Original Effective Date: 12/08/2022
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Last P&T Approval/Version: 07/30/2025
Next Review Due By: 07/2026
Policy Number: C24213-A

Amvuttra (vutrisiran)

PRODUCTS AFFECTED

Amvuttra (vutrisiran)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR), Cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS ASSOCIATED POLYNEUROPATHY (hATTR-PN):
1. Documented diagnosis of hereditary transthyretin-mediated amyloidosis associated polyneuropathy (hATTR-PN)

AND

2. Documentation of BOTH of the following [DOCUMENTATION REQUIRED]:
   (a) Pathogenic transthyretin (TTR) mutation verified by genetic testing
   Note: More than 120 different transthyretin (TTR) gene mutations have been identified, with predominant symptom presentation varying by genotype. The most common mutations in the US are V122I, T60A, and V30M.
   AND
   (b) ONE of the following: Polyneuropathy disability (PND) score ≤ IIIb, Familial amyloidotic polyneuropathy (FAP) stage 1 or 2, OR Neuropathy impairment score (NIS) between 10 and 130

AND

3. Documentation of presence of clinical signs and symptoms of the disease such as: Peripheral sensory-motor neuropathy (e.g., neuropathic pain, paresthesia, weakness, bilateral carpal tunnel syndrome, difficulty walking), Autonomic neuropathy (e.g., hypotension, recurrent urinary tract infections, sexual dysfunction, sweating abnormalities, urinary retention), Gastrointestinal manifestations (e.g., diarrhea, nausea, vomiting, unintentional weight loss), Cardiovascular manifestations (e.g., arrhythmias, conduction abnormalities, heart failure)
   AND
4. Documentation member has tried or is currently receiving at least one systemic agent for symptoms of polyneuropathy from one of the following pharmacologic classes: a gabapentin-type product (e.g., gabapentin, pregabalin) or a tricyclic antidepressant (e.g., amitriptyline, nortriptyline), or Serotonin/Norepinephrine Reuptake Inhibitors (e.g., duloxetine)

B. CARDIOMYOPATHY:

1. Documented diagnosis of cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM)
   AND
2. Documentation of BOTH of the following [DOCUMENTATION REQUIRED]:
   a. Member must have presence of amyloid deposits in biopsy tissue
      AND
   b. Documentation of presence of a variant TTR genotype and/or TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry
   AND
3. Documentation member has evidence of cardiac involvement by echocardiography with an end-diastolic interventricular septal wall thickness >12 mm
   AND
4. Documentation of the presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction) and baseline functional status assessment (e.g., 6 minute walk test [6MWT], Kansas City Cardiomyopathy Questionnaire-Overall Summary [KCCQ-OS]) to be used to assess drug therapy efficacy at renewal
   AND
5. Documentation of baseline clinical manifestations as evidenced by ONE of the following [DOCUMENTATION REQUIRED]:
   a. Documented diagnosis of NYHA functional class I, II, or III heart failure with at least one prior hospitalization for heart failure
      OR
   b. Clinical evidence of HF (without hospitalization) manifested by signs or symptoms of volume overload or elevated intracardiac pressures (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) requiring treatment with a diuretic for improvement
   AND
6. Prescriber attests that member will not receive Amvuttra in combination with TTR-lowering agents (e.g., patisiran, inotersen, eplontersen) OR Tetramer stabilizers (e.g., diflunisal, tafamidis, acoramidis) (See Background – Concurrent Use with TTR Stabilizer)

CONTINUATION OF THERAPY:

A. HEREDITARY TRANSTHYRETIN-MEDIATED AMYLOIDOSIS ASSOCIATED POLYNEUROPATHY (hATTR-PN):

1. Documentation of a positive response to therapy (e.g., improved neurologic impairment, motor function, slowing of disease progression, cardiac parameters, improvement in baseline scores: Polyneuropathy disability (PND) score ≤ IIIb OR FAP Stage 1 or 2, neuropathy impairment score) [DOCUMENTATION REQUIRED]
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

