Vutrisiran (Amvuttra) – PA Criteria

HCPC: J0225

Amvuttra is a anti-transthyretin small interfering ribonucleic acid (siRNA) agent indicated for the treatment of polyneuropathy associated with hereditary transthyretin-mediated amyloidosis (hATTR) in adults ≥18 year of age. It is covered by South Dakota Medicaid following prior authorization when the following criteria are met:

- **Initial Therapy (must meet all):**
  - Therapy is prescribed by or in consultation with a neurologist
  - Individual has a diagnosis of hATTR amyloidosis as documented by amyloid deposition on tissue biopsy and presence of a pathogenic TTR variant using molecular genetic testing is confirmed
  - Individual has mild to moderate polyneuropathy
  - Documentation of at least **one** of the following:
    - Clinical signs and symptoms of peripheral neuropathy (such as tingling, or increased pain in the hands, feet and/or arms, loss of feeling in the hands and/or feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature, difficulty with fine motor skills, weakness in the legs, difficulty walking)
    - Clinical signs and symptoms of autonomic neuropathy symptoms (such as orthostasis, abnormal sweating, dysautonomia, constipation and/or diarrhea, nausea, vomiting, anorexia and early satiety)
  - Other causes of the polyneuropathy have been ruled out
  - Individual does not have a history of liver transplant
  - Therapy is not being used in combination with other transthyretin (TTR) reducing agents (Ex. inotersen, tafamidis, patisiran, etc.)
  - Individual is ≥18 years of age
  - Approval duration: 1 year
- **Continuation of Therapy (must meet all):**
  - Individual continues to meet initial criteria
  - Documentation is submitted indicating improvement or stabilization in clinical signs and symptoms of disease (improvement in ambulation, neurologic symptom burden, or activities of daily living)
  - Approval duration: 1 year