| Field Name | Field Description |
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| Prior Authorization Group Description | **Transthyretin-mediated Amyloidosis Agents** |
| Drugs | **Preferred:**<br>Onpattro (patisiran), Amvuttra (vutrisiran)<br>**Non-preferred**:<br>Tegsedi (inoterson)<br>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.<br>For continuation of therapy the request will be approved for 6 months.<br>If all of the criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review. |
| Other Criteria | **Initial Authorization**:<br>• Regimen does not exceed FDA-approved dose/frequency<br>• Patient has not undergone a liver or heart transplant<br>• Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, Amvuttra, Vyndaqel, or Vyndamax<br>• Patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by:<br>o Documented transthyretin variant by genotyping<br>o One of the following:<br>▪ Patient has baseline polyneuropathy disability (PND) score ≤ IIIb<br>▪ Patient has a baseline FAP Stage 1 or 2<br>▪ Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130<br>o Patient has clinical signs/symptoms of neuropathy<br>o For Tegsedi, patient has contraindication to/or previous trial and failure of use of Onpattro or Amvuttra<br><br>**Re-authorization (for continuing and new patients to the plan)** : |

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| Revision/Review Date:1/2023 | • Patient's regimen does not exceed FDA-approved dose/frequency for the agent<br>• Patient has not undergone a liver or heart transplant<br>• Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, Amvuttra, Vyndaqel, or Vyndamax<br>• 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.)<br><br>**<u>Continuation of Therapy/Grandfathering Provision:</u>**<br>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.<br><br>**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.** |