Clinical Policy Title:	inotersen
Policy Number:	RxA.506
Drug(s) Applied:	Tegsedi®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hereditary Transthyretin-Mediated Amyloidosis (hATTR) (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. Member has not had a prior liver transplant;
5. Recent (within the past 30 days) platelet count ≥ 100 x 10^9 /L;
6. Tegsedi is not prescribed concurrently with Onpattro™.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

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 28, 2024.
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 28, 2024.
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 28, 2024.

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: 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	08/03/2022	10/19/2022

the last month) platelet count ≥ 100 x 109/L; 6. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024