Tysabri

India · access guide

How to access Tysabri (natalizumab) from India: the CDSCO named-patient pathway

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Quick orientation

Tysabri (natalizumab) is an FDA-approved anti-alpha-4 integrin monoclonal antibody developed by Biogen, first approved in 2004. It is a humanised monoclonal antibody against the alpha-4 subunit of alpha-4-beta-1 and alpha-4-beta-7 integrins, blocking leukocyte migration across the blood-brain barrier and into inflamed gut tissue. FDA-approved indications cover relapsing forms of multiple sclerosis in adults and moderate-to-severe Crohn's disease in adults with inadequate response or intolerance to conventional therapies and anti-TNF agents, with use restricted by an FDA REMS programme (TOUCH) due to progressive multifocal leukoencephalopathy (PML) risk. Tysabri is given as an intravenous infusion of 300 mg every four weeks, run over approximately one hour with post-infusion observation. A subcutaneous 300 mg formulation administered every four weeks is also FDA-approved for eligible patients.

US WAC reference: approximately USD 95,000 per year at monthly infusion dosing. approximately USD 7,500 to 8,000 per monthly infusion at US WAC.

Why Indian patients route Tysabri via the named-patient pathway

India's pharmaceutical access framework is governed by the Central Drugs Standard Control Organisation (CDSCO) under the Drugs and Cosmetics Act, 1940 and the New Drugs and Clinical Trials Rules, 2019. Rule 36 of these Rules provides a named-patient import mechanism that allows a licensed physician (or the patient, with prescription) to import a specific medicine for a specific patient where the locally available channel does not meet the clinical need.

The most common Rule 36 triggers for Tysabri are: (a) the prescribed presentation, strength, or formulation is not locally registered or not currently in stock at the patient's tertiary centre, (b) registration of a newer indication has lagged behind the FDA approval, (c) the patient requires the originator manufacturer for continuity from a prior course of treatment, or (d) local supply has been inconsistent and the treating physician judges that bridge supply is clinically necessary.

Natalizumab use in India is concentrated at MS and IBD tertiary centres with JCV-antibody testing and MRI surveillance infrastructure; named-patient routing is sometimes requested to align supply with infusion-suite scheduling or to bridge patients during local-supply gaps. Because Tysabri requires cold-chain handling (refrigerated 2 to 8 degrees Celsius), supply continuity and presentation fidelity matter, and a coordinated named-patient channel can offer better assurance than ad-hoc local sourcing.

The Indian tertiary-hospital ecosystem - Apollo, Tata Memorial, AIIMS, CMC Vellore, Max, Kokilaben, Medanta, Fortis, Manipal - has the MS neurologists and inflammatory-bowel-disease gastroenterologists, infusion-suite or self-injection-training infrastructure, and laboratory monitoring capacity to support Tysabri therapy once supply is in hand. The named-patient channel exists to bridge the supply side; the clinical infrastructure is already there.

Indian payers (public and private) treat Tysabri unevenly. Public-channel access is limited. Private insurers and corporate plans sometimes reimburse named-patient imports on case-by-case approval but typically require prior-authorisation and documented failure or inadequate response on conventional therapy. Most patients budget for cash-pay as the default and submit for reimbursement after the fact.

The CDSCO named-patient pathway for Tysabri, step by step

1. **Consultation with your treating neurologist (MS) or gastroenterologist (Crohn's).** Eligibility for Tysabri is a clinical decision based on diagnosis, prior therapy, and indication-specific criteria.
2. **Clinical rationale documented.** Your physician documents the indication, dose, prior-therapy history, and the reason the local channel does not meet the need (the formulary-gap or supply-gap justification under Rule 36).
3. **CDSCO application filed.** Your physician (or the importing pharmacy partner) files the personal-import / named-patient documentation with CDSCO. The application identifies the patient (anonymised reference), specifies the medicine, dose, and quantity, and attaches the prescription and clinical letter.
4. **US-side sourcing.** Reserve Meds coordinates with our US-licensed specialty wholesale partner under DSCSA chain-of-custody, with manufacturer-direct sourcing where possible.
5. **Cold-chain shipment.** Temperature-controlled transport (2 to 8 degrees Celsius) with a temperature logger documenting the transit excursion record on arrival, with documented chain of custody from US dispensing pharmacy to Indian tertiary centre.
6. **Arrival and administration.** Tysabri is delivered to the designated tertiary centre or, where the presentation supports it, directly to the patient for at-home administration. Tysabri is given as an intravenous infusion of 300 mg every four weeks, run over approximately one hour with post-infusion observation.
7. **Ongoing coordination.** Reserve Meds supports re-supply cadence aligned to the dosing schedule and coordinates documentation for follow-up CDSCO filings if required.

Where Tysabri is administered or dispensed in India

Indian tertiary centres with the MS neurologists and inflammatory-bowel-disease gastroenterologists infrastructure to support Tysabri typically include:

- **Apollo Hospitals, Indraprastha (Delhi)** and the broader Apollo network across Chennai, Hyderabad, Bengaluru, and Mumbai
- **Tata Memorial Hospital (Mumbai)** for oncology-adjacent and complex-comorbidity cases
- **All India Institute of Medical Sciences, AIIMS (Delhi)** for tertiary specialty consultations
- **Christian Medical College, CMC Vellore** for neurologist and related care
- **Max Super Speciality Hospital, Saket (Delhi)**
- **Kokilaben Dhirubhai Ambani Hospital (Mumbai)**
- **Medanta - The Medicity (Gurgaon)**
- **Fortis Memorial Research Institute (Gurgaon)**
- **Manipal Hospitals (Bengaluru)** and the broader Manipal network

Choice of centre is a clinical decision; Reserve Meds coordinates supply to the centre your treating physician designates and does not direct referral.

