Vpriv access in India

How Indian families with Type 1 Gaucher disease pursue Vpriv (velaglucerase alfa), a recombinant enzyme replacement therapy for one of the more recognised lysosomal storage disorders in India.

Last reviewed 2026-05-12 by Reserve Meds clinical & regulatory team. This page combines the India country regulatory module with the Vpriv drug module to describe the path families actually walk.

Quick orientation

Vpriv (velaglucerase alfa) is a recombinant human glucocerebrosidase enzyme replacement therapy approved by the US Food and Drug Administration in February 2010 for long-term enzyme replacement therapy in pediatric and adult patients with Type 1 Gaucher disease. The product is marketed approximately by Takeda following its acquisition of Shire. Velaglucerase alfa is delivered as a 60-minute intravenous infusion every other week at a weight-based dose, typically 60 units per kilogram, though clinical practice individualises the dose. Type 1 Gaucher disease is the most common lysosomal storage disorder in India and globally, with hematologic, hepatosplenic, and skeletal manifestations and an Ashkenazi Jewish founder effect that does not apply prominently to India but where the Indian patient population is substantial through other GBA variants. Reserved for you.

Why this drug is hard to source in India

Gaucher disease in India is well recognised among metabolic genetics specialists at AIIMS, the Centre for DNA Fingerprinting and Diagnostics in Hyderabad, Tata Memorial Centre, and academic pediatric and hematology programs across major cities. The Indian National Policy for Rare Diseases designates Type 1 Gaucher among the named treatable lysosomal storage disorders eligible for Centre of Excellence care. The first-line enzyme replacement therapy registered in India for Gaucher disease has been imiglucerase (Cerezyme, Sanofi Genzyme), delivered through specialty importers and institutional channels for many years. Vpriv has been used in select Indian patients on a case-by-case import basis. As of this review date, Vpriv does not have routine CDSCO registration in India equivalent to imiglucerase. For patients on imiglucerase whose treating physician judges that transition to velaglucerase alfa is clinically appropriate, or for newly diagnosed patients where velaglucerase is the preferred option, the import pathway is the route.

The CDSCO personal-import pathway under Rule 36

The legal foundation for personal import of an unregistered medicine into India is Rule 36 of the Drugs and Cosmetics Rules 1945. Rule 36 permits import of a small quantity 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; Form 12B is the permit. For Vpriv, the clinical justification letter documents the Type 1 Gaucher diagnosis with enzymatic activity confirmation (deficient beta-glucocerebrosidase activity in peripheral blood leukocytes) and genetic confirmation (pathogenic variants in the GBA gene), the patient's clinical phenotype, the weight-based dose calculation typically at 60 units per kilogram every other week, the institutional infusion capability, and the planned monitoring schedule.

Real costs in INR and USD

The US wholesale acquisition cost for Vpriv is approximately USD 240,000 to 320,000 per year for a typical adult patient on every-other-week dosing, with substantial variation by body weight. In INR at the prevailing 94 to 95 range, that translates to approximately INR 2.3 crore to 3 crore per year. An Indian-made generic or biosimilar of velaglucerase alfa does not exist as of this review date. The National Policy for Rare Diseases 2021 designates Gaucher disease among the named lysosomal storage disorders eligible for support through the designated Centre of Excellence network and the Rashtriya Arogya Nidhi umbrella scheme with the INR 50 lakh per patient ceiling. The annual Vpriv course exceeds the NPRD ceiling and families typically combine NPRD coverage where granted with private resources, foundation grants, or in some cases foreign-funded support routed through compliant channels.

Timing, what to expect

From physician decision to first infusion, a Vpriv case runs three to five weeks. Documentation assembly takes one to two weeks, including the enzymatic activity report, the GBA genetic confirmation, the disease severity assessment, and the institutional infusion capability statement. The Form 12B permit issues in one to two business days. US-side sourcing and cold-chain shipment runs one to two weeks. For ongoing every-other-week infusions, Reserve Meds aligns supply cycles to a monthly reorder rhythm with cold-chain handling on each shipment.

What your physician needs

The clinical justification letter documents the Type 1 Gaucher disease diagnosis with enzymatic and genetic confirmation, the disease severity assessment (hematologic,

hepatosplenic, skeletal manifestations), the prior therapy course including any imiglucerase exposure and the rationale for transition or velaglucerase as first-line, the weight-based dose at typically 60 units per kilogram, the infusion capability statement, the pre-medication protocol, and the planned monitoring schedule including chitotriosidase or glucosylsphingosine biomarkers, hematology parameters, organ volume assessment, and bone densitometry. The treating metabolic genetics specialist's NMC registration number appears on the prescription.

