JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP082
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	Subject **Onpattro**	*Revision Date*	04/19/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Onpattro

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I. POLICY

A. Onpattro (patisiran) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Onpattro may be approved for patients who meet the following:
   1. Documentation has been submitted showing the following:
      a. Patient has a diagnosis of polyneuropathy of hereditary transthyretinmediated amyloidosis (also called transthyretin-type familial amyloid polyneuropathy [ATTR-FAP])
      b. The diagnosis has been confirmed by detection of a mutation of the TTR gene
      c. Patient exhibits clinical manifestations of ATTR-FAP, such as any of the following:
         I. amyloid deposition in biopsy specimens
         II. TTR protein variants in serum
         III. progressive peripheral sensory-motor polyneuropathy
      d. Patient is not a liver transplant recipient.
      e. Prescriber is, or has consulted with, a neurologist, geneticist, or physician specializing in the treatment of amyloidosis

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the following:
   1. Patient still meets the criteria noted above,
   2. Patient has had a beneficial response to treatment compared to baseline, evidenced by an improvement of neuropathy severity and rate of disease progression as demonstrated by at least one of the following:
      a. modified Neuropathy Impairment Scale+7 (mNIS+7) composite score
      b. Norfolk Quality of LifeDiabetic Neuropathy (QoL-DN) total score
      c. polyneuropathy disability (PND) score
      d. FAP disease stage

e. manual grip strength

IV. EXCLUSIONS

A. Onpattro will not be covered for the following:
   1. Concurrent use with inotersen (Tegsedi), tafamidis (Vyndaqel, Vyndamax) or vutrisiran (Amvuttra)
   2. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, patisiran, 0.1 mg	J0222

VII. REFERENCES

1. Onpattro [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; May 2021.
2. Adams, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. N Engl J Med. 2018 Jul 5; 379(1):11-21.
3. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, Lewis WD, Obici L, Planté-Bordeneuve V, Rapezzi C, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013; 8:31.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
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