HAP CareSource™

# PHARMACY POLICY STATEMENT
## HAP CareSource™ Marketplace

| DRUG NAME | Tegsedi (inotersen) |
|---|---|
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Tegsedi is a transthyretin-directed antisense oligonucleotide (ASO) indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. It inhibits hepatic synthesis of human transthyretin (TTR) protein by causing degradation of mutant and wild-type TTR mRNA through binding to the TTR mRNA, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Efficacy was demonstrated in the NEURO-TTR clinical trial.
hATTR is a rare and progressive inherited disorder where misfolded TTR accumulates as amyloid fibrils in the body. In polyneuropathy of hATTR (hATTR-PN), these fibrils deposit in the peripheral nerves which leads to pain, muscle weakness, and autonomic dysfunction. Tegsedi has a black box warning for thrombocytopenia and glomerulonephritis and is only available through a REMS program. It is a weekly self-administered subcutaneous injection.

Tegsedi (inotersen) will be considered for coverage when the following criteria are met:

## Hereditary Transthyretin Amyloidosis (hATTR Amyloidosis): Polyneuropathy

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist; AND
3. Member has a diagnosis of hATTR amyloidosis with documentation of a transthyretin (TTR) mutation confirmed by genetic testing; AND
4. Member has signs/symptoms of polyneuropathy; AND
5. Member must have documentation of familial amyloid polyneuropathy (FAP) stage 1 (ambulatory) or stage 2 (ambulatory with assistance); AND
6. Member's platelet count is at least 100 $x10^9$/L; AND
7. Member's eGFR is at least 45 mL/min/1.73 $m^2$; AND
8. Member's urinary protein to creatinine ratio (UPCR) is less than 1000 mg/g; AND
9. Member has NOT had a liver transplant; AND
10. Tegsedi is NOT being used in combination with another hATTR drug (e.g., Amvuttra, Onpattro, Vyndaqel, Vyndamax, Wainua).
11. **Dosage allowed/Quantity limit:** 284 mg injected subQ once weekly. (4 syringes per 28 days)

***If all the above requirements are met, the medication will be approved for 9 months.***

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For **reauthorization**:

1. Chart notes must include documentation of positive clinical response to therapy such as improvement or stabilization of neuropathy impairment.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## HAP 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 | 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. |
| 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:


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