Customs clearance and IOR

Customs at the port of entry reviews the Form 12B permit, the commercial documentation, the airway bill, the cold-chain monitoring record, and the importer's drug licence. Vpriv is stored refrigerated at 2 to 8 degrees Celsius and is light-sensitive. The Importer of Record is the licensed dispensing facility or specialty importer.

Pharmacovigilance

India operates the Pharmacovigilance Programme of India (PvPI) coordinated by the Indian Pharmacopoeia Commission. For velaglucerase alfa, the principal post-marketing concerns are infusion-related reactions and anti-drug antibody formation. The PvPI reference is included in the Reserve Meds physician documentation kit and adverse event reporting is the prescribing physician's responsibility.

Where Reserve Meds fits

Reserve Meds is a US-based concierge coordinator. For a Vpriv case, our work is US-side sourcing, documentation orchestration including coordination with NPRD Centre of Excellence pathways where applicable, cold-chain logistics, and a single named coordinator across the initial cycle and the ongoing every-other-week infusion schedule.

Next step

If a treating metabolic genetics specialist in India is weighing Vpriv for a patient with Type 1 Gaucher disease, the waitlist is the first step. We respond within 24 to 48 hours with an eligibility confirmation and a documentation kit for the physician.

Reserved for you.

Related

- Vpriv clinical resource
- India country page
- CDSCO personal-import pathway

Sources

1. FDA approval, Vpriv (velaglucerase alfa), Takeda (formerly Shire), BLA approval February 2010 for long-term enzyme replacement therapy in Type 1 Gaucher disease.
2. CDSCO, Procedure for Permission to Import Small Quantities of Drugs for Personal Use (Form 12A / Form 12B under Rule 36, Drugs and Cosmetics Rules 1945).
3. National Policy for Rare Diseases 2021, lysosomal storage disorder Centre of Excellence framework and Rashtriya Arogya Nidhi support.

Common questions Indian families ask

Will Star Health, HDFC ERGO, ICICI Lombard, or Niva Bupa cover this? Each Indian private insurer assesses named-patient imports case by case. None of the major private insurers reimburse a Rule 36 personal import as a standard line item. Some have reimbursed full or partial drug cost where the underlying medicine is on the formulary and the named-patient route operated as a stocking workaround. Reserve Meds supplies the documentation that lets your insurer evaluate. The claim itself is filed by the patient or the hospital. Cash-pay remains the default posture for Reserve Meds patient cases.

Will my CGHS or ESIC entitlement cover this? CGHS (Central Government Health Scheme) provides for life-saving and anti-cancer medicines not in the standard formulary to be considered case by case by an Expert Committee under the Special DG (DGHS) where the prescribing specialist documents the requirement. Drugs not approved by the DCGI for use in India face a stricter Expert Committee review. ESIC's formulary is narrower. Neither scheme is structured for routine personal-import reimbursement; check eligibility with your CGHS Wellness Centre or the ESIC dispensary before assuming coverage.

Will my AIIMS, Tata Memorial, Apollo, Fortis, Medanta, Kokilaben, MGM, CMC Vellore, or Manipal physician's letter be sufficient? Yes. A Registered Medical Practitioner with a valid National Medical Commission registration number can support a Form 12A application. Physicians at AIIMS, Tata Memorial Centre, government medical colleges, and state-run tertiary hospitals routinely do so. Private-sector specialists at Apollo, Fortis, Medanta, Kokilaben Dhirubhai Ambani Hospital, MGM Healthcare, CMC Vellore, and Manipal Hospitals also have signing authority subject to their institutional drug licence.

What if my treating institution does not have an import pharmacy desk? The practical route is to work with one of the named tertiary centres that handles compassionate and named-patient imports as established workflow, or with a CDSCO-licensed specialty importer in Mumbai, Delhi, or Bangalore that handles the documentation and chain-of-custody on behalf of smaller hospitals or independent specialists. Reserve Meds aligns with the importer named on the Form 12B permit.

Can I receive the drug at home, or do I need a hospital? The dispensing facility must hold a valid drug licence under the Drugs and Cosmetics Rules. For oral medicines, a hospital outpatient pharmacy or a licensed import pharmacy is the dispensing point. For infusion products, the medicine ships to the infusion centre where the patient will receive it. Direct-to-home delivery outside a licensed dispensing facility is not the model.

What about pediatric patients? The Rule 36 framework applies the same way for pediatric patients. The clinical justification letter typically includes weight-adjusted dosing and pediatric-specific monitoring. AIIMS, Tata Memorial, Apollo, Kokilaben, and CMC Vellore handle pediatric named-patient imports routinely. Where the indication is approved in adults only, the off-label use is the physician's clinical judgement and is documented as such in the Form 12A letter.

