Crysvita

India · access guide

Crysvita access in India: the CDSCO named-patient pathway

Last reviewed 2026-05-16 by Reserve Meds clinical and regulatory team.

Quick orientation

Crysvita (burosumab-twza) is anti-FGF23 fully human IgG1 monoclonal antibody approved by the US FDA in April 2018 for XLH, June 2020 for TIO for X-linked hypophosphataemia (XLH) in adults and paediatric patients 6 months of age and older, and FGF23-related hypophosphataemia in tumour-induced osteomalacia associated with phosphaturic mesenchymal tumours that cannot be curatively resected or localised in adults and paediatric patients 2 years of age and older. The drug is manufactured by Ultragenyx (US) and Kyowa Kirin (international). India patients use the Central Drugs Standard Control Organization named-patient pathway when the locally registered indication, the stocked presentation, or the available payer coverage does not match what the prescribing physician has written. Reserve Meds coordinates the US-side sourcing through a DSCSA-compliant specialty channel, builds the documentation packet your physician needs to file, and orchestrates the logistics into India with a single named coordinator carrying the case end-to-end.

Why Indian patients need Crysvita through the named-patient pathway

India operates a developed pharmaceutical regulatory environment, and Crysvita may be on the local register, may be in commercial review, or may be entirely absent depending on the stage of Ultragenyx (US) and Kyowa Kirin (international)'s regional rollout. Several patterns drive cross-border requests. First, indication lag: newer indications, particularly the April 2018 for XLH, June 2020 for TIO FDA approval timeline, often reach local registration 12 to 36 months later. Second, biomarker-defined eligibility: no specific companion diagnostic; diagnostic confirmation rests on hypophosphataemia with renal phosphate wasting, elevated serum FGF23, and (for XLH) pathogenic PHEX gene variants can be the diagnostic gate, and where the relevant testing infrastructure is still maturing locally, families coordinate the workup before or in parallel with sourcing. Third, payer coverage: Star Health, HDFC ERGO, ICICI Lombard, Bajaj Allianz, Niva Bupa, Care Health, Aditya Birla, Tata AIG, and Manipal Cigna, alongside Ayushman Bharat for eligible beneficiaries each assess specialty therapies case by case, and step-therapy criteria can fail even where the drug is registered. Fourth, stocking gaps: the local agent may not carry every presentation or dose strength reliably, and named-patient import is the operational mechanism that bridges to the exact label the prescriber has written. In each pattern, the named-patient pathway is the legal mechanism that connects a Indian-licensed physician's clinical decision with US-sourced, FDA-labelled product for a specific identified patient.

The CDSCO named-patient pathway for Crysvita

India's personal-import pathway sits under Rule 36 of the New Drugs and Clinical Trials Rules 2019 read with the Drugs and Cosmetics Act 1940. The CDSCO accepts applications via the SUGAM portal at cdscoonline.gov.in for a specific patient where the medicine is approved by a recognised reference authority and a locally registered equivalent is unavailable or unsuitable. Form 12A (institutional Compassionate Use) is the parallel route through a tertiary hospital ethics committee. The framework permits hospitals and licensed pharmaceutical establishments to import a specific medicine for a specific patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and either a clinically equivalent locally registered alternative is not suitable, or the patient's clinical profile does not match the locally approved label.

A complete application for Crysvita typically includes a clinical justification letter from the treating physician documenting the patient's diagnosis (X-linked hypophosphataemia (XLH) and tumour-induced osteomalacia (TIO)), severity assessment, prior systemic therapy history, any relevant biomarker results (no specific companion diagnostic; diagnostic confirmation rests on hypophosphataemia with renal phosphate wasting, elevated serum FGF23, and (for XLH) pathogenic PHEX gene variants), and a clinical rationale for selecting Crysvita over locally available alternatives. The Indian physician's licensure with the Medical Council of India / National Medical Commission and the relevant State Medical Council is verified through the application. The packet also specifies the dispensing facility name and license number, the pharmacy in charge of the facility, full product details (brand name, generic name, manufacturer, strength, dosage form, pack size, quantity, intended treatment duration), and a chain-of-custody plan describing how the medicine will move from the US manufacturer through the importer to the dispensing pharmacy.

For Crysvita specifically, the clinical justification typically frames the case around XLH is the most common form of inherited rickets (1 in 20,000); paediatric endocrinology / metabolic-bone-disease referral is the typical entry, and PHEX sequencing through a clinical-grade panel anchors the diagnosis. Approval timelines are typically 10 to 25 business days for routine Rule 36 cases, with institutional Compassionate Use through the Drugs Controller General of India running on a separate ethics-committee timeline. The CDSCO retains discretion on timing, and we do not promise specific durations.

