Tepezza access in Egypt: the EDA named-patient pathway

How patients in Egypt obtain US-sourced Tepezza (teprotumumab-trbw) for thyroid eye disease as a finite 24-week course of 8 infusions when local-market access does not exist and steroids, orbital radiation, or surgical decompression are the only alternatives.

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Quick orientation

Tepezza (teprotumumab-trbw) is a fully human IgG1 monoclonal antibody that targets the insulin-like growth factor 1 receptor (IGF-1R) on orbital fibroblasts. The FDA approved Tepezza on 21 January 2020 as the first and only therapy indicated for thyroid eye disease (TED), also called Graves' orbitopathy. The label was expanded in April 2023 to cover TED regardless of disease activity or duration. Outside the US, EU (EMA approval 19 June 2025), and UK (MHRA approval 7 May 2025), Tepezza is generally not registered, not stocked, and not reimbursed. In Egypt, there is no confirmed local registration at the time of this page; cash-pay international families pursuing the full 8-infusion course do so through EDA personal importation, with mandatory baseline and on-treatment hyperglycemia and audiologic monitoring built into the case from infusion 1. Reserved for you.

Why patients in Egypt need Tepezza via NPP

Egypt carries a substantial Graves' disease and autoimmune thyroid disease burden, which makes thyroid eye disease a recognised endocrinology and ophthalmology presentation in the country. Before Tepezza, management relied on steroids (with the known toxicity profile of high-dose systemic corticosteroids), orbital radiation, and decompressive surgery, none of which targeted the underlying IGF-1R-driven fibroblast activation that produces proptosis and diplopia. Tepezza is the only therapy demonstrated in randomised Phase 3 data (OPTIC trial, Douglas et al., NEJM 2020) to reduce proptosis as a primary outcome.

Tepezza sits in the country module's third structural access gap: not registered locally at all in Egypt as of this page. The drug is FDA-approved (January 2020), EMA-approved (June 2025), and MHRA-approved (May 2025), with no confirmed PMDA Japan, Health Canada, or MENA-region registrations at the module date. For a treating endocrinologist or ophthalmologist in Egypt to access Tepezza on behalf of a TED patient in the active inflammatory window, EDA personal importation is the route. The clinical case is time-pressured: TED has an active inflammatory window during which intervention has the best evidence base, and watchful waiting can permanently entrench proptosis and diplopia. The 24-week course of 8 infusions is finite, so the question for the family is not chronic re-supply but a single planned procurement arc with predictable infusion cadence and a defined endpoint at infusion 8.

The EDA named-patient pathway for Tepezza

The Egyptian Drug Authority (EDA) was created by Law No. 151 of 2019, issued 25 August 2019 in the Official Gazette No. 34 bis (A), with executive regulations issued by Prime Minister Decision No. 777 of 2020 on 29 March 2020. EDA permits the importation of unregistered medicines for a specific patient under defined conditions, most importantly where no equivalent registered product is available locally. Tepezza qualifies cleanly: it is FDA-, EMA-, and MHRA-approved, and there is no IGF-1R-targeted therapy registered in Egypt that provides an equivalent disease-modifying mechanism for TED. The application is filed through the dispensing institution's import pharmacy.

For Tepezza specifically, the clinical justification angle in the EDA application is institutional capability sign-off as much as patient clinical justification. The letter documents the TED diagnosis (Graves' orbitopathy with proptosis, diplopia, periorbital inflammation, soft-tissue involvement; clinical activity score where relevant), the underlying autoimmune thyroid status, prior therapy (steroid course history with response or intolerance, orbital radiation if applied, surgical history), the rationale for an IGF-1R disease-modifying therapy now versus continued steroid or radiation reliance, and the planned 24-week 8-infusion course. Critically, the letter also confirms the dispensing facility has the infusion-suite infrastructure, the reconstitution and same-day compounding workflow (the prepared bag is intended for immediate use with a short room-temperature stability window), and the baseline and on-treatment monitoring infrastructure for the two label-mandated safety priorities: hyperglycemia (baseline and on-treatment glucose monitoring, with elevated risk in patients with preexisting diabetes or impaired glucose tolerance) and hearing impairment (baseline audiologic assessment and on-treatment monitoring per clinician judgment, given the documented risk of sensorineural hearing loss that may be permanent).

A complete application includes the clinical justification letter on hospital letterhead with the physician's stamp, the prescription specifying brand name (Tepezza), generic name (teprotumumab-trbw), strength (500 mg per single-dose lyophilized powder vial), dosage form (IV infusion after reconstitution and dilution in 0.9 percent sodium chloride), and quantity required for the 24-week course (typically 8 to 12 vials depending on patient weight at the 10 mg/kg first infusion and 20 mg/kg subsequent infusions). The package requires a copy of the patient national ID or passport, the treating physician's Egyptian Medical Syndicate (EMS) membership number and Ministry of Health licence reference, full product details including manufacturer (Amgen Inc., following the October 2023 acquisition of Horizon Therapeutics), country of origin, FDA approval reference (BLA 761143, January 2020), shelf life and storage at 2 to 8 degrees Celsius protected from light, the destination dispensing facility licence with infusion-suite confirmation, and a chain-of-custody plan for cold-chain handling through Cairo International Airport. Routine EDA personal-import authorisations for novel oncology and rare-disease biologic cases typically extend toward the upper end of the 3 to 6 week routine window or beyond, with 8 to 14 weeks possible for first-in-class disease-modifying biologics.

