Medical Policy:
Onpattro® (patisiran) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.119	January 31, 2024	

Definitions

Patisiran was FDA approved for the treatment of the polyneuropathy of hATTR amyloidosis in adults. hATTR amyloidosis is a rapidly progressive, life-threatening disease caused by mutant and wild-type transthyretin (TTR) proteins forming amyloid deposits in tissues throughout the body. More than 95% of TTR circulating in the body is produced by the liver. This amyloid accumulation leads to progressive multisystem dysfunction, including polyneuropathy (e.g., sensorimotor and autonomic neuropathy) and cardiomyopathy. Patisiran is a double-stranded small interfering ribonucleic acid (siRNA) formulated as a lipid nanoparticle complex for delivery to hepatocytes. Patisiran causes the degradation of mutant and wild-type TTR mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues.

Length of Authorization

Initial: Coverage will be provided for 6 months

Renewal: Coverage will be provided for 12 months

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 30 mg every 3 weeks (300 billable units every 3 weeks)

Guideline

I. Initial Approval Criteria

Patisiran *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

Polyneuropathy of hATTR amyloidosis (hATTR)/Familial Amyloidotic Polyneuropathy (FAP)†

1. Patient must be at least 18 years old; **AND**
2. Patient has a definitive diagnosis of hATTR amyloidosis/FAP as documented by identification of a pathogenic TTR variant using molecular genetic testing; **AND**
3. Used for the treatment of polyneuropathy as demonstrated by at least **TWO** of the following criteria:
    a. Subjective patient symptoms are suggestive of neuropathy
    b. Abnormal nerve conduction studies are consistent with polyneuropathy
    c. Abnormal neurological examination is suggestive of neuropathy; **AND**
4. Patient's peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded; **AND**
5. Baseline in strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council (MRC) muscle strength, etc.); **AND**
6. Patient has not been the recipient of an orthotopic liver transplant (OLT); **AND**
7. Patient is receiving supplementation with vitamin A at the recommended daily allowance

† FDA-labeled indication(s);

Limitations/Exclusions

1. Onpattro is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.
2. Concomitant Use With Amvuttra (vutrisiran subcutaneous injection), Tegsedi (inotersen subcutaneous injection), Wainua (eplontersen subcutaneous injection), or a Tafamidis Product.

   Note: Examples of tafamidis products are Vyndaqel and Vyndamax.

II. Renewal Criteria

1. Patient continues to meet Initial approval criteria.
2. Disease response compared to baseline prior to treatment shows improvement or stabilization in one or both of the following:
    a. Neuropathy signs and symptoms
    b. MRC muscle strength

Dosage/Administration

Indication	Dose
hATTR Amloidosis	**Recommended dosage:** • Weight < 100 kg

	○ 0.3 mg/kg intravenously every 3 weeks • Weight ≥ 100 kg ○ 30 mg intravenously every 3 weeks **Preparing for Therapy:** • Dosing is based on actual body weight • Patients should be premedicated with a corticosteroid, acetaminophen and antihistamines. • Infusion should be filtered and diluted and infused, via a pump, over at least 80 minutes. • Patients should receive vitamin A supplementation.

Applicable Procedure Codes

Code	Description
J0222	Injection, patisiran, 0.1mg

Applicable NDCs

Code	Description
71336-1000-01	Onpattro 10mg/5ml single-dose vial

ICD-10 Diagnoses

Code	Description
E85.1	Neuropathic heredofamilial amyloidosis

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/31/2024	Annual Review: added FAP to title for clarity, (was already in criteria); added "Concomitant Use With Amvuttra (vutrisiran subcutaneous injection), Tegsedi (inotersen subcutaneous injection), Wainua (eplontersen subcutaneous injection), or a Tafamidis Product." to limitations/Exclusions
EmblemHealth & ConnectiCare	6/02/2023	Updated length of authorization for renewal criteria: Renewal criteria is 12 months
EmblemHealth & ConnectiCare	5/30/2023	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	09/15/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/7/2021	Removed C Code
EmblemHealth & ConnectiCare	12/30/2020	Annual review: no policy changes

EmblemHealth & ConnectiCare	8/15/2019	Added code J0222, effective 10/1/19.

References

1. ONPATTRO (patisiran) [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; Revised February, 2020.
2. Adams D, Gonzàlez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi therapeutic, for hereditary transthyretin amyloidosis. *N Engl J Med.* 2018;379(1):11-21.
3. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a Phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. BMC Neurol. 2017;17(1):181