Does FCRA affect a patient case? The Foreign Contribution (Regulation) Act 2010 (FCRA), as proposed to be amended by the Foreign Contribution (Regulation) Amendment Bill 2026, regulates foreign donations to Indian organisations and individuals. For a patient family paying for the medicine themselves, FCRA is generally not engaged. Where a foreign foundation or diaspora group is funding a treatment, FCRA registration of the recipient organisation and the donation route can become relevant; the structure should be reviewed with counsel before funds move. Reserve Meds does not provide FCRA legal advice; we flag the question so it reaches the right adviser early.

What is the role of the Indian Pharmacopoeia Commission? The Indian Pharmacopoeia Commission coordinates the Pharmacovigilance Programme of India (PvPI) and publishes the Indian Pharmacopoeia, the legal compendium of pharmaceutical standards in India. For imported originator products under Rule 36, the PvPI reporting framework applies to adverse event surveillance, and the prescribing physician is the reporting party. The Indian Pharmacopoeia is the reference standard against which Indian-manufactured products are tested; imported originator products carry their reference-country pharmacopoeial standards (typically USP for FDA-approved products).

How does this compare with access in the UAE or Saudi Arabia? India's Rule 36 framework with the published Form 12B priority timeline (one to two business days for routine documentation) is often faster than the SFDA Personal Importation Program in Saudi Arabia (typically 10 to 21 business days routine) and broadly comparable to the UAE Emirates Drug Establishment pathway. India's offsetting friction is the customs and logistics layer rather

than the regulator's stamp. India's tertiary specialty hospital depth substantially exceeds any single peer country in the South Asia and GCC region, which usually offsets the longer end-to-end cycle for complex cases.

What documentation does my family need to assemble before contacting Reserve Meds? The minimum useful package is the treating physician's name and registration number, the patient's diagnosis and current treatment summary, recent relevant investigations (imaging, biopsy, molecular pathology, blood work as applicable), and a contact pathway to the dispensing facility you intend to use. With that package, Reserve Meds can complete eligibility within 24 to 48 hours and route the documentation kit to your physician.

How Indian families coordinate across cities and countries

For Indian families, the coordination problem is often distributed across multiple cities and sometimes multiple countries. A grandmother in Hyderabad, an oncologist at Tata Memorial in Mumbai, an adult child in Bangalore managing logistics, and a son in Dubai or London paying the invoice is a common configuration. The Reserve Meds single named coordinator model is built for exactly this pattern. One coordinator carries the case file, one chain of correspondence captures the decisions and documents, and one set of contact records reaches every family member who needs visibility into the case, regardless of how many cities the family touches or how many time zones the case spans. The Reserve Meds patient portal at portal.reservemeds.com holds the document set and the case timeline; the coordinator handles the email, phone, and WhatsApp follow-through that the case needs at each step.

For smaller cities where the local hospital does not maintain an import pharmacy desk, the practical route is to work with a CDSCO-licensed specialty importer in Mumbai, Delhi, Bangalore, Chennai, or Hyderabad. The importer carries the CDSCO relationship, the customs broker relationship, and the chain-of-custody documentation. Reserve Meds aligns with the importer on US-side sourcing and with the treating physician on clinical documentation. The patient sees one face throughout, which is the named coordinator.

The patient experience, step by step

From the family side, the sequence looks like this. Your physician decides this drug is the right next step. That is a clinical decision and stays with them. Your physician or the hospital pharmacy team reaches out to Reserve Meds, or the patient submits a request through the Reserve Meds portal and Reserve Meds connects with the physician. Reserve Meds confirms eligibility within 24 to 48 hours and sends a documentation kit to your physician, including the Form 12A reference, the clinical justification letter template, and

the chain-of-custody plan. Your physician completes the documentation, attaches the prescription with their NMC registration number, and the application goes to CDSCO through the appropriate port office or the DCGI New Delhi office, or via the hospital's licensed importer. The Form 12B permit issues on the documented priority timeline. While the permit issues, Reserve Meds aligns US-side sourcing and the shipment plan with the dispensing pharmacy. The shipment moves cold-chain or ambient as appropriate. Customs at the destination port reviews the permit and clears the consignment. The dispensing pharmacy receives, logs, and stores the medicine according to its drug licence requirements. Your physician initiates therapy. Adverse event reporting through PvPI continues for the duration of therapy.

Review and oversight. Content on this page is reviewed by the Reserve Meds 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 ›
Last medically reviewed: 2026-05-12.