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

How patients in India obtain Wegovy (semaglutide injection 2.4 mg) for chronic weight management, pediatric obesity in patients 12 and older, and cardiovascular risk reduction, through the CDSCO Rule 36 personal-import permit, with DSCSA chain-of-custody as the authenticity backbone against counterfeit semaglutide.

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

### Quick orientation

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Wegovy is the Novo Nordisk brand of semaglutide injection 2.4 mg once weekly, the FDA-approved obesity formulation of the same molecule that appears in Ozempic. The Wegovy label covers chronic weight management in adults with obesity or with overweight plus at least one weight-related comorbidity, pediatric chronic weight management in patients aged 12 years and older with BMI at or above the 95th percentile for age and sex, and cardiovascular risk reduction in adults with established cardiovascular disease and obesity or overweight. Wegovy received CDSCO import-and-market approval in April 2022 and Novo Nordisk's Indian launch followed in 2025. The Indian market has been one of the most active gray-market semaglutide markets globally, and counterfeit risk on unauthorised channels is severe. Reserve Meds proposition is the documented DSCSA chain-of-custody from an authorised US distributor through to the dispensing pharmacy in India, under the CDSCO Rule 36 personal-import permit on Form 12A and Form 12B.

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### Why patients in India reach for Wegovy through NPP

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India faces three patterns of access gap for US originator specialty medicines: registered but not stocked, registered for a different indication, and not registered locally at all. Wegovy sits in the first pattern. CDSCO granted import-and-market approval in April 2022, Novo Nordisk's commercial launch unfolded through 2025, and a CDSCO subject-expert committee recommended conditional approval for an additional MASH-with-fibrosis indication in April 2026. Even with registration in place, on-shelf availability has lagged demand. The Indian premium-tier cash-pay market for obesity therapy has outpaced legitimate supply, and the molecule has been one of the most counterfeited and gray-market-circulated products in the country.

The counterfeit risk is the central reason a careful patient in India looks for a documented cross-border channel. WHO and several national regulators have issued repeated warnings since 2023 about counterfeit semaglutide pens circulating in unauthorised channels in MENA, Latin America, and parts of Asia, and India has been a notable hotspot for non-authorised semaglutide of uncertain provenance. Reserve Meds is not part of any gray-market channel. We source Wegovy exclusively from US authorised distributors operating under the FDA's Drug Supply Chain Security Act (DSCSA), with continuous chain-of-custody documentation, lot and serial

traceability, and validated 2 to 8 degrees Celsius cold-chain handling end to end. Authenticity is the proposition.

## **The CDSCO named-patient pathway for Wegovy**

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The legal foundation for personal import of medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of small quantities of a drug 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 National Medical Commission 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 Wegovy the clinical-justification angle is BMI-anchored and indication-specific. The Reserve Meds documentation kit asks the prescribing physician to name which of the three FDA-approved indications applies (adult obesity with BMI 30 or higher; adult overweight with BMI 27 or higher plus at least one weight-related comorbidity; pediatric obesity at age 12 and above with BMI at or above the 95th percentile; or cardiovascular risk reduction in adults with established CVD plus obesity or overweight), to document the diagnosis with current BMI, and to outline the 16-week titration plan from 0.25 mg to 2.4 mg maintenance. The application typically includes:

- A clinical justification letter naming the on-label indication, current BMI, weight history, and the comorbidity profile (hypertension, type 2 diabetes, dyslipidemia, MASLD, sleep apnea, established cardiovascular disease where applicable)
- The treating physician's NMC registration number and a copy of state council registration where required
- A patient identifier and supporting medical records
- Product details: Wegovy, semaglutide injection, the specific titration pen presentation (0.25 mg, 0.5 mg, 1 mg, 1.7 mg, 2.4 mg), manufacturer Novo Nordisk, quantity (not to exceed one hundred average doses per application)
- The dispensing facility's drug licence
- A chain-of-custody plan from an authorised US distributor under DSCSA to the dispensing pharmacy in India

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. In practice patients plan for a two to four week window from physician decision to dispensed medicine, because the bulk of the elapsed time is upstream documentation assembly and downstream cold-chain logistics rather than the regulator stamp.

