UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1265-6
Program	Prior Authorization/Notification
Medication	Tegsedi® (inotersen)
P&T Approval Date	11/2018, 11/2020, 11/2021, 11/2022, 11/2023, 11/2024
Effective Date	2/1/2025

1. Background:

Tegsedi (inotersen) is a transthyretin-directed antisense oligonucleotide indicated for treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2. Coverage Criteria[a]:

A. Hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy

1. **Initial Authorization**

a. **Tegsedi** will be approved based on **all** of the following criteria:

(1) Diagnosis of hATTR amyloidosis with polyneuropathy

-AND-

(2) Patient has a pathogenic TTR mutation (e.g., V30M)

-AND-

(3) Patient is **not** receiving Tegsedi in combination with **either** of the following:

(a) Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran)]
(b) Tafamidis (e.g., Vyndaqel, Vyndamax)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tegsedi** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Tegsedi therapy

-AND-

(2) Patient is not receiving Tegsedi in combination with **either** of the following:

(a) Oligonucleotide agents [e.g., Onpattro (patisiran), Amvuttra (vutrisiran)]
(b) Tafamidis (e.g., Vyndaqel, Vyndamax)

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Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Tegsedi [package insert]. Boston, MA: Akcea Therapeutics, Inc.; January 2024.

Program	Prior Authorization/Notification – Tegsedi® (inotersen)
Change Control	
11/2018	New program.
11/2020	Annual review. Added examples of tafamidis products but no change to clinical intent. Updated reference.
11/2021	Annual review with no changes to clinical criteria. Reference updated.
11/2022	Annual review. Added Amvuttra (vutrisiran) as an example of not to be used in combination with no change in clinical intent. Added state mandate footnote. Updated reference.
11/2023	Annual review with no change to coverage criteria.
11/2024	Annual review with no change to coverage criteria.

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