Crysvita

Saudi Arabia · access guide

How to access Crysvita for X-linked hypophosphatemia or tumor-induced osteomalacia from Saudi Arabia: 2026 pathway via Saudi Arabia paediatric endocrinology, adult metabolic bone, and oncology coordination

By Reserve Meds clinical & regulatory team. Last reviewed 2026-05-20.

Saudi Arabia has the deepest paediatric endocrinology, adult metabolic bone, nephrology, and oncology infrastructure in the Gulf region for the management of rare bone-mineral disease. King Faisal Specialist Hospital and Research Centre Riyadh runs paediatric endocrinology and adult endocrinology services with extensive experience in genetic phosphate-wasting disorders and the molecular diagnosis of XLH; King Abdulaziz Medical City (Ministry of National Guard Health Affairs) Riyadh and Jeddah runs paediatric endocrinology with the Saudi Society for Paediatric Endocrinology network; King Fahad Medical City Riyadh runs paediatric endocrinology and adult metabolic bone clinics; King Abdulaziz University Hospital Jeddah runs paediatric endocrinology with rare-disease depth; King Fahd Specialist Hospital Dammam and King Fahd Hospital of the University Khobar cover the Eastern Province for paediatric and adult endocrinology; the Saudi Food and Drug Authority governs imported-medicine registration. Crysvita (burosumab-twza, Ultragenyx Pharmaceutical with Kyowa Kirin as ex-US partner) is the anti-FGF23 humanized IgG1 monoclonal antibody, dosed subcutaneously every 2 to 4 weeks, that targets the genetic mechanism of X-linked hypophosphatemia (XLH) and the acquired mechanism of tumor-induced osteomalacia (TIO).

For a Saudi-resident child age 6 months and older with genetic or biochemical XLH, an adult with XLH continuing into adulthood, or an adult with TIO awaiting or following tumor resection, the operational question is no longer whether anti-FGF23 therapy is reachable in the Kingdom: it is whether the case meets the prescribing criteria at a Saudi paediatric or adult endocrinology service, how the discontinuation of conventional oral phosphate and active vitamin D is sequenced, and how the monthly phosphorus-monitoring rhythm fits into the family's life.

This page explains how the pathway works in 2026 for a Saudi-resident patient: who qualifies, where the prescribing paediatric endocrinologist or adult metabolic bone specialist conversation happens, how Crysvita is dispensed and stored, what the dose-titration rhythm looks like over the first year, what the cost band is in SAR, and how the chronic-treatment course fits into a Saudi family's routine. It is concierge documentation written for a family already in conversation with a treating paediatric endocrinologist, adult metabolic bone specialist, or oncology team.

Why Crysvita, and why now

Crysvita is burosumab-twza, a humanized IgG1 monoclonal antibody that binds and neutralises fibroblast growth factor 23 (FGF23). In XLH, an inactivating mutation in the PHEX gene on the X chromosome causes circulating FGF23 to be inappropriately elevated. Excess FGF23 reduces phosphate reabsorption at the renal proximal tubule and suppresses renal 1-alpha-hydroxylase, leading to chronic phosphate wasting, low serum phosphorus, low active 1,25-dihydroxyvitamin D, defective bone mineralisation, paediatric rickets, short stature, dental abscess vulnerability, and adult osteomalacia with bone pain, fractures, and enthesopathy. In TIO, a mesenchymal phosphaturic tumor secretes FGF23 ectopically and produces the same biochemical and skeletal picture in an adult who did not have it as a child.

The historic conventional therapy for XLH was lifelong high-dose oral phosphate salts in multiple daily doses combined with active vitamin D analogs (calcitriol or alfacalcidol), titrated to suppress secondary hyperparathyroidism without overshooting into hypercalciuria and nephrocalcinosis. Conventional therapy is partially effective, requires multiple daily doses, often produces gastrointestinal intolerance, and does not address the underlying FGF23 excess. Crysvita addresses the upstream mechanism. The clinical translation is improvement in serum phosphorus toward the lower-normal range within 4 to 8 weeks of starting, improvement in paediatric radiographic rickets scores over 1 to 2 years, improvement in height velocity in growing children, and reduction in adult bone pain and stiffness over months. The FDA approved Crysvita for paediatric XLH age 1 year and older in April 2018, for adult XLH in September 2018, expanded the paediatric XLH label to age 6 months and older in March 2020, and added the TIO indication for patients age 2 years and older in June 2020.