B. CARDIOMYOPATHY

1. Documentation of clinical improvement in symptoms or evidence of slowing of clinical decline OR decrease in number of hospitalizations or urgent heart failure visits since initial authorization, OR improvement or stabilization of the 6-minute walk test since initial authorization OR stabilization or improvement in KCCQ-OS [DOCUMENTATION REQUIRED]
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a neurologist, cardiologist, geneticist, or a physician who specializes in the treatment of amyloidosis. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
25mg/0.5 mL every 3 months

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Amvuttra (vutrisiran). For information on site of care, see Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous injection

DRUG CLASS:
Small interfering ribonucleic acid (siRNA)

FDA-APPROVED USES:
Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults and the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce

cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

The polyneuropathy disability score is an additional assessment tool with ranking based on different classes I-IV. Higher scores are indicative of more impaired walking ability. The varying classes are defined as follows:
I: preserved walking, sensory disturbances
II: impaired walking without need for a stick or crutches IIIa: walking with one stick or crutch IIIb: walking with two sticks or crutches

Familial Amyloid Polyneuropathy (FAP) clinical staging:
Stage 0: no symptoms
Stage 1: unimpaired ambulation; mostly mild sensory, motor, and autonomic neuropathy in the lower limbs
Stage 2: assistance with ambulation required; mostly moderate impairment progression to the lower limbs, upper limbs, and trunk
Stage 3: wheelchair-bound or bedridden; severe sensory, motor, and autonomic involvement of all Limbs

A. Scoring Scale of mNIS+7 (the higher the score, the less function)

A) mNIS+7

Test	Component	Minimum Score	Maximum Score
NIS	Cranial Nerves	0	40
	Muscle Weakness	0	152
	Reflexes	0	20
	Sensation	0	32
Modified +7	Heart Rate Deep Breathing†	-3.72	3.72
	Nerve Conduction†	-18.6	18.6
	Touch Pressure	0	40
	Heat-Pain	0	40
mNIS+7*	**Composite**	**-22.3**	**346.3**

B. Scoring Scale of Norfolk QoL-DN (the higher the score, the poorer the quality of life)

B) Norfolk QoL-DN

Domain	Items[1,2]	Minimum Score	Maximum Score
Symptoms	Σ (1-7, 9)	0	32
Physical Functioning/Large Fiber Neuropathy	Σ (8, 11, 13-15, 24, 27-35)	-4	56
Small Fiber Neuropathy	Σ (10, 16-18)	0	16
Large Fiber Neuropathy	Σ (19-21)	0	12
Activities of Daily Living	Σ (12, 22, 23, 25, 26)	0	20
Norfolk QoL-DN*	**Total**	**-4**	**136**

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Hereditary transthyretin-mediated amyloidosis (hATTR) is a rare condition affecting about 50,000 people worldwide caused by a genetic mutation in the transthyretin (TTR) gene. Mutations in the TTR gene lead to de-stabilization, misfolding and aggregation into insoluble amyloid fibrils which deposit into multiple sites such as the nervous system, heart, kidneys, and eyes. There are multiple TTR mutations, the most prevalent being TTR V30M. Common symptoms of hATTR amyloidosis include peripheral sensory or autonomic neuropathy, cardiomyopathy, and GI dysfunction. As the disease progresses, symptoms can worsen and lead to life-threatening multiorgan dysfunction.

Hereditary transthyretin-mediated amyloidosis manifests as abnormal buildup of amyloids which are protein fibers that deposit in organs and tissues in consequence interfering with normal functioning. The amyloid deposits usually occur in the peripheral nervous system, which can result in a loss of sensation, pain, or immobility in the arms, legs, hands and feet. They can also deposit in heart, kidneys, eyes and gastrointestinal tract and affect their functioning. The focus of the hATTR treatment is generally symptom management.

