# Tepezza access in Saudi Arabia: the SFDA named-patient pathway

How patients in the Kingdom of Saudi Arabia obtain the full 24-week eight-infusion course of US-sourced Tepezza (teprotumumab-trbw) for thyroid eye disease when local-market alternatives are limited to steroids, orbital radiation, or surgical decompression.

*Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.*

## Quick orientation

Tepezza (teprotumumab-trbw) is the first and only FDA-approved disease-modifying therapy for thyroid eye disease (TED), the disfiguring and sight-threatening autoimmune complication of Graves' disease. A fully human IgG1 monoclonal antibody that blocks the insulin-like growth factor 1 receptor (IGF-1R) on orbital fibroblasts, it is delivered as an intravenous infusion across an eight-dose, 24-week course of care. In the Kingdom of Saudi Arabia, Tepezza is not yet locally registered for routine commercial dispensing as of this page, which positions the SFDA Personal Importation Program as the primary corridor for Saudi TED patients who want a disease-modifying option rather than the symptom-and-structure interventions (steroids, orbital radiation, decompressive surgery) that have historically been the local-market choice. The 24-week course is finite, time-pressured during the active inflammatory window, and operationally demanding. Reserve Meds coordinates the full procurement, cold-chain, and infusion-cadence arc. Reserved for you.

## Why patients in Saudi Arabia need Tepezza via NPP

Thyroid eye disease affects a meaningful patient population across the Kingdom because Graves' disease prevalence is substantial and TED is its most consequential extra-thyroidal manifestation. Until Tepezza's January 2020 FDA approval, the global standard of care for active moderate-to-severe TED was a combination of high-dose corticosteroids, orbital radiation, and decompressive surgery, none of which targets the underlying IGF-1R-driven fibroblast activation. Tepezza is the only therapy ever demonstrated in randomized phase 3 data (the OPTIC trial published in NEJM 2020) to reduce proptosis as a primary outcome.

The Saudi access gap is structural rather than transitional. Tepezza received FDA approval in January 2020, EMA marketing authorisation in June 2025, and MHRA UK approval in May 2025, but it has no confirmed SFDA registration for routine commercial dispensing as of this page, and no confirmed PMDA Japan or Health Canada approvals. Even where Tepezza is now licensed in the EU and UK, national reimbursement and hospital formulary placement lag the regulatory approval by 12 to 24 months. For Saudi families with the means to self-fund treatment, the SFDA Personal Importation Program is the lawful route to the only disease-modifying TED therapy in the world. The clinical urgency matters: TED has an active inflammatory window during which intervention has the best evidence base, and watchful waiting risks permanently entrenching proptosis and diplopia.

## The SFDA Personal Importation Program for Tepezza

The SFDA Personal Importation Program allows a SCFHS-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority and a clinically equivalent locally available alternative is not suitable. Tepezza clears the reference-authority test cleanly (FDA, EMA, MHRA) and meets the equivalence test definitively because no other disease-modifying therapy for TED exists. Steroids, orbital radiation, and surgical decompression are not mechanistically equivalent; they address inflammation or structural consequences without modifying the IGF-1R-driven fibroblast activation that drives proptosis.

The clinical-justification angle in a Tepezza PIP file is among the most concrete in the matrix because the indication is narrow and the course is finite. The letter documents the TED diagnosis with clinical activity score (CAS) where applicable, the patient's proptosis measurement and diplopia status at baseline, the Graves' disease history with current thyroid function status (TED treatment requires euthyroid baseline where achievable), prior TED therapies attempted (steroids and outcome, orbital radiation and outcome, surgical consideration), the rationale for IGF-1R inhibition specifically as a mechanism, the proposed 8-infusion 24-week course (first infusion 10 mg/kg, infusions 2 through 8 at 20 mg/kg, every 3 weeks), and the two mandatory monitoring protocols: baseline glucose with on-treatment glucose monitoring (hyperglycemia reported in approximately 10 percent of patients, elevated risk in preexisting diabetes or impaired glucose tolerance) and baseline audiologic assessment with on-treatment hearing monitoring (hearing impairment reported in approximately 10 percent of patients, including cases of permanent sensorineural hearing loss).

