Pharmacy Drug Policy & Procedure

Policy Name:	Onpattro (patisiran)	Policy #:	2666P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Onpattro (patisiran).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Onpattro (patisiran) under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis
1.2 Documentation that the patient has a pathogenic TTR gene mutation (e.g., V30M)
1.3 Age 18 years of age or older
1.4 Presence of clinical signs and symptoms of the disease (e.g., nerve pain, movement disorders, heart disease, kidney disease)
1.5 One of the following:
- Patient has a baseline polyneuropathy disability (PND) score IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) Stage 1 or 2

1.6 Prescribed by or in consultation with a neurologist (nervous system doctor)

2. Exclusion Criteria

2.1 Members concurrently taking any other hATTR therapy
2.2 Members with previous liver transplant or severe kidney dysfunction

3. Approval Period

3.1 Initial Approval: 12 months
3.2 Reapproval: 12 months with documentation that the patient has experienced a positive clinical response to Onpattro (e.g., improved neurologic impairment, motor function, cardiac function, quality of life assessment, serum TTR levels, etc.)

CPT Codes

HCPCS Codes

J0222	Injection, Patisiran, 0.1mg

References

1. Onpattro (patisiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals Inc; January 2023.
2. Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. N Engl J Med 2018; 379:11.
3. Obici L, Berk JL, Duarte AG, et al. Quality of life outcomes in APOLLO, the phase 3 trial of the RNAi therapeutic patisiran in patients with hereditary transthyretin-mediated amyloidosis. Amyloid. 2020 Sep;27(3):153-162.

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