Onpattro (patisiran)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Onpattro (patisiran) 10 mg/5 mL vial	0.3 mg/kg [max dose 30 mg (3 vials)] every 3 weeks

APPROVAL CRITERIA

Initial requests for Onpattro (patisiran) may be approved if the following criteria are met:

I. Individual has a diagnosis of hereditary transthyretin (hATTR) amyloidosis or familial amyloid polyneuropathy (FAP); **AND**
II. Documentation is provided that individual has a TTR mutation confirmed by genotyping (Adams, 2018); **AND**
III. Documentation is provided that individual has associated mild to moderate polyneuropathy (Adams, 2018).

Continuation requests for Onpattro (patisiran) may be approved if the following criterion is met:

I. Documentation is provided to show clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improved ambulation, improvement in neurological symptom burden, improvement in activities of daily living)

Requests for Onpattro (patisiran) may not be approved for the following:

I. Individual has a history of liver transplantation; **OR**
II. Individual has severe renal impairment or end-stage renal disease; **OR**
III. Individual has moderate or severe hepatic impairment; **OR**
IV. Individual has New York Heart Association (NYHA) class III or IV heart failure (Adams, 2018); **OR**
V. Individual has sensorimotor or autonomic neuropathy not related to hATTR amyloidosis (monoclonal gammopathy, autoimmune disease, etc.) (Adams, 2017); **OR**
VI. Individual is using in combination with Amvuttra, Tegsedi, Vyndaqel or Vyndamax; **OR**
VII. May not be approved when the above criteria are not met and for all other indications.

Key References:

1. Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi therapeutic, for hereditary transthyretin amyloidosis. *N Engl J Med*. 2018;379(1):11-21.
2. 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.
3. Ando Y, Coelho T, Berk JL, et. al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. *Orphanet J Rare Dis*. 2013;8(31).
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 30, 2022.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Gertz MA, Benson MD, Dyck PJ, et. al. Diagnosis, Prognosis, and Therapy of Transthyretin Amyloidosis. *J Am Coll Cardiol*. 2015;66(21):2451-2466.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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