Clinical Policy Title:	Inotersen
Policy Number:	RxA.506
Drug(s) Applied:	Tegsedi®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hereditary Transthyretin-Mediated Amyloidosis (must meet all)**:**

1. Diagnosis of hATTR with polyneuropathy;
2. Documentation confirms presence of a transthyretin (TTR) mutation;
3. Biopsy is positive for amyloid deposits or medical justification is provided as to why treatment should be initiated despite a negative biopsy or no biopsy;
4. Prescribed by or in consultation with a neurologist;
5. Age ≥ 18 years;
6. Member has not had a prior liver transplant;
7. Recent (dated within the last month) platelet count ≥ 100 x 10^9 /L ;
8. Tegsedi is not prescribed concurrently with Onpattro™;
9. Dose does not exceed 284 mg (1 syringe) per week.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Hereditary Transthyretin-Mediated Amyloidosis (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy.
2. Recent (dated within the last month) platelet count ≥ 100 x 109/L;
3. Member is responding positively to therapy, including but not limited to improvement in any of the following parameters:
   a. Neuropathy (motor function, sensation, reflexes, walking ability);
   b. Nutrition (body mass index);
   c. Cardiac parameters (Holter monitoring, echocardiography, electrocardiogram, plasma BNP or NT-proBNP, serum troponin);
   d. Renal parameters (creatinine clearance, urine albumin);
   e. Ophthalmic parameters (eye exam);
4. If request is for a dose increase, new dose does not exceed 284 mg (1 syringe) per week.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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References

1. Ando Y, Coelho T, Berk JL, et al. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013; 8:31. Available at: https://pubmed.ncbi.nlm.nih.gov/23425518/. Accessed August 03, 2022.
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. Available at: https://www.nejm.org/doi/full/10.1056/nejmoa1716793. Accessed August 03, 2022.
3. Adams D, Gonzalez-Duarte A, O'Riordan WD, Yang CC, Ueda M, Kristen AV, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. N Engl J Med. 2018;379(1):11-21. Available at: https://pubmed.ncbi.nlm.nih.gov/29972753/. Accessed August 03, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Initial approval criteria were updated: "Recent (dated within the last month) platelet count is 100 x 10^9 /L or more" and "Member's UPCR is less than 1,000 mg/g" were added. "Member has not had a liver transplant" was updated to "ALT, AST, and total bilirubin should be in normal range (monitored within last month)". 3. Continued therapy approval criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. Commercial approval duration was updated from Length of benefit to 6 months for Initial and to 12 months for continued approval criteria. 5. References were updated.	9/24/2020	12/7/2020
Policy was reviewed: 1. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	09/21/2021	12/07/2021
Policy was reviewed:	08/03/2022	10/19/2022

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1. Initial Approval Criteria 1.A.6: Updated to remove ALT, AST, and total bilirubin should be in normal range (monitored within last month). 2. Initial Approval Criteria I.A.8: Updated to remove member's UPCR is less than 1,000 mg/g. 3. Initial Approval Criteria I.A.6: Updated to add Member has not had a prior liver transplant. 4. Initial Approval Criteria I.A.8: Updated to add Tegsedi is not prescribed concurrently with Onpattro™. 5. Continued Therapy Criteria II.A.2: Updated to add Recent (dated within the last month) platelet count ≥ 100 x 109/L; 6. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023

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