# Louisiana Medicaid Vutrisiran (Amvuttra®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for vutrisiran (Amvuttra®).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

# Cardiomyopathy of Wild-type or Hereditary Transthyretin-mediated Amyloidosis

### **Approval Criteria for Initiation of Therapy**

- The recipient is 18 years of age or older on the date of the request; AND
- The recipient has a diagnosis of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) confirmed by definitive tests [dates, type of testing, and results are stated on the request];
  AND
- ONE of the following is true and stated on the request:
  - The recipient has a medical history of heart failure with at least one prior hospitalization for heart failure within 12 months prior to the date of the request [List most recent date of hospitalization]; OR
  - o The recipient has clinical evidence of heart failure; AND
- The recipient does **NOT** have a diagnosis of New York Heart Association (NYHA) class IV heart failure; **AND**
- The prescriber **states on the request** that the requested medication is not prescribed concurrently with other TTR-directed therapy, such as Vyndamax<sup>TM</sup>, Vyndaqel®, and Attruby<sup>TM</sup>; **AND**
- This medication is prescribed by, or the request states that the medication is being prescribed in consultation with, a cardiologist or physician who specializes in the treatment of amyloidosis.

#### **Approval Criteria for Continuation of Therapy**

- The prescriber **states on the request** that there is evidence of a positive response to therapy as indicated by <u>either</u> maintenance of the current condition <u>or</u> improvement in signs and symptoms compared to baseline (e.g. improved cardiac function, quality of life, slowing of disease progression, decreased hospitalizations); **AND**
- The prescriber **states on the request** that the requested medication is not prescribed concurrently with other TTR-directed therapy, such as Vyndamax<sup>TM</sup>, Vyndaqel®, and Attruby<sup>TM</sup>.

Duration of approval for initiation and continuation of therapy: 12 months

### Polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis

## **Approval Criteria for Initiation of Therapy**

- The recipient is 18 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of polyneuropathy caused by hereditary transthyretin-mediated amyloidosis (hATTR-PN); **AND**
- The recipient has a transthyretin (TTR) mutation confirmed by genetic testing (date and result must be **stated on the request**]; **AND**
- The recipient has symptoms of polyneuropathy (e.g. impaired sensation, motor dysfunction, digestive system dysfunction) [must be **stated on the request**]; **AND**
- The prescriber **states on the request** that the requested medication is not prescribed concurrently with other TTR-directed therapy, such as Onpattro® and Wainua®; **AND**
- This medication is prescribed by, or the request states that the medication is being prescribed in consultation with, a neurologist or physician who specializes in the treatment of amyloidosis.

## **Approval Criteria for Continuation of Therapy**

- The prescriber **states on the request** that there is evidence of a positive response to therapy as indicated by <u>either</u> maintenance of the current condition <u>or</u> improvement in signs and symptoms compared to baseline (e.g. improved quality of life, slowing of disease progression); **AND**
- The prescriber **states on the request** that the requested medication is not prescribed concurrently with other TTR-directed therapy, such as Onpattro® and Wainua®.

# Duration of approval for initiation and continuation of therapy: 12 months

#### References

Amvuttra (vutrisiran) [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; March 2025. <a href="https://www.alnylam.com/sites/default/files/pdfs/amvuttra-us-prescribing-information.pdf">https://www.alnylam.com/sites/default/files/pdfs/amvuttra-us-prescribing-information.pdf</a>

ClinicalTrials.gov. HELIOS-A: A Study of Vutrisiran (ALN-TTRSC02) in Patients With Hereditary Transthyretin Amyloidosis (hATTR Amyloidosis).

https://clinicaltrials.gov/study/NCT03759379?intr=NCT03759379%20&rank=1

ClinicalTrials.gov. HELIOS-B: A Study to Evaluate Vutrisiran in Patients With Transthyretin Amyloidosis With Cardiomyopathy. https://www.clinicaltrials.gov/study/NCT04153149

Siddiqi OK, Ruberg FL. Cardiac amyloidosis: an update on pathophysiology, diagnosis, and treatment. Trends Cardiovasc Med. 2018;28(1):10-21. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741539/

| Revision / Date            | Implementation Date |
|----------------------------|---------------------|
| Policy created / June 2025 | January 2026        |