Where Crysvita gets dispensed in India

A focused group of India institutions handle named-patient specialty-medicine imports as established workflow, with in-house import pharmacy capabilities and physicians experienced with the application set. For Crysvita specifically, the dispensing facility must accommodate the administration profile: outpatient endocrinology, metabolic-bone-disease, or paediatric specialty; subcutaneous injection administered in the clinic or self-administered at home after training; quarterly fasting phosphate, calcium, and 1,25-D monitoring. Tertiary centres that meet this profile include Tata Memorial Centre in Mumbai, Apollo Hospitals (Chennai, Hyderabad, Delhi), Fortis Healthcare network, Max Healthcare network in Delhi NCR, Medanta The Medicity in Gurugram, AIIMS Delhi, CMC Vellore, Kokilaben Dhirubhai Ambani Hospital in Mumbai, Sir Ganga Ram Hospital in Delhi, Manipal Hospitals, and Narayana Health.

For physicians at smaller hospitals without internal import infrastructure, the common pattern is to route through a licensed pharmaceutical establishment that holds the import licence and files the CDSCO application on the prescribing physician's behalf. The medicine then moves under chain-of-custody documentation into the prescribing hospital's outpatient pharmacy for administration.

Real cost picture for Crysvita in India

US WAC for Crysvita is approximately USD 18,400 per 30 mg vial, which translates to an annual WAC in the range of USD 160,000 to USD 220,000 per year depending on weight band and dose for the standard regimen at the labelled dose. The Indian rupee floats; 1 USD is approximately 83 INR as of May 2026. On that basis, the drug cost alone is materially significant before logistics, the CDSCO permit fees (which are nominal relative to drug cost), the destination dispensing hospital's administration fees, and Reserve Meds' concierge fee (which is itemised separately on every firm quote).

International cold-chain or ambient logistics into India typically runs in the low to mid four-figure USD range depending on origin, urgency, and packaging requirements. On the insurance side, Star Health, HDFC ERGO, ICICI Lombard, Bajaj Allianz, Niva Bupa, Care Health, Aditya Birla, Tata AIG, and Manipal Cigna, alongside Ayushman Bharat for eligible beneficiaries each assess named-patient imports case by case. Some reimburse fully when the medicine is on their formulary even if not stocked, some reimburse a percentage subject to copay, and many require pre-authorisation with documented step-therapy failure. We do not promise coverage from any payer. US manufacturer patient assistance programmes do not extend internationally; cross-border patients pay cash or rely on local payer coverage where available.

Clinical evidence and where Crysvita sits in the treatment landscape

the paediatric phase 3 randomised trial (NCT02915705) and the adult phase 3 trial (NCT02526160) showed significant improvements in serum phosphorus, the Rickets Severity Score in children, and walking and stiffness measures in adults. The drug acts as anti-FGF23 fully human IgG1 monoclonal antibody, and the dosing schedule is weight-banded subcutaneous injection every 2 weeks in paediatric patients (starting at 0.8 mg/kg) and every 4 weeks in adults (1.0 mg/kg, capped at 90 mg), titrated to fasting serum phosphorus in the target range.

Within the treatment landscape, Crysvita sits alongside conventional therapy with oral phosphate replacement plus active vitamin D analogues (calcitriol or alfacalcidol); cinacalcet for tertiary hyperparathyroidism in long-treated patients; burosumab is the only targeted FGF23-pathway therapy. The choice between targeted therapies in this space depends on the patient's full clinical profile, prior therapy exposure, biomarker status, comorbidities, and the prescriber's judgment. Reserve Meds coordinates whichever therapy the physician has selected; we do not steer prescribing.

Safety surveillance for Crysvita centres on injection-site reactions, headache, vitamin D / ectopic mineralisation surveillance, hypersensitivity; calcium and 1,25-dihydroxyvitamin D monitoring is part of the routine cadence. The dispensing facility and the prescribing physician retain clinical responsibility for monitoring and adverse-event management; Reserve Meds does not provide medical care.

Typical timeline for Crysvita in India

CDSCO routine processing is typically 10 to 25 business days for routine Rule 36 cases, with institutional Compassionate Use through the Drugs Controller General of India running on a separate ethics-committee timeline from a complete filing. End-to-end, most cases complete within 4 to 8 weeks from first complete documentation, with first-of-kind cases and complex biomarker-dependent workups potentially extending further. Where the administration setting is outpatient endocrinology, metabolic-bone-disease, or paediatric specialty, hospital scheduling and infusion-chair availability are additional sequencing factors that families plan around. We do not promise specific durations; the CDSCO retains discretion on timing, and shipping windows depend on lane and packaging.

