Tegsedi (inotersen)

Coverage Criteria:

1. Patient is an adult diagnosed with hereditary transthyretin-mediated amyloidosis (hATTR); and
2. Medical chart documentation of one of the following baseline scores and severities within the prior 3 months of request:
    A. Polyneuropathy disability score (PND) score <= IIIb (i.e., ambulatory), or
    B. FAP Stage 1 or 2 (i.e., patients must be symptomatic and ambulatory); and
3. Patient is experiencing clinical signs and symptoms of neuropathic disease activity (such as motor impairment, autonomic dysfunction, sensory neuropathy, etc.; and
4. Patient has not had a liver transplant, and liver transplant status is documented in the medical record (ie, documentation of whether or not patient is on waiting list); and
5. Patient is unable to use the preferred product Onpattro (patisiran) due to a documented allergic reaction or a medical contraindication; and
6. Tegsedi will not be used in combination with Onpattro, or after clinical failure of Onpattro where Tegsedi has not been studied and would not be expected to produce different results than Onpattro; and
7. Prescribed within the FDA approved regimen.

Prescriber Restriction:

Prescribed by or in consultation with a neurologist.

Coverage Duration:

Initial and re-authorization will be provided for 6 months.

Renewal Criteria:

0. Patient continues to have one of the following:
    A. Polyneuropathy disability score (PND) score <= IIIb, or
    B. FAP Stage 1 or 2; and
1. Medical documentation demonstrating adherence to the medication; and
2. Tegsedi will not be used in combination with Onpattro; and
3. Prescribed within the FDA approved regimen; and
4. Patient has been clinically evaluated by the provider in the previous 12 months.

P&T Date: 2/4/2019
Effective Date: 5/1/2019