Humana. CareSource™

# PHARMACY POLICY STATEMENT
## Kentucky Medicaid

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

Tegsedi (inotersen) is a **non-preferred** product and 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 AMYLOIDOSIS (hATTR)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with neurologist; AND
3. Member has diagnosis of hATTR confirmed by ALL of the following:
   a) The demonstration of amyloid deposits via tissue biopsy;
   b) Genetic testing confirming TTR gene mutation;
   c) 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
4. Member's platelet count is > 100 x $10^9$/L; AND
5. Member does **not** have ANY of the following:
   a) Prior liver transplant;
   b) Known type 1 or type 2 diabetes mellitus;
   c) Sensorimotor or autonomic neuropathy;
   d) New York Heart Association (NYHA) functional classification of ≥ 3;
   e) Acute Coronary Syndrome or major surgery within 3 months;
   f) Known Primary or Leptomeningeal Amyloidosis;
   g) Anticipated survival less than 2 years; AND
6. Member is not receiving Tegsedi with Vyndagel, Vyndamax or Onpattro.
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 shown improvement of signs and symptoms of disease (e.g., quality of life and motor function improved, neuropathic pain decreased, serum TTR levels reduced); AND
3. Member's platelet count is no less than 100 x $10^9$/L; AND
4. Member did not experience acute glomerulonephritis caused by Tegsedi; AND
5. Member is not receiving Tegsedi with Vyndagel, Vyndamax or Onpattro.

***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 following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Autonomic neuropathy
- Sensorimotor neuropathy

| DATE | ACTION/DESCRIPTION |
|---|---|
| **08/07/2019** | New policy for Tegsedi created. |

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.

Effective date: 09/26/2019
Revised date: 08/07/2019