

Tegsedi (inotersen)
Effective 01/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.			
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671	
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029	
Exceptions	N/A			

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 may be granted for members new to the plan within the past 90 days 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 when the following criteria are met:

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. Member has had an inadequate response, adverse reaction or a contraindication to Onpattro.

Continuation of Therapy

Requests for reauthorization will be approved when all of the following criteria are met:

1. 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:

Drug Name and Dosage Form	Quantity Limit
Tegsedi prefilled syringe	4 inj per 28 days

References

1. Benson MD, Dasgupta NR, Monia BP. Inotersen (transthyretin-specific antisense oligonucleotide) for treatment of transthyretin amyloidosis. *Neurodegener Dis Manag* 2019
2. 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
3. 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
4. Tegsedi (inotersen) [prescribing information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc; October 2018

Review History

06/19/2019 – Reviewed

05/19/2021 – Reviewed and Updated; separated out MH vs. Comm/Exch criteria. Effective 7/1/21.

10/08/2025 – Reviewed and updated at October P&T. Removed Onpattro from the policy. Updated language for members who are new to the plan. Updated policy to indicate it no longer applies to the medical benefit.

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