This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)	✓	Medical Benefit		Medicare Part B
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

Reference #
3025-D

EXCEPTIONS CRITERIA

hATTR DISORDERS

PREFERRED PRODUCT: ONPATTRO

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the products for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis specified in this policy. Coverage for the targeted product 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 applies to members who are new to treatment with a targeted product for the first time.

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

Table. Polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis Products

	Product(s)
Preferred*	• **Onpattro** (patisiran) injection
Targeted	• **Amvuttra** (vutrisiran) injection • **Tegsedi** (inotersen) injection

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

II. EXCEPTION CRITERIA

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

Coverage for the targeted product is provided when either of the following criteria is met:

A. Member is currently receiving treatment with the targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
B. Member has a documented inadequate response or intolerable adverse event with the preferred product.

This policy applies to the following:

	Standard Control (SF)		**Managed Medicaid Template (MMT)**		**ACSF Chart (ACSFC)**	✓	**Medical Benefit**		**Medicare Part B**
	Standard Control – Choice (SCCF)		**Marketplace (MF)**		**SF Chart (SFC)**		**Medical: Advanced Biosimilars First**		**Medicare Part B: Biosimilars First**
	Preferred Drug Plan Design (PDPD)		**Aetna Health Exchange (AHE)**		**VF Chart (VFC)**		**Medical Benefit: Managed Medicaid**		**Medicare Part B: Advanced Biosimilars First**
	Advanced Control Specialty (ACSF)		**IVL**		**New to Market (NTM)**		**Medical Benefit: Add-on**		
	Advanced Control Specialty – Choice (ACSCF)		**Value (VF)**						

Reference #
3025-D

REFERENCES

1. Onpattro [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; January 2023.
2. Tegsedi [package insert]. Waltham, MA: Sobi Inc; June 2022.
3. Amvuttra [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; June 2022.