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

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

Onpattro, Tegsedi, and Amvuttra are indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Onpattro,Tegsedi, and Amvuttraare 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 neurologist, geneticist, or a physician with expertise in the treatment of amyloidosis
- Must be at least 18 years of age
- Must have a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by detection of a mutation of the transthyretin (TTR) gene
- Must not be a liver transplant recipient
- Medication must not be used in combination with inotersen (Tegsedi), vutrisiran (Amvuttra) or tafamidis

2. Tegsedi (inotersen)

- Must be prescribed by or in consultation with a neurologist, geneticist, or a physician with expertise in the treatment of amyloidosisMust be at least 18 years of age
- Must have a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by detection of a mutation of the transthyretin (TTR) gene
- Must have a lab test showing the member's platelet count is > 100 $x10^9$/L
- Must be not a liver transplant recipient
- Medication must not be used in combination with patirisan (Onpattro), vutrisiran (Amvuttra) or tafamidis
- Provider and patient must be enrolled in Tegsedi REMS program

3. Amvuttra (Vutrisiran)

- Must be prescribed by or in consultation with a neurologist, geneticist, or a physician with expertise in the treatment of amyloidosis
- Must be at least 18 years of age
- Must have a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by detection of a mutation of the transthyretin (TTR) gene
- Must be not a liver transplant recipient
- Must be receiving Vitamin A supplementation at the recommended daily allowance
- Medication must not be used in combination with patirisan (Onpattro), inotersen (Tegsedi), or tafamidis

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, Tegsedi, and Amvuttra will be considered investigational or experimental for any other use and will not be covered.

D. <u>Reauthorization Criteria:</u>

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:

MPC Renewal:

- Chart documentation from the prescriber showing the member's condition has improved compared to baseline based upon the prescriber's assessment while on therapy (e.g., improvement of neuropathy severity and rate of disease progression as demonstrated by the modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of LifeDiabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, manual grip strength).

Non-MPC Renewal:

- Members who have previously been taking Onpattro and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
- Member has not been receiving medication samples for Onpattro; AND
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

Tegsedi:
MPC Renewal:

- Chart documentation from the prescriber showing the member's condition has improved compared to baseline based upon the prescriber's assessment while on therapy (e.g., improvement of neuropathy severity and rate of disease progression as demonstrated by the modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of LifeDiabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, manual grip strength).
- Documentation showing the member's platelet count has been monitored by the prescriber and dosing is adjusted per product labeling
- Provider and patient must be enrolled in Tegsedi REMS program

Non-MPC Renewal:

- Members who have previously been taking Tegsedi and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
- Member has not been receiving medication samples for Tegesdi; AND
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

Amvuttra:
MPC Renewal:

- Chart documentation from the prescriber showing the member's condition has improved compared to baseline based upon the prescriber's assessment while on therapy (e.g., improvement of neuropathy severity and rate of disease progression as demonstrated by the modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of LifeDiabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, manual grip strength).
- Member continues to receive Vitamin A supplementation

Non-MPC Renewal:

- Members who have previously been taking Amvuttra and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
- Member has not been receiving samples for Amvuttra
- Provider has documented clinical response of the member's condition which has stabilized or improved based upon the prescriber's assessment

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.
3. Amvuttra (vutrisiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; June 2022.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Addition of Amvuttra	*11/2022*
Selected Revision *Addition of MPC vs Non-MPC Renewal*	*08/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*