Given the magnitude of non-specific symptoms, diagnosis of hATTR is often challenging and is commonly confused with other conditions. Treatment options include liver transplantation and a limited number of pharmacologic therapies. While liver transplantation has been shown to eliminate the production of variant TTR protein and slow disease progression, it does not prevent cardiomyopathy as amyloids can continue to deposit in the heart. One treatment option is Vyndaqel (tafamidis), a transthyretin stabilizer, which stabilizes the tetramer of the TTR transport protein to slow the dissociation into monomers that drives TTR amyloidosis. Vyndaqel is indicated for the treatment of cardiomyopathy of wild type or hATTR amyloidosis. Recently approved treatment options for polyneuropathy of hATTR amyloidosis involve inhibition of hepatic production of TTR using a gene silencing RNA molecule, Onpattro (patisiran), Amvuttra (Vutrisiran) and an antisense oligonucleotide, Tegsedi (inotersen).

Amvuttra is a small interfering ribonucleic acid (siRNA) which works by silencing a portion of RNA involved in causing polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR) in adults. More specifically, Amvuttra prevents production of transthyretin (TTR) which leads to reduction in accumulation of amyloid deposits in peripheral nerves, improving symptoms and helping patients better manage the condition. The FDA approval of Amvuttra is based on positive 9-month results from the Phase 3 HELIOS-A study (NCT03759379), a randomized, open-label, multicenter study of patients with hATTR-PN. The efficacy of Amvuttra was assessed by comparing the Amvuttra group in the HELIOS-A study with the

placebo group from the Phase 3 APOLLO study of Onpattro. The primary endpoint was the change at 18 months from baseline to month 9 in the mNIS+7, an objective assessment of neuropathy that measures deficits in cranial nerve function, muscle strength, reflexes, postural blood pressure, quantitative sensory testing, and peripheral nerve electrophysiology. Participants aged 18-85 years were randomized 3:1 to receive one of the following for 18 months; 25mg of vutrisiran (n=122) via SC once every 3 months or 0.3mg/kg of patisiran (n=42) via IV infusion once every 3 weeks (reference group). The placebo cohort from the APOLLO study of Onpattro (n=77) was used as an external control for this study, in which patients received an IV infusion once every 3 weeks. At 9 months, Amvuttra met the trial's primary endpoint, with patients treated with the drug showing improvement with a 2.2 point mean decrease in mNIS+7 score from baseline, compared with a 14.8-point mean increase in mNIS+7 score in patients in the external placebo group, demonstrating a worsening of the condition at 9 months. Most common adverse reactions (>5%) were arthralgia, dyspnea, and Vitamin A decrease.

The efficacy and safety of Amvuttra was evaluated in a multicenter, international, randomized, double-blind, placebo-controlled trial (HELIOS-B, NCT04153149) in 654 adult patients with wild-type or hereditary ATTR-CM. Patients were randomized 1:1 to receive 25 mg of Amvuttra (n=326) subcutaneously once every 3 months, or matching placebo (n=328). Treatment assignment was stratified by baseline tafamidis use (yes versus no), ATTR disease type (wtATTR or hATTR amyloidosis), and by baseline New York Heart Association (NYHA) Class I or II and age less than 75 years versus all other. At baseline, 40% of patients were on tafamidis. Participants were permitted to initiate open-label tafamidis during the study. A total of 85 participants initiated tafamidis: 44 (22%) in the Amvuttra arm and 41 (21%) in the placebo arm. The median time to initiation of tafamidis for these 85 participants was 18 months. The primary efficacy endpoint was the composite outcome of all-cause mortality and recurrent CV events (CV hospitalizations and urgent heart failure [UHF] visits) during the double-blind treatment period of up to 36 months, evaluated in the overall population and in the monotherapy population (defined as patients not receiving tafamidis at study baseline). Amvuttra led to significant reduction in the risk of all-cause mortality and recurrent CV events compared to placebo in the overall and monotherapy population of 28% and 33%, respectively. The majority of the deaths (77%) were CV-related. Both components of the primary composite endpoint individually contributed to the treatment effect in the overall and monotherapy population. The treatment effect of Amvuttra on functional capacity and health status were assessed by the change from baseline to Month 30 in distance walked on 6-Minute Walk Test (6-MWT), and the Kansas City Cardiomyopathy Questionnaire-Overall Summary (KCCQ-OS) score, respectively. At Month 30, the LS mean difference in change from baseline in distance walked on 6-MWT was 22 (95% CI: 8, 35; p=0.002) meters and 25 (95% CI: 7, 44; p=0.006) meters favoring AMVUTTRA over placebo in the overall population and monotherapy population, respectively. At Month 30, the LS mean difference in the change from baseline in KCCQ-OS was 6 (95% CI: 2, 9; p=0.001) and 8 (95% CI: 4, 13; p=0.0003) favoring Amvuttra over placebo in the overall population and monotherapy population respectively. No new safety issues were identified in HELIOS-B. Eighty-two percent of patients treated with Amvuttra had normal vitamin A levels at baseline, and 80% of those with a normal baseline developed low vitamin A levels.

