Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 7, 2022 September 20, 2022, October 14, 2022

Transthyretin-Mediated Amyloidosis Agents

Non-Preferred Agents: Amvuttra™ (vutrisiran), Onpattro® (patisiran), Tegsedi®(inotersen)*, Vyndaqel® (tafamidis meglumine), and Vyndamax™ (tafamidis)

LENGTH OF AUTHORIZATION: Up to 6 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient is not taking any of these agents concurrently.

Amvuttra, Onpattro and Tegsedi

- Patient must have a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis with documented transthyretin variant by genotyping.
- Patient has clinical signs/symptoms of neuropathy.
- Tegsedi: platelet count, renal function, and liver function tests are required prior to starting therapy and during treatment.

Vyndaqel and Vyndamax

- Patient must have a diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis with documented transthyretin variant by genotyping.
- Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms.
- Patient has not undergone a transplant.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/

*Because of the risk of serious bleeding with severe thrombocytopenia and the risk of glomerulonephritis, Tegsedi is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Tegsedi REMS. Further information is available at www.TegsediREMS.com or 1-844-483-4736.