Where Tepezza gets dispensed in Egypt

Tepezza is administered as a 60- to 90-minute IV infusion, with the first two infusions given over 90 minutes and subsequent infusions potentially shortened to 60 minutes per institutional protocol. The dispensing facility list narrows to institutions with validated 2 to 8 degree Celsius pharmacy storage, infusion-suite reconstitution and same-day compounding capability (the prepared bag has a limited room-temperature stability window), infusion-monitoring

infrastructure, and integrated baseline and on-treatment glucose and audiologic monitoring services on site or by formal referral.

The practical Egypt set for Tepezza includes Dar Al Fouad Hospital (Alameda Healthcare Group, JCI-accredited, Cleveland Clinic cooperation since 1999) with its oncology, neuroscience, and ophthalmology infusion infrastructure, As-Salam International Hospital with one of the most advanced acute-care environments in the country, Cairo University Hospitals (Kasr Al Ainy) with its Drug Information Center, ophthalmology, and endocrinology service lines, Ain Shams University Hospitals with strong endocrinology and ophthalmology programs, and the Cleopatra Hospitals Group's infusion-equipped facilities. The Magdi Yacoub Heart Foundation is not relevant for Tepezza given the absence of a cardiovascular indication. For Children's Cancer Hospital Egypt 57357 patients with paraneoplastic TED-like presentations, coordination would flow through 57357 with the institutional consultant signing the clinical justification, though such cases are uncommon.

Real cost picture for Tepezza in Egypt

Reserve Meds quotes patients in USD and accepts USD wire transfers. Per published US WAC references as of 2025, the wholesale acquisition cost for a single 500 mg vial of Tepezza is approximately USD 14,900 to USD 17,500 per vial, with an 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 EGP has lost more than 70 percent of its value against the US dollar since early 2022, with the USD/EGP rate near 52 to 53 in May 2026; quoting in USD insulates the patient from intra-case currency drift across the 24-week course.

The all-in delivered-to-Egypt cost includes the US drug acquisition at WAC plus margin across 8 to 12 vials, validated 2 to 8 degree Celsius cold-chain international logistics from a US specialty distributor to Cairo International Airport across the infusion-cadenced shipment schedule, regulatory documentation handling fees on the Egyptian side, infusion-suite fees at the receiving facility (separate from drug procurement), and the Reserve Meds coordination fee itemised on the firm quote. Reserve Meds does not promise a quoted price; firm quotes are issued per patient after weight, dispensing facility, and shipping route are confirmed.

On the insurance side, Bupa Egypt, AXA Egypt, MetLife Egypt, Allianz Egypt, Misr Insurance, and other Egyptian carriers each assess high-cost rare-disease biologic named-patient imports case by case. UHIA coverage does not generally extend to specialty imports. Cash-pay is the dominant posture; Egyptian families managing 24-week TED courses often coordinate USD funds across the diaspora.

Typical timeline for Tepezza in Egypt

From waitlist submission to first infusion, the typical Tepezza case in Egypt runs as follows. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to the treating endocrinologist or ophthalmologist, with Arabic-language patient-facing summaries where the family requests them. The dispensing facility files the EDA personal-import application; first-in-class disease-modifying biologic cases typically extend toward the upper end of the 3 to 6 week routine window, sometimes reaching 8 to 14 weeks if supplementary

clarification or institutional capability documentation is requested. In parallel, Reserve Meds aligns US-side specialty distribution sourcing, the cold-chain shipment plan, and coordinates baseline glucose and audiology with the receiving facility before infusion 1 is scheduled. Once EDA authorisation is issued, US release and validated cold-chain transit to Cairo International Airport add 5 to 10 business days. The full cycle from waitlist to first infusion is typically 6 to 12 weeks. Infusions 2 through 8 follow on a once-every-3-weeks cadence, completing 21 weeks of dosing and a 24-week treatment course.

What your physician needs to provide

The clinical justification letter is the cornerstone of the EDA Tepezza package and carries unusual weight because of the mandatory monitoring requirements and the finite-course structure. The letter, on the prescribing institution's letterhead and signed and stamped by an EMS-registered Egyptian endocrinologist, ophthalmologist, or neurosurgeon with an active Ministry of Health licence, typically includes: the TED diagnosis with severity markers (proptosis measurements, diplopia assessment, clinical activity score, soft-tissue involvement), the underlying autoimmune thyroid status, the prior therapy history (steroid courses with response and intolerance documentation, orbital radiation, surgical decompression where applicable), the rationale for an IGF-1R-targeted disease-modifying therapy over continued steroid reliance, the planned 24-week 8-infusion course with weight-based dose calculation (10 mg/kg first infusion, 20 mg/kg subsequent), and the institutional confirmation that the receiving facility has the infusion-suite reconstitution and same-day compounding workflow.