A complete application includes the clinical justification letter on institutional letterhead from the treating endocrinologist, ophthalmologist, or oculoplastics specialist (the prescribing specialist is typically endocrinology or ophthalmology with an oculoplastics or thyroid-eye-disease subspecialty), the physician's active SCFHS license, an anonymised patient identifier with weight (since IV dosing is weight-based), full product details (brand Tepezza, generic teprotumumab-trbw, manufacturer Amgen, strength 500 mg lyophilized powder vial, requested quantity calibrated to the 8-infusion course, lot, expiry), DSCSA pedigree documentation, the destination infusion facility SFDA license, and a chain-of-custody plan documenting validated 2 to 8 degree Celsius cold-chain transit, light protection, continuous temperature monitoring, and same-day reconstitution-and-infusion coordination at the receiving facility. Because the 24-week course consumes 8 to 12 vials per patient depending on patient weight (a 70 kg patient at 20 mg/kg uses roughly 2.8 vials per infusion, rounded up to whole vials), the procurement and cold-chain commitment is meaningful. Routine cases typically run 10 to 21 business days through SFDA review; complex first-mechanism cases extend to 6 to 10 weeks.

## Where Tepezza gets dispensed in Saudi Arabia

Tepezza is delivered exclusively by intravenous infusion in an infusion-suite setting. The dispensing facility list narrows to institutions with hospital outpatient infusion capacity, validated 2 to 8 degree Celsius pharmacy storage for the lyophilized vial, same-day reconstitution-and-infusion compounding capability, baseline and on-treatment glucose and audiology coordination capacity, and the endocrinology or ophthalmology service line to manage the 24-week clinical arc. King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh and Jeddah carries the tertiary endocrinology and ophthalmology infrastructure that supports Tepezza administration. King Abdulaziz Medical City and the Ministry of National Guard Health Affairs network in Riyadh and Jeddah, King Saud University Medical City, and the major private

networks Dr. Sulaiman Al Habib Medical Group, Saudi German Hospital, and Dr. Soliman Fakeeh Hospital in Jeddah maintain infusion-suite capacity and the relevant subspecialty service lines.

For a patient outside Riyadh or Jeddah, the standard route is referral to one of the tertiary centers for the full 24-week course, with an SFDA-licensed specialty importer in Riyadh or Jeddah filing the PIP application and coordinating cold-chain delivery aligned to the every-3-week infusion calendar. The 24-week patient relationship means a single named coordinator carries the case from intake through infusion 8, with cold-chain shipment cadence locked to the infusion calendar at the receiving facility.

## Real cost picture for Tepezza in Saudi Arabia

US wholesale acquisition cost for a single 500 mg vial of Tepezza is approximately USD 14,900 to USD 17,500, with one published Amgen list-pricing reference at USD 17,511.13 per vial as of March 2025. A typical 24-week course of 8 infusions consumes 8 to 12 vials depending on patient weight, placing the all-in US-list course cost in the approximately USD 138,000 to USD 400,000-plus range. The Saudi riyal is pegged at approximately 3.75 SAR to 1 USD, so a single vial at US WAC translates to roughly SAR 56,000 to SAR 65,000, and the 24-week course at US list translates to roughly SAR 520,000 to SAR 1,500,000 before international logistics and coordination.

The all-in delivered-to-Saudi cost typically includes US drug acquisition, validated cold-chain international logistics in the SAR 3,000 to 9,400 (USD 800 to 2,500) range per shipment with the 24-week course typically requiring two to three shipments, SFDA regulatory documentation handling, customs clearance, and the Reserve Meds coordination fee. Reserve Meds quotes the 24-week course case-by-case with patient weight, dispensing facility, and shipment routing confirmed at intake; firm itemised quotes follow documentation review.

