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Tepezza access in the UAE: the EDE named-patient pathway

How patients in the United Arab Emirates obtain US-sourced Tepezza (teprotumumab-trbw) for thyroid eye disease across the eight-infusion 24-week course.

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

Quick orientation

Tepezza (teprotumumab-trbw) is a fully human IgG1 monoclonal antibody that binds and blocks the insulin-like growth factor 1 receptor (IGF-1R) on orbital fibroblasts. It is the first and only FDA-approved disease-modifying therapy for thyroid eye disease (TED), also called Graves' orbitopathy. As of the date of this page, Tepezza has no confirmed UAE registration. Patients in the UAE access Tepezza through the EDE named-patient framework as a finite 24-week course of eight infusions, scheduled every three weeks, with baseline glucose and audiology assessments mandated before the first infusion. Reserved for you.

Why patients in the UAE need Tepezza via NPP

TED is a disfiguring and sight-threatening autoimmune complication of Graves' disease. Before Tepezza's FDA approval in January 2020, management relied on steroids, orbital radiation, and decompressive surgery, none of which target the underlying disease mechanism. The international footprint shifted in 2025 (EU approval on 19 June 2025, UK MHRA on 7 May 2025), but as of this page's review date there is no confirmed local registration in the UAE or other MENA markets. Even where Tepezza is now licensed in the EU and UK, national reimbursement, hospital formulary placement, and infusion-center access typically lag regulatory approval by 12 to 24 months.

This places Tepezza squarely in the third UAE access gap from the country module: not registered locally at all. Cash-pay UAE families pursue the full eight-infusion course via the EDE named-patient pathway because the local alternative is steroids, orbital radiation, or surgical decompression, none of which target the IGF-1R-driven fibroblast activation that drives proptosis. TED has an active inflammatory window during which intervention has the strongest evidence base, and watchful waiting can permanently entrench proptosis and diplopia, so the timing of access is clinically meaningful.

The EDE named-patient pathway for Tepezza

The federal pathway for a UAE-licensed physician to import a medicine not registered locally is the unregistered-medicine import permit, administered through the EDE portal at ede.gov.ae since 29 December 2025. Tepezza qualifies on the recognised-reference-authority test: FDA approval (21 January 2020), EMA marketing authorisation (19 June 2025), and UK MHRA approval (7 May 2025). The framework permits hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when no clinically equivalent

locally registered alternative is available. For TED, the steroid-radiation-surgery toolkit available locally is not a disease-modifying equivalent.

The Tepezza clinical-justification angle in the EDE application is anchored on disease-modifying mechanism plus mandatory baseline monitoring. The letter documents the TED diagnosis, the disease activity status (the April 2023 label expansion clarified that the indication covers TED regardless of disease activity or duration), the severity markers including proptosis measurement, diplopia grading and Clinical Activity Score where applicable, the prior-line history (steroids, orbital radiation if attempted), the rationale for IGF-1R blockade citing the OPTIC phase 3 trial published in NEJM 2020 as the basis for an evidence-based disease-modifying approach, the full 24-week treatment plan (8 infusions, starting at 10 mg/kg, escalating to 20 mg/kg for infusions 2 through 8, every 3 weeks), and the mandatory baseline and on-treatment monitoring plan for hyperglycemia and hearing impairment.

The monitoring framing is critical and distinguishes Tepezza from other biologics in this matrix. Hyperglycemia is reported in approximately 10 percent of patients in clinical trials, with elevated risk in patients with preexisting diabetes or impaired glucose tolerance. Hearing impairment is reported in approximately 10 percent of patients, including cases of sensorineural hearing loss that may be permanent. Baseline glucose testing and baseline audiologic assessment, plus on-treatment monitoring per clinician judgment, are operational prerequisites that Reserve Meds flags in intake. Inflammatory bowel disease flare and infusion reactions are additional label-flagged monitoring items addressed in the application.

A complete application includes the clinical justification letter signed by a UAE-licensed ophthalmologist, oculoplastic surgeon, or endocrinologist (depending on the dispensing facility's TED service ownership), patient identifier, full product details (Tepezza 500 mg lyophilized single-dose vial, manufacturer Amgen following the October 2023 acquisition of Horizon Therapeutics, planned 8-infusion course, vial quantity 8 to 12 depending on patient weight), destination dispensing facility license, infusion suite confirmation, and chain-of-custody plan for the 2 to 8 degree Celsius cold-chain biologic. Approval timelines for routine TED cases are typically 5 to 15 business days; complex first imports of a not-yet-locally-registered biologic may extend to 4 to 6 weeks.

