Tegsedi

Saudi Arabia · access guide

How to access Tegsedi from Saudi Arabia, the named-patient import pathway, 2026

By Reserve Meds · Clinical & regulatory team · Last reviewed 2026-04-23

A Saudi Arabiai patient diagnosed with hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy may receive a prescription for Tegsedi (inotersen) from their treating neurologist, typically at a tertiary Saudi Arabia City referral centre. Tegsedi is FDA-approved for this indication and developed by Ionis Pharmaceuticals. In Saudi Arabia, Tegsedi is not routinely registered for outpatient dispensing, and access is typically coordinated through the named-patient import pathway.

This guide explains the legal pathway, documentation your neurologist prepares, typical timing and cost bands, and where Reserve Meds fits in.

The clinical situation

Tegsedi is a second-generation antisense oligonucleotide that silences hepatic TTR production, administered subcutaneously once weekly. Eligibility requires genetic confirmation of a pathogenic TTR variant and symptomatic polyneuropathy. Tegsedi carries a boxed warning for thrombocytopenia and glomerulonephritis, patients need structured weekly platelet counts and renal monitoring, and enrolment in the manufacturer's REMS-style monitoring programme in the US is paralleled by a monitoring plan in Saudi Arabia. Your neurologist will establish baseline neuropathy scoring and arrange the monitoring cadence.

Is Tegsedi legally importable into Saudi Arabia?

Yes, through the Saudi Arabia Ministry of Health (MOH) named-patient / special-access import framework. The mechanism permits a Saudi Arabia-licensed physician to import a medicine not locally registered when (a) it is approved by a recognised reference authority such as the US FDA, (b) no clinically equivalent registered alternative is suitable, (c) the physician accepts clinical responsibility, and (d) chain of custody is documented. hATTR polyneuropathy has limited disease-specific registered options in Saudi Arabia.

How the pathway works, step by step

1. **Consultation with your treating neurologist.** TTR genetic report, neuropathy scoring, and clinical rationale.
2. **Baseline assessment.** Neuropathy impairment scoring, platelets, renal panel, urinalysis, and monitoring-plan documentation for the boxed-warning effects.
3. **MOH named-patient application.** The physician or hospital pharmacy files clinical rationale, patient reference, dosing schedule, and chain-of-custody commitment.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner to secure Tegsedi from authorised distribution under DSCSA.
5. **Cold-chain shipment.** Tegsedi requires refrigerated handling; shipment follows validated cold-chain protocols with temperature logging.
6. **Arrival and dispensing.** The hospital pharmacy releases the product; weekly self-administration follows clinic-based training.

What documentation your physician needs

- Clinical rationale letter confirming hATTR polyneuropathy and Tegsedi as the indicated therapy
- Verification of Saudi Arabia medical license
- TTR genetic test result
- Baseline neuropathy impairment scoring
- Baseline platelets, renal panel, urinalysis with monitoring-cadence plan
- Planned weekly dosing schedule and documented monitoring protocol for thrombocytopenia and renal safety

Reserve Meds provides a physician documentation kit bundling templates Saudi Arabia MOH reviewers expect for rare-disease neurology named-patient imports, including the safety-monitoring protocol central to Tegsedi adherence.

Costs and timing

Tegsedi's US cash-pay drug-only reference cost sits in an indicative 2026 annual range of roughly USD 400,000-425,000 (dosed weekly). International logistics, MOH documentation handling, cold-chain shipment, and concierge coordination add incremental cost. Reserve Meds issues a transparent quote at the start of intake. Indicative range.

Indicative timing for first dispense after cohort intake opens is 7-14 days from the moment a complete MOH application is submitted.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, tell us at intake. We triage accordingly.

Reserve Meds's role

- **Sourcing.** Through our US-licensed specialty wholesale partner under DSCSA chain-of-custody.
- **Documentation.** Regulatory package for your physician and MOH review.
- **Logistics.** Validated cold-chain shipment to your prescribing hospital pharmacy.
- **Concierge case lead.** A named point of contact coordinating weekly refills and monitoring-cadence reminders.

What we do not do: We are not the prescriber, do not practise medicine, and are not the dispensing pharmacy. All clinical decisions remain with your treating neurologist.

Frequently asked

Is this legal in Saudi Arabia? Yes, when executed through the MOH named-patient framework with appropriate documentation. See our trust and compliance page.

How does Tegsedi compare with Wainzua, Amvuttra, Onpattro? Tegsedi is the first-generation ASO (weekly subcutaneous) with a boxed warning for thrombocytopenia and glomerulonephritis; Wainzua (LICA-ASO) and Amvuttra/Onpattro (siRNA) offer different safety and dosing profiles. Your neurologist will select based on clinical picture, availability, and monitoring capacity.

What monitoring is required? Platelet counts before each dose for at least the first year, renal monitoring with urinalysis; your neurologist will set the full cadence consistent with FDA labeling.

Will insurance cover this? Cash-pay is the default. Some Saudi Arabia private insurers consider rare-disease imports case by case; we supply documentation for your submission but do not process insurance claims directly.

Reserve Meds's role

US-based concierge coordinator for cross-border specialty medicine. We are not the prescriber, not the dispensing pharmacy, and not the manufacturer. All clinical decisions remain with your treating physician.

reservemeds.com · hello@reservemeds.com