Tepezza access in India: the CDSCO Rule 36 named-patient pathway

How patients in India obtain Tepezza (teprotumumab-trbw) for thyroid eye disease through the CDSCO Rule 36 personal-import permit, including the 24-week course architecture and mandatory hyperglycemia plus hearing monitoring protocol.

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

Quick orientation

Tepezza is the Amgen (formerly Horizon Therapeutics) monoclonal antibody approved by the US FDA in January 2020 as the first and only therapy indicated for the treatment of thyroid eye disease (TED), the disfiguring and sight-threatening autoimmune complication of Graves' disease. The label was expanded in April 2023 to cover TED regardless of disease activity or duration. Tepezza is not registered locally in India as of this module date, and access for Indian families runs through the CDSCO Rule 36 personal-import permit on Form 12A and Form 12B, or through institutional Compassionate Use at a tertiary endocrinology or ophthalmology centre. The 24-week course is finite (8 infusions every 3 weeks), and the operational standard at Reserve Meds is mandatory baseline glucose and audiology coordination with the receiving facility before infusion 1 is scheduled. Reserve Meds operates as a legitimate cross-border named-patient channel for families whose treating physician has decided Tepezza is the right next step.

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Why patients in India reach for Tepezza through NPP

India has the largest tertiary specialty hospital network of any Reserve Meds priority country, and Indian manufacturers supply a significant share of the world's generic medicines. For US originator specialty biologics like Tepezza, three patterns of access gap recur. A drug can be registered with CDSCO but the specific brand, strength, or pack size is not stocked in the dispensing pharmacy on the day therapy is meant to start. A drug can be registered for one indication and prescribed for another FDA-approved use that is not on the Indian label. A drug can be FDA-approved in the United States but not registered locally at all. For Tepezza the pattern is the third: there are no confirmed local registrations in India as of this module date, and access in India runs through CDSCO Named Patient Programme pathways on a case-by-case basis.

Tepezza is the only disease-modifying therapy ever approved for thyroid eye disease. The clinical alternatives in India (steroids, orbital radiation, surgical decompression) reduce inflammation or correct structure but do not address the IGF-1R-driven fibroblast activation that drives proptosis and diplopia. The 24-week course is also 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. Even in jurisdictions where Tepezza is now licensed (EU in June 2025, UK in May 2025), national reimbursement and hospital formulary access lag the approval by 12 to 24 months. In India that gap is wider, and families with the means to self-fund treatment

have no local-market route to the drug other than international procurement. Reserve Meds frames Tepezza cases as a documented cross-border channel under the CDSCO Rule 36 framework rather than a workaround.

The CDSCO named-patient pathway for Tepezza

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug, whose import would otherwise be prohibited under Section 10 of the Drugs and Cosmetics Act 1940, for the exclusive personal use of a named patient. Form 12A is the application for the permit. Form 12B is the permit itself, issued by the office of the Drugs Controller General of India (DCGI) at FDA Bhawan, Kotla Road, New Delhi, or by designated CDSCO Port Offices. The application is accompanied by a prescription from a Registered Medical Practitioner (RMP) showing the RMP's NMC registration number and the quantity required for treatment. The quantity of any single drug imported shall not exceed one hundred average doses per application.

For institutional Compassionate Use of drugs not approved for marketing in India at all (Tepezza's current status), the parallel pathway is the Compassionate Use application route to the DCGI by a government hospital, a registered medical practitioner, a pharmaceutical company, or the patient. This route applies when the drug is approved by a recognised reference authority (FDA, EMA, MHRA, Health Canada, PMDA) for a life-threatening condition, a serious permanent disability, or an unmet medical need. Sight-threatening TED with active inflammatory features can qualify; AIIMS and other tertiary institutions have established workflow for this route.

For Tepezza the clinical-justification angle is TED disease activity documentation plus baseline monitoring protocols. A complete CDSCO application typically includes:

- A clinical justification letter naming the diagnosis (thyroid eye disease, with Clinical Activity Score (CAS) or VISA classification documented, proptosis measurement in millimetres, diplopia scoring, and prior steroid or orbital radiation history), the documented reason no Indian-registered alternative is suitable, and the time-pressured nature of the active inflammatory window
- The treating physician's NMC registration number and a copy of state council registration where required
- A patient identifier and supporting medical records, including thyroid function tests, Graves' disease history, prior treatment of orbitopathy, and recent ophthalmology imaging
- Product details: Tepezza (teprotumumab-trbw) 500 mg single-dose lyophilized powder vial, manufacturer Amgen Inc., quantity sufficient for the 24-week 8-infusion course (typically 8 to 12 vials per patient depending on patient weight; the per-application limit of 100 average doses comfortably covers the course)
- The dispensing facility's drug licence and infusion-suite capability (reconstitution requires Sterile Water for Injection, dilution into 0.9% sodium chloride, and same-day administration)
- A chain-of-custody plan from the US specialty-distribution source to the dispensing pharmacy in India, including continuous 2-to-8-degree cold-chain documentation and protection from light
- The mandatory baseline glucose and audiology coordination plan with the receiving facility

CDSCO's published guidance states the Form 12B permit issues on a priority basis, typically within one to two days for routine applications where the documentation is complete.

