Field Name	Field Description
Prior Authorization Group Description	**Transthyretin-mediated Amyloidosis Agents**
Drugs	**Preferred:** Polyneurpathy – Onpattro (patisiran), Amvuttra (vutrisiran), Wainua (eplontersen) Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis), Attruby (acoramidis) **Non-preferred**: Cardiomyopathy – Amvuttra (vutrisiran) Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	Patient must be 18 years of age or older
Prescriber Restrictions	Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis
Coverage Duration	If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.
Other Criteria	**Initial Authorization**: • Regimen does not exceed FDA-approved dose/frequency • Patient has not undergone a liver or heart transplant • Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. **Polyneuropathy-Type** If the request is for Onpattro, Amvuttra, or Wainua: • Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by documented transthyretin variant by genotyping • One of the following: o Patient has baseline polyneuropathy disability (PND) score ≤ IIIb o Patient has a baseline FAP Stage 1 or 2

	○ Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130 • Patient has clinical signs/symptoms of neuropathy **Cardiomyopathy-Type** If the request is for Vyndaqel, Vyndamax, Attruby, or Amyuttra: • Patient has a confirmed diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis • Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging • Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms. • For Amvuttra, patient has contraindication to/or previous trial and failure or continued clinical progression with use of Vyndaqel, Vyndamax or Attruby **<u>Re-authorization (for continuing and new patients to the plan)</u>** : • Patient's regimen does not exceed FDA-approved dose/frequency for the agent • Patient has not undergone a liver or heart transplant • Requests for use multiple agents (different mechanism of action) in this policy for mixed polyneuropathy-cardiomyopathy phenotypes will only be considered if patient meets clinical criteria requirements for each section. • Documented positive clinical response to therapy from baseline (stabilization/slowing of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6 minute walk test, etc.) • If the request is for Vyndaqel/Vyndamax/Attruby/Amyuttra ○ Patient has continued NYHA functional class I, II, or III heart failure symptoms **<u>Continuation of Therapy Provision:</u>** Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product. **Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**

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