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

How patients in India obtain US-sourced original-brand Entresto (sacubitril/valsartan) for chronic heart failure through the CDSCO Rule 36 personal-import permit, when Vymada, Azmarda, Cidmus, and other locally marketed brands are not the patient's preference.

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Quick orientation

Entresto is the Novartis fixed-dose combination of sacubitril and valsartan, the first member of the angiotensin receptor neprilysin inhibitor (ARNI) class. The FDA approved Entresto in July 2015 for adult HFrEF, expanded the pediatric label to patients aged 1 year and older in October 2019, and broadened the adult chronic heart failure indication in February 2021. India is a complex picture: Novartis markets sacubitril/valsartan in India under the brand Vymada, JB Pharma markets the Novartis-licensed brand Azmarda following a 2022 rights transfer, and Dr. Reddy's markets Cidmus, with branded generics from Cipla, Sun Pharma, and others also available. For patients who specifically request US-sourced original-brand Novartis Entresto, the CDSCO Rule 36 named-patient pathway is the route. This is the unusual case where local options exist and the named-patient case rests on patient preference for the originator brand, continuity of therapy for patients titrated in the US, or documentation continuity for cross-border families.

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Why patients in India reach for US-sourced Entresto 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. The Entresto picture sits in a different category from rare-disease orphan therapies: the molecule is widely available in India under multiple branded and branded-generic labels, and locally branded sacubitril/valsartan is dramatically less expensive than US-imported original-brand Entresto. The named-patient case for US-sourced Entresto is therefore narrow but real, and it rests on three patterns.

First, patient preference for the originator. A subset of Indian cardiology patients, particularly those who initiated therapy in a US specialty cardiology centre or who have been stabilised on US-titrated Entresto, prefer to continue on Novartis-manufactured Entresto for reasons of perceived quality consistency, prior treatment continuity, or alignment with trial-protocol experience. The Indian-licensed Vymada is also Novartis-manufactured product but reaches the patient through a different regional supply chain.

Second, continuity-of-therapy for cross-border families. The patient who maintains primary residence in India with extended US family ties, the post-hospitalisation patient stabilised on US-titrated Entresto returning home, or the cardiology-second-opinion patient who initiates therapy in a US centre and wants ongoing supply continuity in India through one documented channel.

Third, dose-strength stocking gaps. Entresto registration in India does not mean every pharmacy carries every strength, particularly the 97/103 mg target dose for fully titrated patients. Where the local Vymada or Azmarda supply at the 97/103 mg strength is intermittent, US-sourced original-brand Entresto can bridge that continuity gap.

Reserve Meds does not source Entresto to bypass an Indian regulatory restriction. We source US-origin Novartis-manufactured product under the patient's Rule 36 personal-import permit when the patient or treating cardiologist requests it. For patients comfortable with the local Vymada, Azmarda, Cidmus, or other branded options, those are excellent and substantially less expensive alternatives, and we will say so plainly at intake.

The CDSCO named-patient pathway for Entresto

The legal foundation for personal import of unregistered medicines into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Entresto is a special case because sacubitril/valsartan is registered in India under multiple brand names (Vymada, Azmarda, Cidmus, and others), but patients requesting US-manufactured original-brand Entresto specifically can route through the same Rule 36 framework. 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 Entresto specifically the clinical-justification angle is brand-continuity rather than novel-mechanism. A complete CDSCO application typically includes:

- A clinical justification letter naming the diagnosis (chronic HFrEF, broader chronic heart failure indication per the 2021 expanded label, or pediatric heart failure due to systemic left ventricular dysfunction), the patient's current titration to the target 97/103 mg twice-daily dose, the prior US prescription history where applicable, and the documented preference for US-sourced original-brand product
- The treating physician's NMC registration number and a copy of state council registration where required
- A patient identifier and supporting medical records, including the heart failure baseline (LVEF, NYHA class, NT-proBNP where measured) and any titration record from the US prescriber
- Product details: Entresto (sacubitril/valsartan), 24/26 mg, 49/51 mg, or 97/103 mg film-coated tablet, manufacturer Novartis Pharmaceuticals Corporation, pack size, quantity (not to exceed one hundred average doses per application, which for a twice-daily 97/103 mg patient is roughly a 50-day supply per filing)
- The dispensing facility's drug licence (hospital pharmacy or specialty importer's wholesale licence)
- A chain-of-custody plan from the US authorised distributor to the dispensing pharmacy in India, with DSCSA T3 documentation (transaction history, transaction information, transaction statement)

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. For Entresto the documentation case is built on patient preference and continuity rather than on local non-availability, and reviewers occasionally request the patient's signed acknowledgment that locally registered alternatives are available before issuing the permit.