Where Tepezza gets dispensed in India

Tepezza is a refrigerated lyophilized biologic delivered by intravenous infusion. The dispensing footprint is the endocrinology and ophthalmology infusion services at tertiary specialty institutions with confirmed cold-chain receiving capability and infusion-suite scheduling. Institutions that file named-patient imports and operate infusion infrastructure include the All India Institute of Medical Sciences (AIIMS) in New Delhi, Apollo Hospitals (Chennai flagship, with Delhi, Bangalore, Hyderabad, and Kolkata), Fortis Memorial Research Institute in Gurgaon and the Fortis Mulund, Bangalore, and Kolkata sites, Medanta in Gurgaon, Kokilaben Dhirubhai Ambani Hospital in Mumbai, MGM Healthcare in Chennai, Christian Medical College (CMC) in Vellore, and Manipal Hospitals in Bangalore.

For TED cases the natural homes are the endocrinology and ophthalmology services at AIIMS Delhi (with its joint endocrinology-ophthalmology orbitopathy multidisciplinary capability), Apollo Chennai and Apollo Delhi, Medanta Gurgaon, Kokilaben Mumbai, and CMC Vellore. Each of these can host the 8-infusion course on a 3-week cadence and integrate the mandatory hyperglycemia and audiology monitoring into the existing clinical workflow. Families in tier 2 cities typically route to one of these centres for the prescription and clinical justification letter, then work with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that files the Form 12A and handles the cold-chain documentation. Smaller infusion centres without baseline audiology capability are not suitable receiving facilities for Tepezza.

Real cost picture for Tepezza in India

US wholesale acquisition cost for a single 500 mg vial of Tepezza is in the range of approximately USD 14,900 to USD 17,500 per vial, 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 maintenance dose of 20 mg/kg 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. Reserve Meds does not promise a quoted price; firm quotes are issued per patient after weight, dispensing facility, and shipping route are confirmed.

The Indian rupee floats against the US dollar. In May 2026 the USD/INR rate sits in the 94 to 95 range. The 24-week course at US WAC translates to roughly INR 1.3 crore to INR 3.8 crore at the prevailing rate, with the patient weight driving the spread. International cold-chain logistics for the lyophilized vials runs at USD 600 to USD 1,500 per shipment (approximately INR 57,000 to INR 1.4 lakh), with shipments typically batched to align with the every-3-week infusion calendar. India's Union Budget 2026-27 expanded the list of life-saving drugs eligible for customs duty exemption, and the specific HSN code and exemption status are confirmed at the documentation stage. GST on most life-saving medicines is 5%.

On the insurance side, Star Health, HDFC ERGO, ICICI Lombard, and Niva Bupa each handle named-patient imports case by case; none reimburse a Rule 36 personal import as a standard line item. CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), with stricter constraints on drugs not approved by the DCGI (Tepezza's current status in India). Cash-pay is the default posture. The 24-week

course architecture means cost is incurred predictably over six months rather than as a single large upfront payment, which simplifies family budgeting and cross-border funds movement.

Typical timeline for Tepezza in India

For an established Tepezza candidate with a clean endocrinology and ophthalmology letter, baseline glucose and audiology evaluations completed, and a tertiary-centre infusion-suite booking, the typical end-to-end cycle from first inquiry to first infusion is 3 to 6 weeks. CDSCO published guidance puts the Form 12B priority window at 1 to 2 days for complete routine documentation; cases routed through Compassionate Use at a Centre of Excellence may extend the front end by 1 to 2 weeks. US-side sourcing through Amgen specialty distribution adds 1 to 2 weeks. International cold-chain transit and Indian customs clearance under the import permit at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad airport adds 3 to 7 days, with continuous temperature monitoring at 2 to 8 degrees Celsius and protection from light. Once infusion 1 is delivered the cadence is fixed at every 3 weeks across 8 infusions, with the cold-chain procurement plan locked to that calendar. Timelines are presented as typical ranges and not as promises; specific dates are confirmed at firm-quote issuance.