Reserve Meds does not advocate Crysvita over conventional therapy in cases where conventional response is adequate. The page describes the Crysvita pathway because Crysvita is the therapy the family has asked about.

What Crysvita is, in plain language

Crysvita is a subcutaneous injection given every 2 to 4 weeks. There is no infusion centre, no inpatient stay. After a supervised first dose at the prescribing endocrinology clinic, the family or patient may be trained for home self-injection in subsequent cycles, although many Saudi families opt for clinic-administered dosing for the first several cycles given the monthly phosphorus-monitoring rhythm. The injection vials are 10 mg, 20 mg, and 30 mg single-dose presentations; the dispensed dose is calculated by weight and titrated by serial phosphorus measurement. Paediatric XLH starting dose is 0.4 to 0.8 mg per kg every 2 weeks. Adult XLH dosing is 1 mg per kg every 4 weeks, capped at 90 mg. TIO dosing is weight-based every 2 weeks.

This is not a short-course therapy. XLH is a lifelong genetic condition; Crysvita is taken for as long as it controls the phosphate-wasting biochemistry and the family elects to continue. TIO patients may discontinue if and when the underlying tumor is fully localised and resected with biochemical cure.

Eligibility at a Saudi paediatric endocrinology or adult metabolic bone clinic

For Saudi-resident patients, the paediatric and adult endocrinology services apply the FDA-label and EMA-label eligibility with local adaptation:

1. Confirmed diagnosis. For XLH: genetic confirmation of a PHEX mutation (genetic testing available through KFSHRC and several regional referral laboratories), OR a clinically compatible picture (low serum phosphorus, normal serum calcium, elevated alkaline phosphatase, elevated FGF23, low or low-normal 1,25-dihydroxyvitamin D) with a positive family history. For TIO: an adult patient with acquired hypophosphatemia, elevated FGF23, oncology team coordination for tumor localisation (Ga-68 DOTATATE or octreotide-based functional imaging plus anatomic localisation), and a resection plan. 2. Age. Paediatric XLH age 6 months and older. Adult XLH age 18 and older. TIO age 2 and older. 3. Baseline biochemistry. Serum phosphorus, calcium, alkaline phosphatase, 1,25-dihydroxyvitamin D, 25-hydroxyvitamin D, intact parathyroid hormone, urine phosphate (fractional excretion of phosphate or tubular reabsorption of phosphate), creatinine and eGFR. 4. Discontinuation plan for conventional therapy. Oral phosphate supplements and active vitamin D analogs (calcitriol, alfacalcidol) must be discontinued before Crysvita is started. This is essential and not negotiable. Crysvita raises endogenous serum phosphorus by restoring renal reabsorption; adding exogenous phosphate or active vitamin D causes hyperphosphatemia and the risk of ectopic calcification. 5. Renal imaging baseline. Renal ultrasound to document baseline nephrocalcinosis status (a known complication of years of conventional therapy in XLH). 6. Hypersensitivity history review. 7. Pregnancy planning discussion for women of childbearing potential.

A Saudi family should arrive at the prescribing conversation with: the paediatric endocrinology or adult metabolic bone documentation, the genetic test result if available (PHEX sequencing) or the family-history pedigree, the most recent serum phosphorus / calcium / ALP / vitamin D / PTH panel, the radiographic rickets score documentation in paediatric cases or skeletal survey in adults, the complete conventional therapy history, and the SFDA registration and insurance preauthorisation paperwork.

The Saudi prescribing and supply picture, plainly

Crysvita SFDA registration status is verified at intake. Ultragenyx commercial supply runs through regional distributors; Kyowa Kirin handles ex-US distribution in many MENA markets. Where in-country registration is complete, in-country pharmacy dispensing applies. Where registration has not yet caught up, the named-patient European-import pathway covers the case. The pathway is:

1. **Prescribing physician**: a board-certified Saudi paediatric endocrinologist for paediatric XLH and paediatric TIO (the Saudi Society for Paediatric Endocrinology accredits practice across the Kingdom) or an adult endocrinologist with metabolic bone expertise for adult XLH and adult TIO. The Saudi services include KFSHRC Riyadh paediatric and adult endocrinology, KAMC (MNGHA) Riyadh and Jeddah paediatric endocrinology, KFMC Riyadh paediatric endocrinology and adult metabolic bone, KAUH Jeddah paediatric endocrinology, KFSH Dammam paediatric endocrinology, and KFHU Khobar adult endocrinology. For TIO cases, oncology team coordination at KFSHRC Riyadh or KAMC for tumor localisation and resection planning is required. 2. **Pharmacy dispensing**: hospital pharmacy with cold-chain refrigeration. Crysvita must be stored at 2 to 8 degrees Celsius; do not freeze; protect from light. 3. **Insurance preauthorisation**: For Saudi nationals at MoH facilities and MNGHA-eligible patients, the institutional rare-disease pathway applies. Bupa Arabia, Tawuniya, MedGulf, and other commercial insurers cover rare-disease therapy with documented confirmed diagnosis and prescribing physician rationale on a case-by-case basis. The financial-readiness conversation with the prescribing office happens in parallel with the clinical-readiness conversation. 4. **Conventional therapy discontinuation**: the most important operational gate. The prescribing endocrinologist sequences discontinuation of oral phosphate supplements and active vitamin D analogs in the days before the first Crysvita dose. Phosphorus and calcium are monitored at baseline, at week 2, and serially thereafter. 5. **Self-injection or clinic injection training**: typically a supervised first dose at the clinic, then a training session if the family elects home administration. Many Saudi families prefer clinic-administered dosing for the first 6 to 12 months given the monthly monitoring rhythm. 6. **Ongoing monitoring**: serum phosphorus, calcium, alkaline phosphatase, 1,25-dihydroxyvitamin D, PTH at week 2, week 4, then monthly during titration, then every 3 months during maintenance. Renal ultrasound annually. Paediatric height and rickets-score reassessment every 6 months.

Cost band

US WAC pricing for Crysvita is weight-dependent. For a paediatric XLH patient, the annual cost band is approximately USD 165,000 to 250,000 depending on body weight and titrated dose. For an adult XLH patient at the 1 mg/kg every-4-week schedule (typical dose 70 to 90 mg per cycle), the annual cost band is approximately USD 240,000 to 340,000. TIO adult dosing follows the paediatric weight-based every-2-week pattern. At 2026 indicative cross rates, the SAR-equivalent annual cost band is approximately SAR 619,000 to 938,000 for paediatric XLH and SAR 900,000 to 1.275 million for adult XLH and TIO. MoH and MNGHA institutional coverage for confirmed-diagnosis rare-disease cases reduces out-of-pocket exposure substantially.

What to expect on Crysvita

Serum phosphorus moves toward the lower end of the age-appropriate normal range within 4 to 8 weeks. In paediatric XLH patients, the radiographic rickets score improves over 1 to 2 years, height velocity improves over the first 12 months, and bowing of the lower extremities slowly remodels. In adult XLH patients, bone pain reduces over months, stiffness improves, and stress-fracture healing accelerates. In TIO patients, biochemical correction precedes definitive surgical tumor resection if resection is delayed, and serves as a bridge.

The most common adverse events are injection-site reactions (very common, usually mild), headache, restless legs symptoms, dizziness, and rarely hypersensitivity. Hyperphosphatemia is possible if conventional therapy is not properly discontinued or if dose titration overshoots; this is why serial phosphorus monitoring is the central operational discipline.

When Crysvita is the wrong drug

Crysvita is the wrong drug for hypophosphatemia that is not FGF23-mediated (nutritional, refeeding, dialysis-related, Fanconi syndrome from drug toxicity, autosomal dominant hypophosphatemic rickets unless FGF23 confirmed elevated). It is the wrong drug in severe renal impairment with elevated serum phosphorus at baseline, in familial-tumoral-calcinosis-like states with hyperphosphatemia, and where the family cannot reliably attend the monthly phosphorus-monitoring visits required for safe titration. For TIO, definitive surgical resection of the localised tumor remains the preferred curative pathway; Crysvita is for cases where the tumor cannot be localised, cannot be fully resected, or where surgery is delayed.

What Reserve Meds does on this case

We are a US-based concierge coordinator. We are not the prescriber and not the dispensing pharmacy. On a Saudi Crysvita case we build the documentation pack with the treating paediatric endocrinologist or adult metabolic bone specialist office, confirm SFDA registration status and the appropriate dispensing pathway, run the institutional or insurance preauthorisation conversation, coordinate the cold-chain supply logistics, organise the conventional-therapy discontinuation sequencing with the prescribing office, and stay with the case through the first year of titrated dosing with handoff to the local prescriber for ongoing surveillance. Clinical decisions remain with your treating endocrinologist or metabolic bone team.

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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