Where Entresto gets dispensed in India

Entresto is a room-temperature oral tablet. There is no infusion-centre requirement, no cold-chain, and the dispensing footprint is broader than for biologics. Tertiary cardiology departments with established import-pharmacy infrastructure handle US-sourced Entresto as occasional rather than routine workflow, because most India patients use the locally available Vymada, Azmarda, or Cidmus. Institutions that file named-patient imports as established practice 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 heart failure cases the natural homes are the advanced heart failure and transplantation programmes at MGM Healthcare Chennai, Medanta Gurgaon, Apollo Chennai, AIIMS Delhi, and Kokilaben Mumbai. 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 documentation. Because Entresto is ambient-stable, the importer's cold-chain credentials are less relevant than its CDSCO and customs-broker relationships.

Real cost picture for Entresto in India

US wholesale acquisition cost for Entresto is approximately USD 12.50 per day at published payer references, equating to roughly USD 4,500 per year at WAC for daily dosing across the three strengths. Cash-pay retail pricing in the United States ranges from approximately USD 600 to USD 700 per 30-day supply, equating to USD 7,200 to USD 8,400 per year at retail without discount. The order-of-magnitude reference for US-sourced NPP Entresto is therefore approximately USD 4,500 to USD 8,400 per year at US list, before specialty pharmacy markup, ambient logistics, customs handling, and the Reserve Meds coordination fee.

The locally available Indian brands (Vymada, Azmarda, Cidmus, Sacurise, and others) are dramatically less expensive than US-imported original-brand Entresto, often in the range of one-tenth to one-twentieth of the US-list cost. For patients who are clinically comfortable with the locally available branded product, that is the substantially cheaper option, and Reserve Meds will say so plainly at intake. The cost premium for US-sourced original-brand Entresto is real, and the named-patient case rests on the patient's documented preference rather than on a Reserve Meds recommendation.

The Indian rupee floats against the US dollar. In May 2026 the USD/INR rate sits in the 94 to 95 range. Annual US-sourced Entresto at WAC translates to roughly INR 4.2 lakh to INR 4.3 lakh at the prevailing rate, with international logistics adding another INR 38,000 to INR 70,000 per shipment. India's Union Budget 2026-27 expanded the list of life-saving drugs eligible for customs duty exemption; GST on most life-saving medicines is 5%. Star Health, HDFC ERGO, ICICI Lombard, and Niva Bupa each handle named-patient imports case by case; for Entresto,

where locally registered alternatives exist, private insurance reimbursement of US-sourced product is unusual. CGHS coverage flows through the Special DG (DGHS) Expert Committee, with stricter constraints on US-sourced product when DCGI-approved brands are available.

Typical timeline for Entresto in India

For an established Entresto candidate with a documented US titration history and a tertiary-centre 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, though brand-continuity cases may attract additional review. US-side sourcing through standard wholesale distribution (open distribution, no REMS, no specialty pharmacy gate for Entresto) adds 1 week. International ambient transit and Indian customs clearance at Delhi, Mumbai, Bangalore, Chennai, or Hyderabad airport adds 3 to 5 days. Entresto is room-temperature stable with a shelf life of 36 months, so timelines are not pinched by cold-chain logistics. 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 US-sourced Entresto is the centrepiece of the CDSCO package. For this product the letter typically includes:

