Amyloidosis Therapy
Onpattro (patisiran)
Tegsedi (inotersen)
Effective 01/01/2022

<table>
<tr><td>Plan</td><td>☐ MassHealth
☒ MH UPPL
☐Commercial/Exchange</td><td rowspan="2">Program Type</td><td rowspan="2">☒ Prior Authorization
☐ Quantity Limit
☐ Step Therapy</td></tr>
<tr><td>Benefit</td><td>☐ Pharmacy Benefit
☒ Medical Benefit (NLX)</td></tr>
<tr><td>Specialty Limitations</td><td colspan="3">N/A</td></tr>
<tr><td rowspan="8">Contact Information</td><td colspan="3">Specialty Medications</td></tr>
<tr><td>All Plans</td><td>Phone: 866-814-5506</td><td>Fax: 866-249-6155</td></tr>
<tr><td colspan="3">Non-Specialty Medications</td></tr>
<tr><td>MassHealth</td><td>Phone: 877-433-7643</td><td>Fax: 866-255-7569</td></tr>
<tr><td>Commercial</td><td>Phone: 800-294-5979</td><td>Fax: 888-836-0730</td></tr>
<tr><td>Exchange</td><td>Phone: 855-582-2022</td><td>Fax: 855-245-2134</td></tr>
<tr><td colspan="3">Medical Specialty Medications (NLX)</td></tr>
<tr><td>All Plans</td><td>Phone: 844-345-2803</td><td>Fax: 844-851-0882</td></tr>
<tr><td>Exceptions</td><td colspan="3">N/A</td></tr>
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Overview

The indications below including FDA-approved indication is considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

No PA	Drugs that require PA
	Onpattro® (patisiran)[PD] Tegsedi® (inotersen)

[PD] Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class.

FDA-Approved Indication

Treatment of hereditary transthyretin mediated amyloidosis in adults

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

Onpattro® (patisiran)

1. Diagnosis of hATTR amyloidosis
2. Member is ≥18 years of age
3. Member's current weight (use to verify correct dosing; may take this information over the phone if missing on PA request)
4. Documentation of baseline polyneuropathy disability (PND) score of I, II, IIIa, or IIIb
5. Appropriate dosing

Tegsedi® (inotersen)

1. Diagnosis of hATTR amyloidosis
2. Member is ≥18 years of age
3. Prescriber is a specialist (e.g. rheumatologist or neurologist) or specialist consult notes are provided
4. Results from genetic testing showing mutations in the TTR gene
5. Inadequate response, adverse reaction, or contraindication to Onpattro® (patisiran)
6. Documentation of baseline polyneuropathy disability (PND) score of I, II, IIIa, or IIIb
7. Appropriate dosing

Continuation of Therapy

Reauthorizations will be granted with documentation of ALL of the following:

1. Documentation of positive response to therapy
2. For Onpattro: Updated weight (use to verify correct dosing; may take this information over the phone if missing on PA request)

† The polyneuropathy disability score is an additional assessment tool with ranking based on classes I-IV. Higher scores are indicative of more impaired walking ability. The classes are defined as follows:

I: preserved walking, sensory disturbances
II: impaired walking without need for a stick or crutches
IIIa: walking with one stick or crutch
IIIb: walking with two sticks or crutches
IV: confined to wheelchair or bedridden

Limitations

1. Initial approvals and reauthorizations for Onpatrro will be granted for 12 months
2. Initial approvals and reauthorizations for Tegsedi will be granted for 6 months

Appendix

Appendix A: Dosing for Onpattro

Onpattro 10mg/5mL	IV: Dosing is based on actual body weight
	< 100kg: 0.3mg/kg once every 3 weeks
	≥ 100kg: 30mg once every 3 weeks
Tegsedi 284mg/1.5mL	284mg once weekly

References

1. Onpattro (patisiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; August 2018.
2. Kristen AV, Ajroud-Driss S, Conceição I, et al. Patisiran, an RNAi therapeutic for the treatment of hereditary transthyretin-mediated amyloidosis. Neurodegener Dis Manag 2019; 9:5

Review History

05/19/2021 – Created and Reviewed; separated out MH vs. Comm/Exch criteria. Effective 07/01/2021.
11/17/2021 – Reviewed and updated; added Tegsedi to policy. Matched MH UPPL effective 1/1/2022.

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