INOTERSEN

Generic	Brand	HICL	GCN	Exception/Other
INOTERSEN SODIUM	TEGSEDI	45353		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - Physician attestation that the patient has Stage 1 or 2 polyneuropathy
   - The patient has documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
     - Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR protein **OR**
     - DNA genetic sequencing to confirm hATTR mutation

   If yes, **approve for 6 months by HICL with a quantity limit of #6mL per 28 days (each prefilled syringe is 284mg/1.5mL).**
   APPROVAL TEXT: Renewal requires physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

   If no, do not approve.
   INTIAL DENIAL TEXT: The guideline named **INOTERSEN (Tegsedi)** requires a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy. In addition, the following criteria must be met:
   - The patient is 18 years of age or older
   - The requested medication is prescribed by or given in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - Physician attestation that the patient has Stage 1 or 2 polyneuropathy
   - The patient has documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by **ONE** of the following:
     - Biopsy of tissue/organ to confirm amyloid presence **AND** chemical typing to confirm presence of TTR protein **OR**
     - DNA genetic sequencing to confirm hATTR mutation

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INOTERSEN

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary TTR amyloidosis (hATTR) with polyneuropathy **AND** meet the following criterion?
   - Physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)

     If yes, **approve for 12 months by HICL with a quantity limit of #6mL per 28 days (each prefilled syringe is 284mg/1.5mL).**

     If no, do not approve.
     RENEWAL DENIAL TEXT: The guideline named **INOTERSEN (Tegsedi)** requires a diagnosis of hereditary TTR amyloidosis (hATTR) with polyneuropathy and physician attestation that the patient has not progressed to stage 3 polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden).

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Tegsedi.

REFERENCES

- Inotersen [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/19
Created: 10/18
Client Approval: 05/19
P&T Approval: 04/19