On the insurer side, Bupa Arabia, Tawuniya, and MedGulf Arabia each assess high-cost specialty named-patient imports case by case under CCHI rules. Tepezza sits at the high end of the specialty-drug cost spectrum, and pre-authorisation with the clinical justification letter, prior-therapy documentation, CAS score, and proptosis measurements is typical. Public-sector tertiary centers may carry institutional coverage programs that vary by case. Cash-pay is the default operating posture, with reimbursement sought after delivery where the plan permits.

## Typical timeline for Tepezza in Saudi Arabia

From waitlist submission to first infusion, the typical Tepezza case in Saudi Arabia runs as follows. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to the treating physician. Because Tepezza is a first-mechanism therapy and likely a first SFDA review at the institution, the PIP application typically clears in 4 to 8 weeks (longer than the 10 to 21 business-day routine timeline) given the depth of clinical review for a new mechanism. In parallel, Reserve Meds aligns US-side specialty distribution sourcing, baseline glucose and audiology assessments at the receiving facility, and the cold-chain shipment plan timed to a planned infusion-1 start date. Once SFDA approval is issued, US release and cold-chain shipment add 5 to 10 business days. From intake to first infusion, the cycle is typically 8 to 12 weeks for a first case. Once infusion 1 has been administered, the subsequent infusions follow the every-3-week protocol over 21 weeks of dosing, completing the 24-week treatment course. Cold-chain procurement is calibrated to deliver vials in advance of each infusion date, typically in two or three batches across the course rather than a single up-front shipment.

## What your physician needs to provide

The clinical justification letter for Tepezza is one of the most specific in the matrix because the indication is narrow and the course is finite. On institutional letterhead, signed by a SCFHS-licensed endocrinologist, ophthalmologist with oculoplastics subspecialty, or thyroid-eye-disease specialist, the letter typically includes diagnosis (thyroid eye disease, ICD-10 H05.2) with disease severity classification, clinical activity score (CAS), proptosis measurements (Hertel exophthalmometry), diplopia status, and any visual acuity or optic nerve compromise findings, the Graves' disease history with current thyroid function status (TSH, free T4, free T3, TRAb where measured), prior TED therapies attempted (corticosteroid course and outcome, orbital radiation and outcome, any surgical evaluations), the rationale for IGF-1R inhibition now and the urgency of intervention during the active inflammatory window, the proposed 8-infusion 24-week course (first infusion 10 mg/kg, infusions 2 through 8 at 20 mg/kg, every 3 weeks, total course over approximately 21 weeks of dosing), the mandatory baseline assessments (fasting glucose, HbA1c, baseline audiometry), and the on-treatment monitoring plan (glucose monitoring across the course given approximately 10 percent hyperglycemia incidence, on-treatment audiology assessment given approximately 10 percent hearing impairment incidence and the potential for permanent sensorineural hearing loss, infusion-reaction monitoring during and after each infusion, IBD-flare surveillance).

The patient's weight is captured at intake and at planned re-weight check-ins across the 24-week course because dosing is weight-based, and weight changes during corticosteroid taper or as TED inflammation resolves can shift the vial count per infusion. The physician confirms their SCFHS license is active for the full 24-week treatment course given the physician-license-tied nature of PIP applications. Baseline glucose and audiology must be in place before infusion 1 is scheduled.

## Common questions about Tepezza in Saudi Arabia

### Will Bupa Arabia, Tawuniya, or MedGulf cover Tepezza?

Each insurer assesses high-cost specialty named-patient imports case by case. Tepezza sits at the high end of the cost spectrum, and pre-authorisation with the full clinical justification letter, CAS and proptosis measurements, and prior-therapy documentation is typical. Public-sector tertiary centers may carry institutional coverage programs. Reserve Meds supplies the documentation set the insurer or hospital needs; the claim itself sits with you or your institution.