- The patient's confirmed diagnosis: chronic heart failure with reduced ejection fraction (HFrEF), chronic heart failure across a broader range of ejection fractions per the 2021 expanded label, or pediatric heart failure due to systemic left ventricular dysfunction for patients aged 1 year and older
- Baseline cardiac documentation: LVEF, NYHA class, NT-proBNP where measured, prior hospitalisation history, and current guideline-directed medical therapy stack (beta-blocker, MRA, SGLT2 inhibitor)
- Prior ARNI or ACE-inhibitor/ARB history, including the documented 36-hour washout from any prior ACE inhibitor
- The dosing plan: starting dose 49/51 mg twice daily in patients previously tolerating moderate-to-high doses of an ACE inhibitor or ARB, or 24/26 mg twice daily reduced start (low-dose ACE/ARB, eGFR less than 30 mL/min/1.73 m squared, moderate hepatic impairment); titration doubled every 2-4 weeks to target 97/103 mg twice daily; for pediatric patients aged 1 year and older, weight-based dosing per the package insert
- The patient's documented preference for US-sourced original-brand Novartis Entresto, with acknowledgment that locally registered alternatives (Vymada, Azmarda, Cidmus) are available
- The monitoring plan: baseline and periodic blood pressure, serum creatinine and eGFR, and serum potassium; more frequent monitoring during titration, in chronic kidney disease, on potassium-sparing diuretics or potassium supplements, and in elderly patients; immediate discontinuation for signs of angioedema
- 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.

Common questions about Entresto in India

Vymada, Azmarda, Cidmus are available locally. Why import? Most patients should use the locally registered brand. The named-patient case for US-sourced Entresto rests on patient preference for the originator, continuity of therapy for patients titrated in the US, or documentation continuity for cross-border families. Reserve Meds will say plainly at intake that locally registered alternatives are substantially less expensive.

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover US-sourced Entresto? Each plan handles named-patient imports case by case. None reimburse a Rule 36 personal import as a standard line item, and for Entresto specifically the existence of locally registered alternatives makes private insurance reimbursement of the US-sourced version unusual. Cash-pay is the default posture.

Will CGHS or ESIC cover this? 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. Where locally registered DCGI-approved brands are available (Vymada, Azmarda, Cidmus), the Expert Committee threshold for approving US-sourced original-brand is materially higher.

Can a pediatric patient receive Entresto? Yes. The FDA pediatric indication covers heart failure due to systemic left ventricular dysfunction in patients aged 1 year and older, dosed weight-based per the package insert. AIIMS, Apollo, Kokilaben, and CMC Vellore handle pediatric named-patient imports routinely.

What is the safety profile? The most frequent adverse events in clinical trials were hypotension, hyperkalemia, cough, dizziness, and renal impairment. Angioedema occurred at a low rate (0.1 to 0.5 percent), with higher incidence in Black patients. Pregnancy is contraindicated. A 36-hour washout is required when switching from or to an ACE inhibitor.

Why Entresto versus enalapril? PARADIGM-HF (NEJM 2014) demonstrated that sacubitril/valsartan reduced the composite of cardiovascular death or heart failure hospitalization by 20 percent versus enalapril in HFrEF patients, and reduced all-cause mortality by 16 percent. The trial was stopped early for efficacy. Major guidelines (ACC/AHA/HFSA in the US, ESC in Europe) now position ARNI as a Class I recommendation for symptomatic HFrEF.

Where Reserve Meds fits in Entresto cases

Reserve Meds is a US-based concierge coordinator. We do not replace your cardiologist, do not replace CDSCO, and do not replace the dispensing pharmacy or the licensed importer. For Entresto specifically we orchestrate the US-side sourcing through authorised distributors with DSCSA T3 chain-of-custody documentation, the regulatory documentation kit your physician needs for Form 12A (US prescription history reference, titration record template, dosing reference by patient age and renal function, monitoring plan summary, PvPI reporting reference), international ambient-controlled logistics, and a single named coordinator who carries the family from intake through delivery and into the reporting period. Entresto is the unusual case where local alternatives are good and substantially less expensive, and our intake conversation will acknowledge that openly. We do not source Entresto to bypass an Indian regulatory restriction; we source it under Rule 36 when the patient or treating cardiologist requests the US-sourced original brand specifically.

Next step

If your cardiologist has decided US-sourced original-brand Entresto is the right next step for documented continuity reasons, 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 an honest comparison with the locally available branded options.

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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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