Reference number(s)
7454-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☑
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☑
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Combined Benefit Management (CBM)	☐
Combined Benefit Management Pharmacy (CBMP)	☐
Medical Benefit Managed Medicaid (MMMB)	☐

Exceptions Criteria Transthyretin Amyloidosis Cardiomyopathy (ATTR-CM) and Polyneuropathy (ATTR-PN)

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Standard Formulary Chart (SFC), and Advanced Control Specialty Formulary Chart (ACSFC).

Plan Design Summary

This program applies to the transthyretin stabilizer products specified in this document. Coverage for the targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program also applies to members who are new to treatment with Attruby or Amvuttra for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table 1. Cardiomyopathy of Transthyretin-Mediated Amyloidosis (ATTR-CM) Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Vyndamax (tafamidis)
Target	• Amvuttra (vutrisiran) • Attruby (acoramidis)

Table 2. Polyneuropathy of Transthyretin-Mediated Amyloidosis (ATTR-PN) Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	• Onpattro (patisiran)
Target	• Amvuttra (vutrisiran)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Cardiomyopathy of Transthyretin-Mediated Amyloidosis (ATTR-CM)

Coverage for Amvuttra is provided when any of the following criteria are met:

- Member is currently receiving treatment with Amuvttra, excluding when Amvuttra is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with the preferred product Vyndamax.
- Member also has polyneuropathy of transthyretin-mediated amyloidosis (ATTR-PN).

Coverage for Attruby is provided when either of the following criteria are met:

- Member is currently receiving treatment with Attruby, excluding when Attruby is obtained as samples or via manufacturer's patient assistance programs.

- Member has a documented inadequate response or intolerable adverse event with the preferred product Vyndamax.

Polyneuropathy of Transthyretin-Mediated Amyloidosis (ATTR-PN)

Coverage for Amvuttra is provided when any of the following criteria are met:

- Member is currently receiving treatment with Amuvttra, excluding when Amvuttra is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with the preferred product Onpattro.
- Member also has cardiomyopathy of transthyretin-mediated amyloidosis (ATTR-CM).

References

1. Amvuttra [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; March 2025.
2. Attruby [package insert]. Palo Alto, CA: BridgeBio Pharma, Inc.; August 2025.
3. Onpattro [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; September 2025.
4. Vyndamax [package insert]. New York, NY: Pfizer Labs; October 2023.