Where Tepezza gets dispensed in the UAE

Tepezza requires infusion-suite capability with cold-chain pharmacy storage, same-day compounding (the reconstituted and diluted infusion solution has a short room-temperature stability window per the package insert and is intended for immediate use), and a TED-aware ophthalmology or oculoplastic service. The dispensing facility list narrows to institutions with infusion-suite capacity, complex autoimmune service lines, and TED-experienced specialists: Cleveland Clinic Abu Dhabi (M42 group, ophthalmology and complex autoimmune), Sheikh Khalifa Medical City (SEHA network, ophthalmology service line), American Hospital Dubai (Mayo Clinic Care Network member, ophthalmology), King's College Hospital London Dubai, and Mediclinic City Hospital in Dubai Healthcare City. The facility must also provide baseline audiology coordination, either in-house or with a confirmed external referral, before infusion 1.

For patients without ready access to one of these centers, routing through a Dubai- or Abu Dhabi-based specialty importer holding a pharmaceutical establishment license is the practical path. The importer files the EDE permit, performs customs clearance for the refrigerated biologic, and delivers under chain-of-custody documentation to the prescribing hospital's infusion pharmacy in coordination with the every-three-week infusion calendar.

Real cost picture for Tepezza in the UAE

Per published US WAC references as of 2025, the wholesale acquisition cost for a single 500 mg vial of Tepezza is in the range of approximately USD 14,900 to USD 17,500, with one 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 (a 70 kg patient at the 20 mg/kg maintenance dose uses roughly 2.8 vials per infusion, rounded up to whole vials per institutional waste rules). At list price, a full course is widely cited in the range of approximately USD 138,000 to USD 400,000-plus depending on patient weight and waste assumptions. The AED is pegged to the US dollar at approximately 3.67 AED to 1 USD, so a full course translates to approximately AED 506,000 to AED 1.5M before logistics and coordination overhead.

The all-in delivered-to-UAE cost typically includes US drug acquisition through specialty distribution, validated cold-chain international logistics in the USD 600 to 2,500 (approximately AED 2,200 to 9,200) range per shipment scheduled against the 3-week infusion cadence, nominal EDE permit and UAE customs fees, regulatory documentation handling, and the Reserve Meds coordination fee. Reserve Meds does not promise a quoted price; firm quotes are issued per patient after weight, dispensing facility, infusion calendar, and shipping route are confirmed.

Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, and Orient assess novel-mechanism rare-disease biologic imports case by case. Coverage for a first-and-only-mechanism therapy in a not-yet-locally-registered space tends to require detailed pre-authorisation, documented disease activity, and severity scoring. Many UAE Tepezza cases are cash-pay at the order point, with the patient or hospital pursuing partial reimbursement after the fact.

Typical timeline for Tepezza in the UAE

A 24-week cold-chain biologic course with a fixed every-3-week infusion calendar requires more disciplined upfront planning than ad-hoc cases. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit including the baseline glucose and audiology coordination checklist. EDE permit review for a first-cycle Tepezza application typically runs 5 to 15 business days for routine cases and can extend to 4 to 6 weeks for the first import of this novel-mechanism biologic into a not-yet-locally-registered jurisdiction. Baseline glucose and audiology assessment are scheduled in parallel and must be complete before infusion 1. Initial procurement of infusion 1 vials (and ideally a buffer cycle's worth for infusion 2) plus cold-chain shipping add 5 to 10 business days once the permit is issued. The full cycle from waitlist to first infusion is typically 4 to 7 weeks. Subsequent infusion procurements align with the every-3-week calendar; the Concierge Patient Coordinator and Cold Chain Quality Specialist hold the calendar across the 24-week arc.

What your physician needs to provide

The clinical justification letter, on the prescribing institution's letterhead and signed by a UAE-licensed ophthalmologist, oculoplastic surgeon, or endocrinologist practicing in the emirate of the dispensing facility, typically includes: TED diagnosis with disease activity and severity documentation, proptosis measurement and diplopia grading, Clinical Activity Score where applicable, prior-line history with steroids and orbital radiation if attempted, the rationale for IGF-1R blockade as the only disease-modifying mechanism, the full 24-week 8-infusion treatment plan with dose escalation from 10 mg/kg at infusion 1 to 20 mg/kg for infusions 2 through 8, weight-based vial calculation, and the mandatory baseline and on-treatment monitoring plan covering hyperglycemia (baseline glucose, on-treatment glucose monitoring with elevated

attention in diabetes or impaired glucose tolerance) and hearing impairment (baseline audiologic assessment, on-treatment monitoring per clinician judgment, with awareness that sensorineural hearing loss may be permanent). Inflammatory bowel disease history and infusion-reaction premedication preferences are addressed.

