Vutrisiran (Amvuttra™)	Place of Service Office Administration Infusion Center Administration Outpatient Facility Infusion Administration* [*Prior authorization required – see section (1)] HCPCS: **J0225** per 1 mg

Condition listed in policy (*see criteria for details*)

- Hereditary transthyretin amyloidosis (hATTR) with polyneuropathy

AHFS therapeutic class: Central Nervous System Agent

Mechanism of action: A transthyretin-directed small interfering RNA.

(1) Special Instructions and pertinent Information

Covered under the medical benefit, please submit clinical information for prior authorization review via fax.

****CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION ****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015, Amvuttra PI, Alnylam Pharmaceuticals, 2022

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, Medi-Cal, ASO, Shared Advantage, and HMO (non-direct contract)** may be required to have their medication administered at a preferred site of service, including the home, a physicians' office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF Amvuttra IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (Supporting Documentation must be submitted)

1. **Patient is receiving their first infusion of Amvuttra or is being re-initiated on Amvuttra after at least 6 months off therapy.** *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

Or

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. **Patient has experienced a previous severe adverse event on Amvuttra based on documentation submitted.**

3. **Patient continues to experience moderate to severe adverse events on Amvuttra based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.**

4. **Patient is clinically unstable based on documentation submitted.**

5. **Patient is physically or cognitively unstable based on documentation submitted.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for vutrisiran (Amvuttra™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Hereditary transthyretin amyloidosis (hATTR) with polyneuropathy

1. Patient is ≥ 18 years of age, **AND**
2. Prescribed by or in consultation with a neurologist, **AND**
3. Documented diagnosis of hATTR with polyneuropathy confirmed by documentation of a pathogenic TTR mutation, **AND**
4. Not to be used in combination with agents for hATTR [i.e., patisiran (Onpattro), inotersen (Tegsedi), tafamidis (Vyndaqel, Vyndamax)]

Covered Doses
25 mg administered by subcutaneous injection once every 3 months

Coverage Period
Indefinite

ICD-10:
E85.1

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for vutrisiran (Amvuttra™) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 25 mg/0.5 mL solution in a single-dose 1-mL prefilled syringe

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Amvuttra (vutrisiran) [Prescribing Information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; 02/2023.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No clinical changes to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee