STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

INOTERSEN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
INOTERSEN SODIUM	TEGSEDI	45353		GPI-10 (6270104010)	

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
   - Therapy is prescribed by or in consultation with a neurologist, cardiologist, hATTR specialist, or medical geneticist
   - 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
     - DNA genetic sequencing to confirm hATTR mutation
   - The patient has FAP stage 1 or 2 OR up to PND stage IIIb polyneuropathy
   - The patient had a trial of or contraindication to the preferred agent: Amvuttra

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for approval:
   A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a rare genetic disorder) with polyneuropathy (widespread nerve pain/damage)
   B. You are 18 years of age or older
   C. Therapy is prescribed by or in consultation with a neurologist (a type of brain doctor), cardiologist (a type of heart doctor), hATTR specialist, or medical geneticist (doctor who treats gene disorders)
   D. You have a documented diagnosis of hereditary TTR amyloidosis (hATTR) as confirmed by ONE of the following:
      1. Biopsy (surgical removal of a sample) of tissue/organ to confirm amyloid (abnormal protein that can build up in any tissue or organ) presence AND chemical typing to confirm presence of TTR (protein
      2. DNA genetic sequencing (lab test for genes) to confirm hATTR mutation
   E. You have familial amyloidotic polyneuropathy (FAP) stage 1 or 2 OR up to polyneuropathy disability (PND) stage IIIb polyneuropathy
   F. You had a trial of or contraindication (harmful for) to the preferred medication: Amvuttra
   (Initial denial text continued on next page)

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STANDARD COMMERCIAL DRUG FORMULARY
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INOTERSEN

INTIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy **AND** meet the following criterion?
   - The patient has not progressed to FAP stage 3 OR PND stage IV polyneuropathy as evidenced by functional decline (e.g., wheelchair-bound, bedridden)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #6mL per 28 days.** If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **INOTERSEN (Tegsedi)** requires the following rule(s) be met for renewal:
   A. You have hereditary transthyretin-mediated amyloidosis (hATTR: a rare genetic disorder) with polyneuropathy (widespread nerve pain/damage)
   B. You have not progressed to familial amyloidotic polyneuropathy (FAP) stage 3 OR polyneuropathy disability (PND) stage IV polyneuropathy as shown by functional decline such as being wheelchair-bound or bedridden

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

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

REFERENCES

- Tegsedi [Prescribing Information]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 10/18
Client Approval: 09/22
P&T Approval: 07/22