BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

Pharmacy Medical Necessity Policy

Amyloidosis Therapies – Unified Formulary

Policy Number: 9.227
Version Number: 1.1
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth ACO ☒ MassHealth MCO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit – Tegsedi® ☒ Medical Benefit – Onpattro®

Note: Disclaimer and audit information is located at the end of this document.

Policy

Reference Table:

Drugs that require PA	No 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 is required.

Approval Criteria:

Approval Criteria:	**Initial Authorization:**
Onpattro® (patisiran)	1. Documentation of diagnosis of hereditary transthyretin0mediated (hATTR) amyloidosis; **AND** 2. Member is at least18 years of age; **AND** 3. Member's current weight (use to verify correct dosing; **AND**)

	4. Documentation of baseline polyneuropathy disability (PND) score of I, II, IIIa, or IIIb; **AND** 5. Appropriate dosing **<u>Continuation of Therapy:</u>** 1. Documented diagnosis of hereditary transthyretin-mediated amyloidosis; **AND** 2. Member is at least 18 years of age; **AND** 3. Documentation of positive response to therapy has been submitted (e.g. improved neurological impairment, motor function, quality of life, or ambulation); **AND** 4. Member's current weight (use to verify correct dosing); **AND** 5. Appropriate dosing
Tegsedi® (inotersen)	**<u>Initial Authorization:</u>** 1. Documentation of diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis; **AND** 2. Member is at least18 years of age; **AND** 3. Prescriber is a specialist (e.g. rheumatologist or neurologist) or specialist consult notes are provided; **AND** 4. Documentation of results from genetic testing showing mutations in the TTR gene are provided; **AND** 5. Documentation of inadequate response, adverse reaction, ,or contraindication to Onpattro® (patisiran); **AND** 6. Documentation of baseline polyneuropathy disability (PND) score of I, II, IIIa, or IIIb; **AND** 7. Appropriate dosing **<u>Continuation of Therapy:</u>** 1. Documented diagnosis of hereditary transthyretin-mediated amyloidosis; **AND** 2. Documentation of transthyretin (TTR) mutation; **AND** 3. Prescriber is a specialist (e.g. rheumatologist or neurologist) or specialist consult notes are provided; **AND** 4. Member is at least 18 years of age; **AND** 5. Documentation of positive response to therapy has been submitted (e.g. improved neurological impairment, motor function, quality of life, or ambulation)
Duration of Authorization:	**Onpattro®**: Initial approvals and reauthorizations will be granted for 12 months**.** **Tegsedi®**: Initial approvals and reauthorizations will be granted for 6 months
Limitations	• **Tegsedi** (inotersen) has a quantity limit of 4 prefilled syringes (6mL) per month • Members new to the plan and stable on treatment should be reviewed against Continuation of Therapy criteria

.

Appendix:
Appendix A: Dosing Information

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 syringe	1 syringe weekly

Codes

Code	Description
J0222	Injection, patisiran, 0.1mg

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	7/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
5/13/2021	Created policy for MH Unified Formulary, policy date 3/1/21	7/1/2021	P&T Committee
10/1/2021	Updated to add criteria for Tegsedi	1/1/2022	P&T Committee

Next Review Date

2/2022

Other Applicable Policies

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

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.