What your physician needs to provide

The clinical justification letter for Tepezza is the centrepiece of the CDSCO package. For this product the letter typically includes:

- The patient's confirmed diagnosis of thyroid eye disease, with Clinical Activity Score (CAS) or VISA classification documented, proptosis measurement in millimetres (Hertel exophthalmometry), diplopia scoring (Gorman or equivalent), and a recent ophthalmology imaging summary
- Graves' disease history and thyroid function status (the underlying autoimmune driver, with current thyroid function tests)
- Prior orbitopathy management: steroid course (oral or IV pulse, dose, duration, response), orbital radiation if performed, and any surgical decompression history
- Justification for why a locally registered alternative is not suitable, which for Tepezza is the absence of any disease-modifying therapy registered in India for TED
- The dosing plan: 10 mg/kg IV for infusion 1, 20 mg/kg IV for infusions 2 through 8, every 3 weeks over approximately 21 weeks of dosing, completing a 24-week course; first two infusions administered over 90 minutes, subsequent infusions over 60 minutes if well tolerated; premedication for infusion reactions at clinician discretion
- **The mandatory monitoring plan: hyperglycemia monitoring (baseline fasting glucose and HbA1c, on-treatment glucose checks before each infusion; elevated risk in preexisting diabetes or impaired glucose tolerance, reported in approximately 10 percent of clinical trial patients) and hearing impairment monitoring (baseline audiologic assessment before infusion 1, on-treatment audiology per clinician judgment; sensorineural hearing loss may be permanent, reported in approximately 10 percent of clinical trial patients)**
- Additional monitoring items per the label: inflammatory bowel disease flare, infusion reactions during and after each infusion

- The PvPI adverse-event reporting plan as part of the Pharmacovigilance Programme of India obligation

The treating physician's NMC registration number must appear on the prescription. State-council registration is required for practice in a particular state. Reserve Meds will not schedule infusion 1 without confirmation that baseline glucose and audiology evaluations have been completed and documented.

Common questions about Tepezza in India

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Tepezza? Each plan handles named-patient imports case by case. None reimburse a Rule 36 personal import as a standard line item, and for Tepezza specifically the lack of Indian regulatory approval makes private insurance reimbursement unusual. Cash-pay is the default posture.

Will CGHS or ESIC cover Tepezza? CGHS provides for life-saving medicines not in the standard formulary to be considered by an Expert Committee under Special DG (DGHS), case by case. Drugs not approved by the DCGI face a stricter Expert Committee review, which applies to Tepezza in India. ESIC's formulary is narrower and not structured for routine personal-import reimbursement.

Why baseline audiology and glucose testing? Both hyperglycemia and hearing impairment occurred in approximately 10 percent of clinical trial patients, and hearing loss may be permanent. Reserve Meds requires documented baseline glucose (fasting glucose and HbA1c) and baseline audiology (pure-tone audiometry) before scheduling infusion 1, with on-treatment monitoring at the receiving facility per clinician judgment. This is a hard intake gate, not a recommendation.

What if my Clinical Activity Score is low? The 2023 FDA label expansion clarified that the indication covers TED regardless of disease activity or duration, so a low CAS does not exclude a patient. Active inflammatory features remain the strongest evidence base, and the treating endocrinologist or oculoplastics specialist makes the activity assessment.

Is there a re-treatment option after infusion 8? 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 routine label regimen; Reserve Meds will support a second course filing where the treating physician documents the rationale.

Why Tepezza versus steroids? Steroids reduce inflammation but do not address the IGF-1R-driven fibroblast activation that drives proptosis. Tepezza is the only therapy demonstrated in randomized Phase 3 data (OPTIC, NEJM 2020) to reduce proptosis as a primary outcome.

Where Reserve Meds fits in Tepezza cases

Reserve Meds is a US-based concierge coordinator. We do not replace your endocrinologist or oculoplastic specialist, do not replace CDSCO, and do not replace the dispensing pharmacy or the licensed importer. For Tepezza specifically we orchestrate the US-side sourcing through Amgen-aligned specialty distribution, the regulatory documentation kit your physician needs for Form 12A (TED activity scoring reference, prior-therapy documentation template, dosing reference by patient weight, the mandatory baseline glucose and audiology protocol, PvPI reporting reference), validated cold-chain international logistics under chain-of-custody at 2 to 8 degrees Celsius with light protection, and a single named coordinator who carries the family across the

full 24-week arc through all 8 infusions and into the reporting period. The case archetype is a 24-week patient relationship with predictable infusion cadence, planned cold-chain procurement against a fixed calendar, and a defined endpoint at infusion 8. Coordinator continuity across the 24-week arc is the operating standard.

Next step

If your endocrinologist or oculoplastic specialist has decided Tepezza is the right next step for active or recently active thyroid eye disease, the Rule 36 personal-import pathway through CDSCO is the route. Join the waitlist below and we will confirm eligibility within 24 to 48 hours and route the documentation kit to your physician, including the mandatory baseline glucose and audiology protocol that gates infusion 1.

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Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to retained outside counsel. Review methodology ›

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