Real cost picture for Tysabri in India via the named-patient pathway

The cash-pay total for Tysabri via this channel decomposes into three components: drug cost, logistics, and concierge coordination.

- **Drug cost (US WAC reference).** approximately USD 95,000 per year at monthly infusion dosing. At an indicative 83 INR per USD reference, annual drug-only cost translates to roughly INR 79 lakh before infusion-centre, logistics, and concierge fees.
- **Logistics and 3PL.** Cold-chain shipment with validated 2 to 8 degrees Celsius packaging, temperature monitoring, and customs handling. Indicative incremental cost is in the low-thousands USD per shipment depending on quantity and transit window.
- **Reserve Meds concierge fee.** Tiered as a percentage of drug cost, disclosed at intake on the firm quote.

Reserve Meds issues an indicative range at the start of intake and a firm delivered quote after your physician's documents are uploaded. We do not collect a deposit at intake; payment is wired only after a firm quote is accepted. See our cost-range methodology.

Some Indian private insurers reimburse named-patient imports on case-by-case approval. We supply documentation for your submission; reimbursement is not guaranteed and is not promised by Reserve Meds.

Typical timeline

From the moment a complete CDSCO application is filed to the moment Tysabri arrives at the designated Indian tertiary centre, the indicative timeline is 10 to 21 days. CDSCO review of a well-documented Rule 36 application typically takes 5 to 10 working days; US-side sourcing and release add 2 to 5 working days. For cold-chain shipments, transit is sequenced to minimise excursion exposure and is typically 3 to 5 days from US release to Indian tertiary-centre receipt.

Re-supply is generally faster (7 to 14 days end-to-end) once the pathway is established and the patient profile is on file.

Fulfillment availability is limited to our first cohort, and all timelines published on this site are indicative. If your clinical situation is time-sensitive, flag that when you

What your physician needs to provide

The CDSCO named-patient application is built around the physician's clinical letter and the prescription. Your treating neurologist (MS) or gastroenterologist (Crohn's) will typically need to provide:

- **Clinical justification letter.** Diagnosis, prior-therapy history, response and tolerability of prior agents, and the clinical rationale for Tysabri as the indicated next step.
- **MCI / NMC registration.** Verification of the physician's Indian medical-council registration (Medical Council of India, now National Medical Commission).
- **Patient identifier.** Anonymised reference where possible, full identification where the application requires it.
- **Prescription.** Brand name, strength, dose, quantity, and duration of supply.
- **Formulary-gap or supply-gap justification.** Specific statement of why the local channel does not meet the clinical need for this patient (the Rule 36 trigger).
- **Monitoring plan.** Jc virus antibody status before initiation and every six months during therapy (jcv-positive patients face higher pml risk), mri surveillance every 6 to 12 months, and infusion-reaction monitoring at every dose.
- **Adverse-event reporting commitment.** A statement that the physician will report any serious adverse events through CDSCO pharmacovigilance channels.

Reserve Meds provides a physician documentation kit that bundles the templates CDSCO reviewers expect and a worked example for your physician's reference.

Frequently asked

What is PML and why does it matter for Tysabri? Progressive multifocal leukoencephalopathy is a rare but often fatal demyelinating brain infection caused by reactivated JC virus. JCV-antibody-positive patients with longer treatment duration and prior immunosuppression face higher risk.

How often is JCV-antibody status checked? Before initiation and every six months during therapy. Rising JCV-antibody index is a discontinuation prompt.

Can the subcutaneous formulation be coordinated instead of IV? Yes, where your neurologist or gastroenterologist prescribes it. The subcutaneous 300 mg every-four-weeks presentation is FDA-approved.

Where is the Tysabri infusion administered in India? At a qualified tertiary infusion suite. Apollo, Medanta, Kokilaben, AIIMS, and CMC Vellore have established Tysabri protocols.

Is Tysabri used in Crohn's disease commonly in India? Use in Crohn's is uncommon, typically reserved for patients with inadequate response to anti-TNF agents and where vedolizumab or ustekinumab are not options.

Is this legal? Yes, when executed through the CDSCO Rule 36 personal-import / named-patient framework. See our trust and compliance page.

Can Reserve Meds promise insurance reimbursement? No. Reimbursement is determined by your insurer and your specific policy. We supply documentation; we do not promise outcomes.

Where Reserve Meds fits in

Reserve Meds is a US-based concierge coordinator for cross-border specialty medicine. For Tysabri specifically, we provide:

- **Sourcing.** US-licensed specialty wholesale partner under DSCSA chain-of-custody, manufacturer-direct where possible.
- **Documentation.** CDSCO-ready documentation package for your physician and a worked example for the Rule 36 application.
- **Logistics.** Cold-chain shipment with validated packaging and temperature monitoring, customs handling, and delivery to the designated tertiary centre.
- **Concierge case lead.** A named point of contact throughout intake, application, shipment, and re-supply cadence.

What we do not do. We are not the prescriber. We do not practice medicine. We are not the dispensing pharmacy. All clinical decisions remain with your treating physician. Our case team responds to intakes within 24 to 48 hours. **If Tysabri is already available to you locally for your indication, stay on the local channel.**

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.

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