Tegsedi (inotersen)

Effective Date: January 1, 2021  Number: MG.MM.PH.309

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Definitions

Tegsedi is an antisense oligonucleotide indicated for treatment of adults with polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR). Tegsedi binds to TTR messenger RNA, causing degradation of mutant and wild-type TTR mRNA. This reduces serum TTR protein and TTR protein deposits in tissues.

Dosing

Max Units (per dose and over time) [Medical Benefit]:

- 284 mg weekly (maximum of 4 syringes/28 days)

Length of Coverage

- Approvals will be granted for 12 months

Guideline

Polyneuropathy of Hereditary Transthyretin–Mediated Amyloidosis (hATTR)

- The patient has a transthyretin (TTR) mutation as confirmed by genetic testing; AND
- The patient has symptomatic peripheral neuropathy.
Note: Examples of peripheral neuropathy include reduced motor strength/coordination, impaired sensation (e.g., pain, temperature, vibration, touch); AND

- The patient has tried or is currently receiving at least one systemic agent for symptoms of polyneuropathy from one of the following pharmacologic classes: a gabapentin-type product, duloxetine, or a tricyclic antidepressant.

Note: Examples of gabapentin-type products include gabapentin (Neurontin) and pregabalin (Lyrica). Examples of tricyclic antidepressants include amitriptyline and nortriptyline; AND

- The patient is 18 years of age or older; AND

- Tegsedi is prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.

Limitations/Exclusions

- Concomitant Use with Onpattro (patisiran lipid complex intravenous infusion) or a Tafamidis Product

- Coverage is not recommended for circumstances not listed in the Guideline. Criteria will be updated as new published data are available.

Applicable Procedure Codes

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<th>Code</th>
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<td>J3490</td>
<td>Unclassified drugs, Drugs unclassified injection</td>
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Applicable NDCs

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<td>72126-0007-01</td>
<td>Tegsedi 284 mg/1.5ml pre-filled syringe</td>
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Applicable Diagnosis Codes

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<th>ICD-10 Description</th>
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<td>E85.1</td>
<td>Neuropathic heredofamilial amyloidosis</td>
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Revisions

<table>
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<th>Date</th>
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<tbody>
<tr>
<td>1/1/2021</td>
<td>Criteria apply to Commercial, Medicare, and Medicaid members.</td>
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References: