Gateway Health℠ It's Wholecare.

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PARP Approved: xx/2020

Prior Authorization Criteria

Onpattro (patisiran) and Tegsedi (inotersen)

All requests for Onpattro (patisiran) and Tegsedi (inotersen) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis and the following criteria is met:

- Member must be 18 years of age and older
- Prescribed by or in consultation with a neurologist, cardiologist, gastroenterologist, or ophthalmologist
- Diagnosis of hATTR amyloidosis with polyneuropathy with a documented transthyretin (TTR) mutation (e.g., V30M, A97S, T60A, E89Q, S50R)
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Onpattro (patisiran) only:**
    - Documentation the member has one of the following:
        - Baseline polyneuropathy disability (PND) score ≤ IIIb, OR
        - Baseline familial amyloid polyneuropathy (FAP) Stage 1 or 2
- **Tegsedi (inotersen) only:**
    - Documentation laboratory testing for thrombocytopenia (platelet count) and glomerulopheritis [measure the serum creatinine, estimated glomerular filtration rate (eGFR), urine protein to creatinine ratio (UPCR), and perform a urinalysis] have been performed
    - Baseline modified Neuropathy Impairment Scale +7 (mNIS+7) composite score and Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score have been performed
- **Initial Duration of Approval:** 12 months

- **Reauthorization criteria**
    - Documentation the member is tolerating the medication and has had a clinical response to patisiran or inotersen (e.g. improved neurologic impairment or mNIS+7 score, cardiac function, serum TTR levels, motor function, QoL-DN score, etc.)

  Onpattro (patisiran) only:
        - Documentation the member has one of the following:
            - Continues to have a PND score ≤ IIIb, OR
            - Continues to have a FAP Stage 1 or 2

  Tegsedi (inotersen) only:
        - Documentation laboratory testing for thrombocytopenia (platelet count) and glomerulopheritis [serum creatinine, eGFR urinalysis, and UPCR] have been monitored
        - Documentation the modified Neuropathy Impairment Scale +7 (mNIS+7) composite score and Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score have been performed and evaluated

- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.