Amvuttra™ (vutrisiran)

Humana

Pharmacy Coverage Policy

Effective Date: September 28, 2022
Revision Date: September 27, 2023
Review Date: September 20, 2023
Line of Business: Medicare, Commercial, Medicaid - South Carolina, Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected

Amvuttra subcutaneous syringe

Listed Indications

Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis

Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis

Does the member meet all of the following criteria?	
Criteria #1	The member is at least 18 years of age
Criteria #2	The member has documentation in the medical record of a mutation in the TTR gene
Criteria #3	The member currently experiences polyneuropathy and a comprehensive neurologic examination has ruled out other known causes of sensoriomotor/autonomic neuropathy (e.g. chronic inflammatory demyelinating polyneuropathy)
Criteria #4	The member has a polyneuropathy disability score of IIIb or lower
Criteria #5	The member does not have a history of a previous liver transplant
For continuation of therapy requests, does the member meet all of the following renewal criteria?	
Renewal Criteria #1	The member has demonstrated and maintained stability or an improvement in polyneuropathy disability score from baseline
Renewal Criteria #2	The member has not had a liver transplant
Approval Duration	
Initial	plan year duration

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Background

This is a prior authorization policy about Amvuttra (vutrisiran).

- Hereditary transthyretin-mediated amyloidosis is an inherited systemic disorder characterized by the extracellular deposition of misfolded transthyretin (TTR) proteins. TTR gene mutations destabilize the protein causing a tetramer dissociation into monomers, which aggregate into amyloid fibrils and further distribute and accumulate in organs throughout the body. Hereditary transthyretin-mediated amyloidosis differs from non-hereditary or wild-type transthyretin-mediated amyloidosis in that rather than primarily affecting the heart, hereditary transthyretin-mediated amyloidosis affects multiple organ systems including the heart, gastrointestinal tract, kidneys and nervous system. In addition to polyneuropathy caused by amyloid deposits in the nervous system, hereditary transthyretin-mediated amyloidosis can lead to significant disabilities including decreased ambulation with the loss of the ability to walk unaided, a reduced quality of life, and a decline in cardiac function. Hereditary transthyretin-mediated amyloidosis is rapidly progressive and often times fatal.
- Hereditary transthyretin-mediated amyloidosis is a relatively rare disease affecting approximately 50,000 individuals worldwide. Due to the progressive nature of the disease, managing symptoms and maintaining quality of life is an ongoing process. Prior to the FDA approval of siRNA molecules the only treatment was orthotopic liver transplantation (OLT).

Precautions

- Reduced serum vitamin A levels and recommended supplementation: Supplement with the recommended daily allowance of vitamin A. Refer to an ophthalmologist if ocular symptoms suggest a vitamin A deficiency.

Amvuttra (vutrisiran) is a small interfering RNA (siRNA) that is directed to the liver, the primary site of TTR synthesis, by conjugation to a triantennary N-acetylgalactosamine (GalNAc) ligand that binds the asialoglycoprotein receptor expressed on the surface of hepatocytes. This conjugate enhances stability and allows for once every 3 month administration.

Amvuttra (vutrisiran) is a double-stranded siRNA-GalNAc conjugate that causes degradation of mutant and wild-type TTR mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues.

Amvuttra is indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Vutrisiran is available as Amvuttra 25mg/0.5mL single-dose prefilled syringe.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Amvuttra; vutrisiran; subcutaneous; siRNA; small interfering RNA; hereditary transthyretin mediated amyloidosis; pharmacy

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. Lexi-Comp [database online]. Hudson, OH Lexi-comp, Inc.: URL: http://online.lexi.com. Updated periodically.
3. Micromedex Healthcare Series: DRUGDEX. Thomson Micromedex, Greenwood Village, CO. 2021. Updated periodically.
4. Amvuttra (vutrisiran) [package insert]. Cambridge, Massachusetts; Alnylam Pharmaceuticals, Inc. Revised February 2023.

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