The infusion suite confirms infusion-day compounding capability and a 60 to 90 minute infusion window (90 minutes for the first two infusions, optionally 60 minutes for subsequent infusions if well tolerated). The physician confirms their UAE license is in active standing at filing. The chain-of-custody plan for the cold-chain biologic is supplied by Reserve Meds for inclusion in the application.

Common questions about Tepezza in the UAE

Will Daman, Thiqa, GIG Gulf, Sukoon, ADNIC, or Orient cover Tepezza?

Coverage for a first-and-only-mechanism disease-modifying biologic in a not-yet-locally-registered space is assessed case by case and typically requires detailed pre-authorisation with documented disease activity and severity scoring. Some plans reimburse a percentage subject to copay; many require step therapy documentation. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you or your hospital.

Will my DHA-licensed or DOH-licensed ophthalmologist's letter be sufficient?

Yes. Any UAE-licensed ophthalmologist, oculoplastic surgeon, or endocrinologist practicing in good standing in the emirate of the dispensing facility has signing authority on the clinical justification letter. The dispensing facility's TED service ownership typically determines which specialty signs the letter.

Why are baseline glucose and audiology assessments mandatory before infusion 1?

Hyperglycemia is reported in approximately 10 percent of patients in clinical trials, with elevated risk in patients with preexisting diabetes or impaired glucose tolerance. Hearing impairment is reported in approximately 10 percent of patients, including cases of sensorineural hearing loss that may be permanent. Baseline assessment establishes the comparison point for on-treatment monitoring and is a Reserve Meds case protocol prerequisite, not an optional step.

Why Tepezza rather than steroids or orbital decompression?

Steroids reduce inflammation but do not address the IGF-1R-driven fibroblast activation that drives proptosis. Orbital radiation and surgical decompression are structural interventions, not mechanism-of-action therapies. Tepezza is the only therapy demonstrated in randomised phase 3 data (OPTIC, NEJM 2020) to reduce proptosis as a primary outcome. The choice between these options is an ophthalmology- or oculoplastic-led discussion; Reserve Meds procures only against a prescriber-issued direction.

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 outside the routine label regimen. A second course requires a new EDE application.

What is the safety profile beyond hyperglycemia and hearing impairment?

The most frequently reported adverse reactions per the FDA label include muscle spasm, nausea, alopecia, diarrhea, fatigue, dysgeusia, headache, and dry skin. Infusion reactions are described and require monitoring during and after each infusion. Inflammatory bowel disease flare is an additional label-flagged monitoring item.

Where Reserve Meds fits in Tepezza cases

Reserve Meds is a US-based concierge coordinator. We do not replace the treating ophthalmologist or oculoplastic surgeon, do not replace the EDE or any emirate-level authority, and do not replace the UAE dispensing pharmacy or infusion suite. What we do is orchestrate the US-side procurement of authentic Amgen-supplied Tepezza, weight-based vial calculation across the 8-infusion course, validated 2 to 8 degree Celsius cold-chain logistics scheduled against the every-3-week infusion calendar, the regulatory documentation kit the treating physician needs, the baseline monitoring coordination checklist, and a single named Concierge Patient Coordinator carrying the case from intake through final infusion. The AI Cold Chain Quality Specialist signs off on every shipment release. The AI International Logistics Specialist handles UAE customs documentation. Tepezza cases are flagged in intake for mandatory baseline glucose and audiology coordination with the receiving facility before infusion 1 is scheduled. No prior Reserve Meds case experience with Tepezza specifically at the time of this page; standard NPP coordination plus the Tepezza-specific 24-week protocol applies.

Next step

If the ophthalmologist or oculoplastic surgeon has recommended Tepezza for TED and UAE access is the open question, the waitlist is the first step. We confirm eligibility within 24 to 48 hours and send the physician's documentation kit including the baseline monitoring checklist.

Reserved for you.

This guide is informational, not medical or legal advice. The EDE named-patient framework requires a licensed UAE physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.