Onpattro *(patisiran)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Onpattro lipid complex injection contains a transthyretin-directed small interfering RNA and is indicated for the treatment of the polyneuropathy of hereditary transthyretin- mediated (hATTR) amyloidosis.
Exclusion Criteria	Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Amvuttra) – and – Patient must not have had a liver transplant.
Required Medical Information	1. Medical records supporting the request must be provided. 2. Must provide patient's current weight. 3. Must have documentation of a transthyretin (TTR) mutation (e.g., V30M). 4. Must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2. 5. Must have documentation of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.).
Age Restriction	Must be at least 18 years of age.
Prescriber Restrictions	None.
Coverage Duration	One year initial and reauthorization. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice. **For reauthorization:** Must have a positive clinical response to Onpattro compared to baseline (e.g., improved neuropathy symptoms, motor function, quality of life; slowing of disease progression).
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.

HCPCS	Description	Billing Units/How Supplied
J0222	Onpattro (patisiran)	**Billing unit: 0.1 mg** 10 mg/5 mL SDV

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025