tegsedi concomitantly with Onpattro, Vyndaqel or Vyndamax.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Tegsedi (inotersen) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/07/2019	New policy for Tegsedi created.
07/06/2020	Removed “office” from site of service allowed. Expanded prescriber to include 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.
12/22/2021	Removed prescriber specialty requirement.

References:

1. Tegsedi [prescribing information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; October, 2018.
2. ClinicalTrials.gov Identifier: NCT01737398. Efficacy and Safety of Inotersen in Familial Amyloid Polyneuropathy. Available at: https://www.clinicaltrials.gov/ct2/show/NCT01737398?term=NCT+01737398&rank=1.
3. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013;8:31.
4. National Institutes of Health (NIH). Transthyretin amyloidosis. Available at: https://ghr.nlm.nih.gov/condition/transthyretin-amyloidosis.
5. 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
6. BioNews Services, LLC. Stages of familial amyloid polyneuropathy. Available at: https://fapnewstoday.com/stages-of-familial-amyloid-polyneuropathy/
7. Ruberg FL, Grogan M, Hanna M, et al. Transthyretin amyloid cardiomyopathy. J Am Coll Cardiol. 2019 Jun, 73 (22) 2872-2891.

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