BlueCross BlueShield of North Carolina

Onpattro
Medicare Part B Prior Authorization

PART B PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation
Onpattro (patisiran) will be approved when ALL of the following are met:

1. The patient is *at least* 18 years of age
   AND
2. The patient has a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) [medical record documentation required]
   AND
3. The diagnosis has been confirmed by both of the following:
   a. Genetic testing demonstrating TTR gene mutation [medical record documentation required]
      AND
   b. Presence of clinical signs and symptoms of hATTR [medical record documentation required]

   AND
4. The patient has peripheral neuropathy associated with hATTR with all of the following:
   a. ONE of the following:
      i. Baseline polyneuropathy disability (PND) score of IIIb or lower [medical record documentation required]
         OR
      ii. Baseline Familial Amyloid Polyneuropathy (FAP) stage 1 or 2 [medical record documentation required]

      AND
   b. Abnormal electrodiagnostic (nerve conduction) studies consistent with hATTR-associated polyneuropathy [medical record documentation required]
      AND
   c. Other causes of peripheral neuropathy have been excluded [medical record documentation required]

   AND
5. The patient has NOT had prior liver transplantation
   AND
6. The patient will NOT receive the requested medication in combination with Amvuttra (vutrisiran), Tegsedi (inotersen), or Wainua (eplontersen) used for the same indication
   AND
7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist or specialist in the treatment of amyloidosis) or has consulted with a specialist in the area of the patient's diagnosis

Length of approval: 12 months

Renewal Evaluation
Onpattro (patisiran) will be approved when ALL of the following are met:

1. ONE of the following:
   a. The patient was approved through Blue Cross NC initial criteria for approval
      OR
   b. The patient would have met initial criteria for approval at the time they started therapy

AND

2. ONE of the following:
    a. The patient continues to have a PND score of IIIb or lower [medical record documentation required]
    OR
    b. The patient continues to have FAP stage 1 or 2 [medical record documentation required]

AND

3. The patient has demonstrated a positive clinical response (e.g., improved neurologic impairment, motor function, quality of life, and/or ambulation) while using the requested medication [medical record documentation required]

AND

4. The patient will NOT receive the requested medication in combination with Amvuttra (vutrisiran), Tegsedi (inotersen), or Wainua (eplontersen) used for the same indication

AND

5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist or specialist in the treatment of amyloidosis) or has consulted with a specialist in the area of the patient's diagnosis

Length of approval: 12 months

NOTES:

- Length of approval may be shorter due to provider network participation status.
- Coverage of one Medicare Part B Prior Authorization medication could equate to multiple medication authorizations when they share the same Medicare Part B Prior Authorization criteria.

Revision History

June 2024 policy creation for September 12, 2024 implementation.