



**Onpatro (patisiran)
Tegsedi (inotersen)
Effective June 19, 2019**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Onpatro is covered through the medical benefit while Tegsedi is covered on the pharmacy benefit.		

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.

FDA-Approved Indication

Treatment of the polyneuropathy of hereditary transthyretin mediated amyloidosis in adults

Coverage Guidelines

Authorization of 12 months may be granted for members who are currently receiving treatment with Onpatro or Tegsedi excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR

AllWays Health Partners may authorize Onpatro or Tegsedi when the following criteria have been met and documentation has been provided:

1. Member has documented diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) through genetic testing confirming a pathogenic variant in TTR
2. Member has peripheral neuropathy associated with hATTR with a baseline polyneuropathy disability score of IIIb or lower †
3. Member is at least 18 years of age
4. Prescriber is a specialist in rheumatology or neurology OR specialist consult is provided
5. **For Tegsedi only:** Member has had an inadequate response, adverse reaction or a contraindication to Onpatro.

Continuation of Therapy



Reauthorizations will be granted with documentation of positive clinical response has been submitted as evidenced by improved neurological impairment, motor function, quality of life or ambulation

† 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. Approvals will be granted for 12 months
2. The following quantity limits apply:

Tegsedi inj 284/1.5	4 inj per 28 days
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References

1. Onpattro (patisiran) [prescribing information]. Cambridge, MA: Alnylam Pharmaceuticals, Inc; August 2018.
2. Tegsedi (inotersen) [prescribing information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc; October 2018
3. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. *N Engl J Med*. 2018;379(1):22-31. doi: 10.1056/NEJMoa1716793
4. 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
5. Benson MD, Dasgupta NR, Monia BP. Inotersen (transthyretin-specific antisense oligonucleotide) for treatment of transthyretin amyloidosis. *Neurodegener Dis Manag* 2019

Review History

06/19/2019 – Reviewed

05/19/2021 – Reviewed and Updated; separated out MH vs. Comm/Exch criteria.

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.