

This policy applies to the following:

Standard Control (SF)	Value (VF)	ACSF Chart (ACSFC)	✓	Medical Benefit	Medicare Part B	Reference # 3025-D
Preferred Drug Plan Design (PDPD)	Managed Medicaid Template (MMT)	SF Chart (SFC)		Medical Benefit: Biosimilars First	Medicare Part B: Biosimilars First	
Advanced Control Specialty (ACSF)	Marketplace (MF)	VF Chart (VFC)		Medical Benefit: Add-on	Medicare Part B: Add-on	
Balanced (BF)	New to Market (NTM)	IVL		Medical Benefit: Managed Medicaid	Aetna Health Exchange (AHE)	

## 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*	<ul style="list-style-type: none"> <li>Onpattro (patisiran) injection</li> </ul>
Targeted	<ul style="list-style-type: none"> <li>Tegsedi (inotersen) injection</li> </ul>

\*: 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:

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

#### REFERENCES

- Onpattro [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; May 2021.
- Tegsedi [package insert]. Boston, MA: Akcea Therapeutics, Inc. May 2021.