## **Where Wegovy gets dispensed in India**

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Wegovy is a refrigerated biologic-class injection in single-patient-use prefilled pens. The dispensing facility must hold a valid drug licence and must be able to receive and store the product at 2 to 8 degrees Celsius. Tertiary endocrinology, obesity-medicine, and bariatric services routinely handle this category. Institutions with established import-pharmacy and cold-chain infrastructure for refrigerated biologics include the All India Institute of Medical Sciences (AIIMS) in New Delhi, Apollo Hospitals (Chennai flagship, Delhi, Bangalore, Hyderabad, Kolkata)

with established bariatric and metabolic programmes, 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.

Patients managed by an endocrinologist, bariatric surgeon, or obesity-medicine specialist outside a tertiary hospital typically route the import through a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the Form 12A filing, the customs broker, and the chain-of-custody documentation from the US authorised distributor to the dispensing pharmacy. For pediatric Wegovy cases (patients aged 12 and older), the pediatric services at AIIMS, Apollo, Kokilaben, and CMC Vellore are natural homes for the clinical letter and the BMI documentation.

## **Real cost picture for Wegovy in India**

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US wholesale acquisition cost for Wegovy is publicly listed by Novo Nordisk at approximately USD 1,349 per 28-day supply, or roughly USD 16,000 to USD 17,600 per year at list. Cash-pay self-pay through NovoCare Pharmacy in the United States is currently offered at USD 349 per month, well below WAC; this US-only programme does not extend to international patients. International payer landscapes vary sharply. UAE, KSA, and India retail cash-pay pricing tracks closer to US WAC than to EU payer prices.

The Indian rupee floats against the US dollar. In May 2026 the USD/INR rate sits in the 94 to 95 range. Monthly drug acquisition at US WAC translates to roughly INR 127,000 per 28-day supply at the prevailing rate. International logistics for a refrigerated GLP-1 pen typically runs at USD 500 to USD 1,000 per shipment (approximately INR 47,000 to INR 95,000), inclusive of validated cold-chain packaging, temperature loggers, and the customs handover. India's Union Budget 2026-27 customs duty exemptions focus on cancer and rare-disease medicines; the specific HSN code and duty status for any Wegovy shipment is confirmed at the documentation stage. GST on most life-saving medicines is 5%; other medicines fall in the 12% band, and the applicable rate is confirmed in the firm quote.

On the insurance side, Star Health and Allied Insurance, HDFC ERGO, ICICI Lombard, and Niva Bupa handle named-patient imports case by case; none reimburse a Rule 36 personal import as a standard line item. Indian private insurance coverage for chronic obesity therapy remains limited as a general matter. Cash-pay is the default posture.

## **Typical timeline for Wegovy in India**

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For a patient with documented obesity or overweight-plus-comorbidity, current BMI, and a current Wegovy prescription, the typical end-to-end cycle is 2 to 4 weeks. CDSCO published guidance puts the Form 12B priority window at 1 to 2 days for complete routine documentation. US-side sourcing through an authorised distributor adds roughly 1 to 2 weeks, with allocation to specific titration strengths (especially 0.25 mg and 0.5 mg starter pens) sometimes tightening. International cold-chain transit and Indian customs clearance at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad airport are typically 3 to 5 days inside the unopened-pen stability envelope, with the pen tolerating up to 28 days of room-temperature storage after first removal from refrigeration. The 28-day room-temperature window provides usable slack on cross-border transit but is consumed by any customs delay. Timelines are presented as typical ranges and not as promises; specific dates are confirmed at firm-quote issuance.

## What your physician needs to provide

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The clinical justification letter for Wegovy is BMI-anchored and indication-specific. For Reserve Meds intake the letter typically includes:

- Confirmation of which on-label indication applies: adult chronic weight management at BMI 30 or higher; adult overweight at BMI 27 or higher with at least one weight-related comorbidity such as hypertension, type 2 diabetes, or dyslipidemia; pediatric chronic weight management at age 12 or older with BMI at or above the 95th percentile for age and sex; or cardiovascular risk reduction in adults with established cardiovascular disease and obesity or overweight
- Current measured BMI, weight history, and the comorbidity profile
- The diet and physical-activity component of the regimen, since Wegovy is an adjunct to reduced-calorie diet and increased physical activity, not a stand-alone
- The titration plan: 0.25 mg weekly for weeks 1 to 4, 0.5 mg weekly for weeks 5 to 8, 1 mg weekly for weeks 9 to 12, 1.7 mg weekly for weeks 13 to 16, and 2.4 mg weekly from week 17 onward as maintenance
- The screening for the boxed warning: confirmation that the patient does not have a personal or family history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia syndrome type 2, and counselling on symptoms (neck mass, dysphagia, dyspnea, persistent hoarseness)
- The monitoring plan: pancreatitis vigilance (severe persistent abdominal pain), acute gallbladder disease, acute kidney injury particularly with significant GI adverse events, hypoglycemia when used with insulin or sulfonylureas, diabetic retinopathy progression in patients with type 2 diabetes, suicidal behavior and ideation as a class-labeled concern
- 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. Endocrinology, bariatric, and obesity-medicine specialists at AIIMS, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, and Manipal routinely sign these letters as part of established institutional workflow.

