Pharmacy Medical Necessity Guidelines: Hereditary Amyloidosis Products (Onpattro™ [patisiran] and Tegsedi™ [inotersen])

Effective: July 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED/ RX	Department to Review	PRECERT /MM/ RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
Onpattro
Commercial Products:
PRECERT:617.972.9409

Tufts Health Public Plans:
MM: 888.415.9055

Tegsedi
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMISTRATION (FDA)-APPROVED INDICATIONS

Onpattro (patisiran) contains a transthyretin-directed small interfering RNA and is indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

Tegsedi (inotersen) is a transthretin-directed antisense oligonucleotide indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

COVERAGE GUIDELINES

The plan may authorize coverage of **Onpattro (patisiran) or Tegesdi (inotersen)** for Members when the following criteria are met:

Initial Authorization

1. Documented diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy

AND

2. Documentation in the Member's medical record of transthyretin (TTR) mutation

AND

3. Prescribed by or in consultation with a neurologist or a provider who specializes in amyloidosis

AND

4. Documented diagnosis of baseline polyneuropathy disability (PND) score ≤IIIb

AND

5. The Member is at least 18 years of age

AND

6. Documentation the Member has not had a prior liver transplant

Reauthorization

1. Documented diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy

AND

2. Documentation in the Member's medical record of TTR mutation

AND

3. Prescribed by or in consultation with a neurologist or a provider who specializes in amyloidosis

AND

4. Documentation of both of the following:
   a. Polyneuropathy disability (PND) score has remained ≤IIIb
   b. Positive clinical response as evidenced by improved or stable motor function, neurologic impairment and quality of life

AND

5. The Member is at least 18 years of age

AND

6. Documentation the Member has not had a prior liver transplant

LIMITATIONS

- Initial approval of hereditary amyloidosis products will be given in 12 month intervals. Subsequent authorization requests may be given in 12 month intervals when Reauthorization criteria above have been met.
- Members new to the plan stable on treatment with a hereditary amyloidosis product must meet Initial Authorization criteria if on treatment for less than a year and must meet Reauthorization criteria if on treatment for more than a year.
- Combination hereditary amyloidosis product therapy will not be authorized.
- Treatment of sensorimotor or autonomic neuropathy not related to hereditary transthyretin-mediated amyloidosis will not be approved.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J0222	Injection, patisiran, 0.1 mg

Note: Medical billing codes may not be used for Tegsedi. Tegsedi must be obtained via the Member's pharmacy benefit.

REFERENCES

1. Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi therapeutic, for hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):11-21.
2. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet Journal of Rare Diseases. 2013;8(31):1-18.
3. Benson MD, Waddington-Cruz M, Berk J, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):22-31.
4. Brannagan T, Wang AK, Coelho T, et al. Open label extension of the phase 3 study NEURO-TTR to assess the long-term efficacy and safety of inotersen in patients with hereditary transthyretin amyloidosis. Neurology. 2018;90(15 Suppl). Abstract P1.324.
5. Lasser KE, Mickle K, Chapman R, et al. Inotersen and patisiran for hereditary transthyretin amyloidosis: effectiveness and value. Evidence report. 2018 August 29. Available from Internet. Accessed 2018 September 12.
6. Onpattro (patisiran) [package insert]. Cambridge, MA: Alnylam Pharmaceuticals, Inc.; August 2018.
7. Suhr OB, Gonzalez-Duarte A, O'Riordan W, et al. Long-term use of patisiran, an investigational RNAi therapeutic, in patients with hereditary transthyretin-mediated amyloidosis: baseline demographics and interim data from global open label extension study. Presented at 2018 International Symposium on Amyloidosis. Kumamoto, Japan; 2018 March.
8. Tegsedi (inotersen) [package insert]. Boston, MA: Akcea Therapeutics, Inc.; October 2018.

APPROVAL HISTORY

December 19, 2018: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 10, 2019: No changes.
2. February 11, 2020: No changes.
7. February 9, 2021: Removed the following Limitation "The plan will not cover Tegsedi (inotersen) unless the Member has either failed an adequate trial of or has a contraindication to Onpattro (patisiran). Coverage criteria for Onpattro (patisiran) above apply." Tegsedi (inotersen) will have the same coverage criteria as Onpattro (patisiran). Effective July 1, 2021, added the following provider requirements "Prescribed by or in consultation with a neurologist or a provider who specializes in amyloidosis."

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review,

consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.