The letter also captures the two mandatory monitoring priorities. Hyperglycemia: baseline fasting glucose and HbA1c, on-treatment glucose monitoring, with elevated risk in patients with preexisting diabetes or impaired glucose tolerance and a documented plan for diabetes-management coordination across the 24-week course. Hearing impairment: baseline audiologic assessment, on-treatment monitoring per clinician judgment, with patient counselling on the risk of sensorineural hearing loss that may be permanent. Additional label-flagged monitoring items include inflammatory bowel disease flare risk and infusion reactions, with premedication and monitoring at the discretion of the treating clinician. The physician confirms their EMS membership and MoH licence are in active standing at the time of filing.

Common questions about Tepezza in Egypt

Will Bupa Egypt, AXA Egypt, MetLife, Allianz, or Misr Insurance cover Tepezza?

Each insurer assesses high-cost rare-disease biologic imports case by case, and the 24-week course magnitude (often six figures in USD) makes pre-authorisation universally required where any coverage path exists. Some plans reimburse a percentage when the underlying condition is covered; many will not engage at the list price level. We do not promise coverage. We supply the documentation set; the claim sits with you or your hospital.

What is the safety profile and why are hyperglycemia and hearing monitoring mandatory?

The FDA-approved labeling documents hyperglycemia in approximately 10 percent of patients in clinical trials, with elevated risk in patients with preexisting diabetes or impaired glucose tolerance, requiring baseline and on-treatment glucose monitoring. Hearing impairment, including cases of sensorineural hearing loss that may be permanent, was reported in approximately 10 percent of patients, requiring baseline audiologic assessment and on-treatment

monitoring per clinician judgment. Inflammatory bowel disease flare and infusion reactions are additional label-flagged monitoring items. Reserve Meds case protocols mandate baseline glucose and audiology coordination before infusion 1 is scheduled.

Is there an alternative therapy for thyroid eye disease?

No FDA-approved disease-modifying alternative exists for TED. Steroids, orbital radiation, and surgical decompression are symptom and structure interventions that do not address the underlying IGF-1R-driven fibroblast activation. Tepezza is the only therapy demonstrated in randomised Phase 3 data (OPTIC trial, Douglas et al., NEJM 2020) to reduce proptosis as a primary outcome. The clinical decision rests with the treating endocrinologist or ophthalmologist.

What is the course duration and can it be re-administered?

Eight infusions over approximately 21 weeks of dosing, completing a 24-week treatment course. There is no maintenance dosing after the 8-infusion course completes. Re-treatment has been studied in the OPTIC-X extension trial for patients who did not respond to the initial course or who relapsed, but re-treatment is a clinician-led decision and is outside the routine label regimen.

Can the infusions be administered at a Cairo hospital or do I need to travel?

The infusions are administered at the licensed Egyptian dispensing facility with infusion-suite capability. Dar Al Fouad Hospital, As-Salam International Hospital, Cairo University Hospitals (Kasr Al Ainy), Ain Shams University Hospitals, and Cleopatra Hospitals Group facilities all carry the infrastructure. The patient does not need to travel internationally for the infusions themselves; the drug is imported to the receiving facility, the patient is infused locally, and baseline and on-treatment glucose and audiology monitoring run in parallel through the hospital's diagnostic services.

What pharmacovigilance reporting applies?

The treating physician and dispensing pharmacy report adverse events to the Egyptian Pharmacovigilance Center (EPVC) per Yellow Card or CIOMS reporting standards, with the obligation running through the full 24-week course of therapy and into the post-course follow-up period.

Where Reserve Meds fits in Tepezza cases

Reserve Meds is a US-based concierge coordinator. We do not replace the treating endocrinologist or ophthalmologist, do not replace EDA, do not replace the Egyptian dispensing pharmacy, and do not act as an importer of record in Egypt. What we do is orchestrate US-side specialty distribution sourcing of Amgen-manufactured Tepezza with DSCSA chain-of-custody documentation across the 8- to 12-vial procurement arc, prepare the regulatory documentation kit the treating physician needs for the EDA filing, coordinate validated 2 to 8 degree Celsius cold-chain international logistics to Cairo International Airport aligned to the every-3-week infusion cadence, and run a single named Concierge Patient Coordinator throughout the 24-week case in both English and Arabic. The AI Cold Chain Quality Specialist signs off on every shipment release, and the AI International Logistics Specialist handles per-country 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 applies.

Next step

If the endocrinologist or ophthalmologist has recommended Tepezza for an active or expanded-indication TED patient, the waitlist is the first step. We confirm eligibility within 24 to 48 hours and send the physician documentation kit, with Arabic-language patient summaries where the family requests them.

Reserved for you.

This guide is informational, not medical or legal advice. The EDA personal-importation framework requires a licensed Egyptian physician's clinical judgment; Reserve Meds is the coordinator, not the prescriber.