## Common questions about Wegovy in India

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**How do I know the Wegovy you ship is authentic, given the counterfeit problem?** Reserve Meds sources Wegovy exclusively from US authorised distributors operating under the FDA's Drug Supply Chain Security Act (DSCSA). Every shipment carries DSCSA-compliant chain-of-custody documentation, lot and serial traceability, manufacturer-sealed cartons, and continuous cold-chain temperature monitoring with data loggers in every parcel. This DSCSA chain is the central authenticity proposition against the documented counterfeit-pen risk in Indian gray-market channels.

**Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover Wegovy?** Each plan handles named-patient imports case by case. None reimburse a Rule 36 personal import as a standard line item, and Indian private insurance coverage for chronic obesity therapy is limited generally. Where the case includes the cardiovascular risk reduction indication or weight-related

comorbidities, the insurer assessment may be more favourable. We supply the documentation set that lets your insurer evaluate. Cash-pay is the default posture.

**What about pediatric Wegovy?** Wegovy is approved for pediatric chronic weight management in patients aged 12 years and older with BMI at or above the 95th percentile standardized for age and sex. Reserve Meds will not coordinate intake for patients under 12. The pediatric Wegovy letter typically includes growth-chart documentation, the pediatric-specific BMI percentile, and the family-engagement component of the lifestyle programme.

**What if I have type 2 diabetes? Should I be on Wegovy or Ozempic?** Ozempic is the on-label semaglutide for type 2 diabetes glycemic control, cardiovascular risk reduction in T2D with established CVD, and reduction of kidney disease progression in T2D with CKD. Wegovy is the on-label semaglutide for obesity and CV risk reduction with obesity or overweight. The two products share an active ingredient but are labeled and titrated differently. The clinical question of which is appropriate is for the treating physician.

**Should I be on Wegovy or Zepbound?** Zepbound (tirzepatide, Eli Lilly) is the obesity-indicated brand of tirzepatide. SURMOUNT-5 head-to-head data suggests tirzepatide produces greater mean weight loss than semaglutide at maximum doses. Only Wegovy currently carries an FDA-approved indication for cardiovascular risk reduction with obesity or overweight. Choice is clinician-driven. Reserve Meds scope for Zepbound is separate.

**What is the safety profile?** Most common adverse events are gastrointestinal (nausea, diarrhea, vomiting, constipation, abdominal pain). Serious events listed in the prescribing information include acute pancreatitis, gallbladder disease and cholelithiasis, acute kidney injury, hypoglycemia with insulin or sulfonylureas, diabetic retinopathy complications, increased resting heart rate, hypersensitivity reactions, and suicidal behavior and ideation as a class-labeled concern. The FDA prescribing information carries a boxed warning for thyroid C-cell tumors based on rodent studies; human relevance is undetermined.

## **Where Reserve Meds fits in Wegovy cases**

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Reserve Meds is a US-based concierge coordinator. We do not replace your endocrinologist, obesity-medicine specialist, or bariatric surgeon, do not replace CDSCO, and do not replace the dispensing pharmacy or the licensed importer. For Wegovy specifically we orchestrate the US-side sourcing through an authorised distributor under DSCSA, the regulatory documentation kit your physician needs for Form 12A (indication-specific letter template with BMI anchors, 16-week titration reference, boxed-warning screening checklist, monitoring plan summary, PvPI reporting reference), international cold-chain logistics with temperature loggers and validated 2 to 8 degrees Celsius packaging, and a single named coordinator who carries the case from intake through delivery and into the recurring-fill cadence. DSCSA chain-of-custody is the authenticity proposition that distinguishes this channel from the documented counterfeit-semaglutide risk in Indian gray-market channels.

## **Next step**

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If your physician has decided Wegovy is the right next step for chronic weight management or for cardiovascular risk reduction with obesity, and local stocking is the bottleneck, 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.

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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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