### Will my SCFHS-licensed endocrinologist or ophthalmologist's letter be sufficient?

Yes. SCFHS-licensed endocrinologists, ophthalmologists with oculoplastics subspecialty, and TED specialists at KFSH&RC, KAMC, MNGHA, KSUMC, and the major private networks have full signing authority on PIP applications. Because Tepezza is the first disease-modifying TED therapy and may be a first SFDA review of this mechanism inside the institution, the letter benefits from depth on the IGF-1R mechanism, OPTIC trial evidence, and the prior-therapy outcome history.

### Why Tepezza rather than steroids or orbital radiation?

Steroids reduce inflammation but do not address the IGF-1R-driven fibroblast activation that drives proptosis. Orbital radiation modulates inflammation but is not mechanism-of-action therapy. Surgical decompression addresses structural consequences once the active inflammatory window has closed. Tepezza is the only therapy demonstrated in randomized phase

3 data (OPTIC, NEJM 2020) to reduce proptosis as a primary outcome. The clinical decision sits with the treating physician.

### What about the mandatory hyperglycemia and hearing impairment monitoring?

Baseline fasting glucose and HbA1c are required, with on-treatment glucose monitoring across the 24-week course because hyperglycemia was reported in approximately 10 percent of trial patients, with elevated risk in preexisting diabetes or impaired glucose tolerance. Baseline audiologic assessment is required, with on-treatment hearing monitoring per clinician judgment because hearing impairment was reported in approximately 10 percent of trial patients, including cases of sensorineural hearing loss that may be permanent. Reserve Meds flags Tepezza cases at intake for mandatory baseline glucose and audiology coordination with the receiving facility before infusion 1 is scheduled.

### Can Tepezza be re-administered after the 24-week course?

Re-treatment has been studied in the OPTIC-X extension trial for patients who did not respond to the initial course or who relapsed. Re-treatment is a clinician-led decision and is outside the routine label regimen. Reserve Meds coordinates re-treatment courses on the same SFDA PIP framework if the treating physician determines re-treatment is clinically indicated.

### What is the safety profile beyond glucose and hearing?

Per the OPTIC trial and FDA labeling, the most frequently reported adverse reactions include muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, and dry skin. Infusion reactions are documented and require monitoring during and after each infusion. Inflammatory bowel disease flare is a label-flagged item. The full safety profile is documented in the FDA package insert and the EMA SmPC.

## Where Reserve Meds fits in Tepezza cases

Reserve Meds is a US-based concierge coordinator. We do not replace the treating endocrinologist, ophthalmologist, or TED specialist, do not replace SFDA, and do not replace the Saudi infusion facility. What we do is orchestrate US-side specialty distribution sourcing of Amgen-manufactured Tepezza with full DSCSA pedigree, prepare the regulatory documentation kit the treating physician needs, coordinate validated 2 to 8 degree Celsius cold-chain international logistics across two or three planned shipments during the 24-week course, and assign a single named coordinator who carries the case from intake through infusion 8. Tepezza is the prototypical 24-week patient relationship: predictable infusion cadence, planned cold-chain procurement against a fixed calendar, defined endpoint at infusion 8, and mandatory baseline plus on-treatment monitoring coordination. Reserve Meds flags Tepezza cases at intake for the mandatory glucose and audiology baseline coordination. No prior Reserve Meds dispensed-case experience as of this page; standard NPP coordination applies, with first cases tending toward the longer end of the SFDA timeline before the operational rails accelerate the next case at the same institution.

## Next step

If the endocrinologist, ophthalmologist, or TED specialist has recommended Tepezza and the Saudi local-market route is limited to steroids, radiation, or surgery, the waitlist is the first step. We confirm eligibility within 24 to 48 hours and send the physician documentation kit, including the baseline glucose and audiology coordination protocol.

Reserved for you.

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*This guide is informational, not medical or legal advice. The SFDA Personal Importation Program requires a SCFHS-licensed physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.*