Concurrent Use with TTR Stabilizer

The 2020 American Heart Association (AHA) scientific statement Cardiac Amyloidosis: Evolving Diagnosis and Management addresses the treatment strategies for transthyretin amyloid cardiomyopathy (ATTR-CM). In this statement, the AHA concluded that, as of 2020, data were insufficient to support the use of combination therapy involving both transthyretin (TTR) stabilizers and TTR silencers for ATTR-CM. The 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure do not address the concurrent use of TTR silencers with stabilizers. The 2023 ACC Expert Consensus Decision Pathway on Comprehensive Multidisciplinary Care for the Patient With Cardiac Amyloidosis acknowledges tafamidis as the only FDA-approved medication for ATTR-CM and does not provide recommendations on combination therapy. While clinical trials such as the HELIOS-B have permitted patients previously on tafamidis to continue its use alongside vutrisiran, the results of these studies have not yet led to guideline changes regarding combination therapy. HELIOS-B was not powered or designed to study the benefit of combined therapy. Therefore, current guidelines remain unchanged, and combination therapy is not yet recommended.

Patient specific exception should be reviewed when there is documented clinically significant progression of ATTR-CM symptoms on current therapy and provider has submitted clinical rationale for combination therapy with lack of alternative options.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Amvuttra (vutrisiran) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Amvuttra (vutrisiran) include: No labeled contraindications.

Exclusions/Discontinuation:
Amvuttra has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions (coverage is not recommended for the following circumstances): NYHA heart failure classification >2, Primary or leptomeningeal amyloidosis, Sensorimotor or autonomic neuropathy not related to hATTR amyloidosis, or concurrent use with TTR-lowering agent, including Tegsedi and Onpattro OR TTR-stabilizing agent, including diflunisal, Attruby, Vyndaqel, Vyndamax (See Background – Concurrent Use [HELIOS-B trial]).

OTHER SPECIAL CONSIDERATIONS:
Amvuttra is for subcutaneous use only and should be administered by a healthcare professional. Amvuttra can lead to reduced serum vitamin A levels, vitamin A supplementation is advised if patient is taking Amvuttra. Vitamin A is essential for normal embryofetal development; however, excessive levels of vitamin A are associated with adverse developmental effects. The effects on the fetus of a reduction in maternal serum TTR caused by Amvuttra and of vitamin A supplementation are unknown. Refer to an ophthalmologist if ocular symptoms suggestive of vitamin A deficiency occur. Amvuttra has not been studied in patients with severe renal or hepatic impairment.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J0225	Injection, vutrisiran, 1 mg

AVAILABLE DOSAGE FORMS:
Amvuttra SOSY 25MG/0.5ML single-dose prefilled syringe (in a carton containing one single dose)

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Duration of Approval Background References	Q3 2025

REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements FDA-Approved Uses Background Coding/Billing Information Template References	Q2 2025
REVISION- Notable revisions: References	Q3 2024
REVISION- Notable revisions: Required Medical Information FDA-Approved uses Other Special Considerations Coding/Billing Information References	Q3 2023
NEW CRITERIA CREATION	Q3 2022