RX.PA.027.MPC Onpattro (Patisiran Sodium) and Tegsedi (Inotersen)

The purpose of this policy is to define the prior authorization process for Onpattro (patirisan sodium) and Tegsedi (inotersen)

Onpattro is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Tegsedi is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults

Onpattro and Tegsedi are subject to the prior authorization process.

PROCEDURE
Initial Authorization Criteria:

A. CLINICAL CRITERIA (*Use for ALL Drug Requests*)

Must meet all of the criteria listed under the respective product:

1. Onpattro (patirisan sodium)
- Must be prescribed by or in consultation with a provider who specializes in the treatment of inherited disorders
- Must be at least 18 years of age
- Must have a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis

2. Tegsedi (inotersen)
- Must be prescribed by or in consultation with a provider who specializes in the treatment of inherited disorders
- Must be at least 18 years of age
- Must have a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis
- Must have a lab test showing the member's platelet count is > 100 $x10^9$/L

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Onpattro and Tegsedi will be considered investigational or experimental for any other use and will not be covered.

D. Reauthorization Criteria:

All prior authorization renewals are reviewed to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon all of the following listed under the respective product:

Onpattro:

- Chart documentation from the prescriber showing the member's condition has improved based upon the prescriber's assessment while on therapy

Tegsedi:

- Chart documentation from the prescriber showing the member's condition has improved based upon the prescriber's assessment while on therapy
- Documentation showing the member's platelet count has been monitored by the prescriber and dosing is adjusted per product labeling

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

HCPCS Code(s):

Code	Description
J0222	Injection, patisiran, 0.1 mg

REFERENCES

1. Onpattro [package insert]. Alnylam Pharmaceuticals Inc: Cambridge, MA; August 2018.
2. Tegsedi (inotersen) [prescribing information]. Boston, MA: Akcea Therapeutics, Inc; September 2020.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*