CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Onpattro (patisiran)
BILLING CODE	J0222 (1 unit = 0.1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see **Dosage allowed** below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Onpattro (patisiran) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

POLYNEUROPATHY OF HEREDITARY TRANSTHYRETIN-MEDIATED (hATTR) AMYLOIDOSIS

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of amyloidosis (e.g., hematologist, geneticist, etc.); AND
3. Member has diagnosis of hATTR Amyloidosis with polyneuropathy confirmed by chart notes; AND
4. Member has documented transthyretin (TTR) gene mutation as confirmed through genetic testing (documentation required); AND
5. Documentation of familial amyloid polyneuropathy (FAP) stage 1 (unimpaired ambulation; mostly mild sensory, motor, and autonomic neuropathy in the lower limbs) or stage 2 (assistance with ambulation required; mostly moderate impairment progression to the lower limbs, upper limbs, and trunk). See *Appendix* for details on all stages of FAP for your reference; AND
6. Member does **not** have ANY of the following:
   a) Prior liver transplant;
   b) Known human immunodeficiency virus (HIV) infection;
   c) Hepatitis B virus (HBV) and hepatitis C virus (HCV); AND
7. Member is **not** using Onpattro concomitantly with Tegsedi, Vyndaqel or Vyndamax.
8. **Dosage allowed:** For members weighting less than 100 kg: 0.3 mg/kg every 3 weeks IV. For members weighing 100 kg or more, the recommended dosage is 30 mg every 3 weeks.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member continues to have FAP stage 1 or stage 2; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease (e.g., quality of life and motor function improved, neuropathic pain decreased, serum TTR levels reduced); AND
3. Member is not using Onpattro concomitantly with Tegsedi, Vyndaqel, or Vyndamax.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Onpattro (patisiran) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
08/05/2019	New policy for Onpattro created.
07/02/2020	Simplified diagnostic requirement of hATTR to just any method of confirmation by chart notes. Separated genetic testing and FAP staging into their own mandatory requirements. Expanded prescriber to include physicians who specialize in treating amyloidosis.

References:

1. Onpattro [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; August, 2018.
2. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013;8:31.
3. ClinicalTrials.gov Identifier: NCT01960348. APOLLO: The Study of an Investigational Drug, Patisiran (ALN-TTR02), for the Treatment of Transthyretin (TTR)-Mediated Amyloidosis. Available at: https://clinicaltrials.gov/ct2/show/NCT01960348?term=01960348&rank=1.
4. National Institutes of Health (NIH). Transthyretin amyloidosis. Available at: https://ghr.nlm.nih.gov/condition/transthyretin-amyloidosis.

Effective date: 10/1/2021
Revised date: 07/02/2020

Appendix. Stages of FAP.

Stage 0

This is an asymptomatic stage. Patients in this stage do have a mutation in the TTR gene and show evidence of amyloid deposits, but do not show any symptoms of the disease.

Stage 1

Symptoms are mild at this stage, with the functioning of the lower limbs affected but not impaired. This is the stage for early detection of FAP symptoms.

Stage 2

Symptoms turn from mild to moderate in severity in stage 2. Lower limb function is even more affected, with patients possibly requiring walking assistance. Further damage to nerves caused by amyloid deposits is observed.

Stage 3

Symptoms have significantly worsened in stage 3, and the patient needs a wheelchair for mobility. There is no data to support the efficacy of drug therapies at this stage of the disease.