**Ocrevus**

India · access guide

# How to access Ocrevus (ocrelizumab) from India: the CDSCO named-patient pathway

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## Quick orientation

Ocrevus (ocrelizumab) is an FDA-approved anti-CD20 monoclonal antibody developed by Genentech (Roche), first approved in 2017. It is a humanised monoclonal antibody that selectively targets CD20-positive B cells and depletes them, addressing the B-cell contribution to MS demyelination and chronic inflammation. FDA-approved indications cover relapsing forms of multiple sclerosis (including clinically isolated syndrome, relapsing-remitting, and active secondary progressive disease) and primary-progressive multiple sclerosis in adults. Ocrevus is given as an intravenous infusion. The initial dose is 300 mg followed by a second 300 mg infusion two weeks later. Maintenance is 600 mg infused once every six months. A subcutaneous formulation (Ocrevus Zunovo) is also FDA-approved for select patients.

US WAC reference: approximately USD 70,000 per year at every-six-month infusion dosing. approximately USD 35,000 per infusion (two per year).

## Why Indian patients route Ocrevus 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 Ocrevus 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.

Ocrelizumab is registered in India and infused at major MS centres, but cohort size and infusion-slot capacity are limited; where treatment-initiation timing matters (active disease, new MRI lesions), a coordinated named-patient route is sometimes used to align supply with infusion-suite scheduling. Because Ocrevus 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, infusion-suite or self-injection-training infrastructure, and laboratory monitoring capacity to support Ocrevus 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 Ocrevus 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 Ocrevus, step by step

1. **Consultation with your treating neurologist (MS specialist where available).** Eligibility for Ocrevus 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.** Ocrevus is delivered to the designated tertiary centre or, where the presentation supports it, directly to the patient for at-home administration. Ocrevus is given as an intravenous infusion.
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 Ocrevus is administered or dispensed in India

Indian tertiary centres with the MS neurologists infrastructure to support Ocrevus 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 Ocrevus in India via the named-patient pathway

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

- **Drug cost (US WAC reference).** approximately USD 70,000 per year at every-six-month infusion dosing. At an indicative 83 INR per USD reference, annual drug-only cost translates to roughly INR 58 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 Ocrevus 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 specialist where available) will typically need to provide:

- **Clinical justification letter.** Diagnosis, prior-therapy history, response and tolerability of prior agents, and the clinical rationale for Ocrevus 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.** Hepatitis b screening prior to first dose, cd19 b-cell counts and igg levels over time, infection surveillance, and infusion-reaction monitoring with premedication for each 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

**Where is the Ocrevus infusion administered?** At a qualified Indian infusion centre or hospital day-care unit. Apollo, Kokilaben, Medanta, and CMC Vellore have established MS infusion suites.

**How long does each infusion take?** The first 300 mg infusion runs approximately 2.5 hours. Maintenance 600 mg infusions run approximately 3.5 hours, or 2 hours with the shorter-infusion protocol in eligible patients.

**What pre-infusion testing is required?** Hepatitis B screening (HBsAg and anti-HBc) before the first dose, plus baseline IgG and a current health assessment to rule out active infection.

**Is Ocrevus effective in primary-progressive MS?** Yes. Ocrevus is the only FDA-approved disease-modifying therapy for primary-progressive MS, based on the ORATORIO trial.

**What is the cancer-risk signal?** Long-term anti-CD20 therapy carries a modest signal for breast cancer and other malignancies. Your neurologist will coordinate age-appropriate screening.

**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 Ocrevus 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 Ocrevus 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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