What your Indian physician needs to provide

For a Indian-licensed specialist prescribing Crysvita through the CDSCO pathway, the clinical justification letter is the cornerstone of the application. The letter typically documents the patient's diagnosis (X-linked hypophosphataemia (XLH) and tumour-induced osteomalacia (TIO)), the relevant biomarker work (no specific companion diagnostic; diagnostic confirmation rests on hypophosphataemia with renal phosphate wasting, elevated serum FGF23, and (for XLH) pathogenic PHEX gene variants), prior systemic therapy history, the FDA-approved indication being invoked, and the clinical rationale for Crysvita as the appropriate next step.

The letter also specifies the exact dosing plan per the FDA-approved label: weight-banded subcutaneous injection every 2 weeks in paediatric patients (starting at 0.8 mg/kg) and every 4 weeks in adults (1.0 mg/kg, capped at 90 mg), titrated to fasting serum phosphorus in the target range. The monitoring plan references injection-site reactions, headache, vitamin D / ectopic mineralisation surveillance, hypersensitivity; calcium and 1,25-dihydroxyvitamin D monitoring is part of the routine cadence. The treating physician's licence number with the Medical Council of India / National Medical Commission and the relevant State Medical Council, the dispensing facility license number, and the pharmacy in charge of dispensing complete the package. Where biomarker testing requires reference-lab coordination, the physician documents the assay used and the report; Reserve Meds can route this through a US-side reference laboratory where the regional pathway is unavailable.

Common questions about Crysvita in India

Will Star Health or other major Indian insurers cover Crysvita? Each insurer assesses named-patient imports case by case. Some reimburse fully when Crysvita is on their formulary even if not currently stocked; others assess based on step-therapy criteria and biomarker documentation. We supply the documentation set that allows your insurer to assess the case; the claim itself sits with you, your physician, or your hospital. We do not promise coverage from any payer.

Is Crysvita registered locally in India? Local registration status changes as Ultragenyx (US) and Kyowa Kirin (international) pursues regional rollout; even where the drug is registered, the specific indication, presentation, or dosing strength your prescriber has written may not align with what is currently stocked. The CDSCO named-patient pathway exists precisely to bridge these gaps for individually identified patients.

What about competitor therapies? The treatment landscape includes conventional therapy with oral phosphate replacement plus active vitamin D analogues (calcitriol or alfacalcidol); cinacalcet for tertiary hyperparathyroidism in long-treated patients; burosumab is the only targeted FGF23-pathway therapy. The choice depends on the patient's full clinical profile and prescriber judgment. Reserve Meds coordinates whichever medicine the physician has prescribed; we do not steer prescribing decisions and we do not have a financial relationship with any specific manufacturer.

How is the cold chain or storage managed? Crysvita ships in validated thermal packaging with continuous temperature logging through the lane. The cold-chain handoff or temperature-controlled handoff ends at the dispensing pharmacy; home storage instructions, where the patient takes the medicine home for self-administration, are part of the patient onboarding kit.

Do US manufacturer patient assistance programmes (such as Ultragenyx (US) and Kyowa Kirin (international) co-pay or PAP programmes) extend to India patients? No. US-resident patient assistance programmes are limited to US-resident patients with US prescription coverage by programme design. Cross-border patients pay cash for the drug and the coordination fee, with local payer reimbursement assessed separately.

Can the case be resupplied year over year if the patient responds? Yes. Reserve Meds maintains the case file and re-files CDSCO permits at the relevant intervals (or coordinates with the dispensing hospital's pharmacy if they hold the permit). Patients on long-term therapy typically settle into a quarterly or biannual resupply cadence after the first cycle.

What is the administration setting? Outpatient endocrinology, metabolic-bone-disease, or paediatric specialty; subcutaneous injection administered in the clinic or self-administered at home after training; quarterly fasting phosphate, calcium, and 1,25-d monitoring.

My physician is at a smaller hospital without an internal import pharmacy. Can the case still proceed? Yes. The common pattern is to route through a Dubai, Riyadh, Mumbai, Cairo, Karachi, or other regional licensed pharmaceutical establishment that holds the import licence and files the CDSCO application on the prescribing physician's behalf. The medicine moves into the prescribing hospital's outpatient pharmacy under chain-of-custody documentation.

Where Reserve Meds fits in Crysvita cases

Reserve Meds is a US-based concierge coordinator. We do not replace your Indian specialist, we do not replace the CDSCO, and we do not replace your dispensing pharmacy. For Crysvita specifically, we orchestrate the US-side sourcing through a DSCSA-compliant specialty channel, build the documentation packet your physician submits, coordinate logistics into India, and assign a single named coordinator through the case. The pharmacist-of-record review, prescription validation, biomarker confirmation, and physician sign-off are the recurring operational fundamentals for this drug.

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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reserved for you.

Composite case examples. This document is for general information only and does not constitute medical advice. Please consult your treating physician.
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