

Ultragenyx / Kyowa Kirin 10 / 20 / 30 mg/mL preservative-free SDV Subcutaneous (NOT IV) Reviewed: May 2, 2026 ASP: Q2 2026

HCPCS J0584 1 mg = 1 unit	ADULT XLH DOSE ~60 u 1 mg/kg q4wk · max 90 mg	MODIFIER JZ / JW Required (waste from fixed vials)	ADMIN CPT 96372 Therapeutic SC (NOT chemo)	MEDICARE ASP+6% \$498.716 /mg · \$29,922.96/60 mg
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CONTRAINDICATED with oral phosphate + active vitamin D analogs (calcitriol, paricalcitol, doxercalciferol). Discontinue both ≥1 week before first Crysvita dose. Document discontinuation date + prescriber note in chart. Failure causes severe hyperphosphatemia. Cholecalciferol (D3) and ergocalciferol (D2) are OK.

CODES & NDC

HCPCS	J0584 — "Inj, burosumab-twza 1 mg" (permanent)
NDC 10 MG/ML	69794-101-01 — pediatric & small-dose
NDC 20 MG/ML	69794-202-01 — mid-range pediatric / small adult
NDC 30 MG/ML	69794-203-01 — adult standard (combine 2-3 vials for >30 mg)
CLASS	First-in-class anti-FGF23 mAb — no biosimilar, no generic, no class peer
BENEFIT	Medical (provider buy-and-bill) OR specialty pharmacy after self-admin training

ICD-10 BY INDICATION

CODE	FOR
E83.31	XLH (primary) — familial hypophosphatemia
M89.9	Bone disease NOS (XLH supplementary)
M85.x	Other bone density disorders (XLH supplementary)
D48.0	TIO — neoplasm of uncertain behavior of bone
D49.81	TIO cryptic — neoplasm unspecified behavior, soft tissue
M83.x	Adult osteomalacia (TIO supplementary)
E83.39	Other phosphorus metabolism disorder

DOSING — XLH VS TIO

	XLH	TIO
Pediatric	≥6 mo: start 0.8 mg/kg q2wk, titrate to max 2 mg/kg, max 90 mg	≥2 yr: 0.5 mg/kg q4wk, titrate
Adult	1 mg/kg q4wk, round to nearest 10 mg, max 90 mg	0.5 mg/kg q2wk, titrate
Duration	Lifelong (genetic)	Until tumor resected, OR lifelong if unresectable
Monitoring	Serum phosphate q4wk, titrate	Serum phosphate q4wk, titrate

PAYER REQUIREMENTS (MAY 2026)

PAYER	PA	KEY REQUIREMENT
UnitedHealthcare	Yes	PHEX gene OR clinical XLH; specialist; washout doc
Aetna	Yes	Geneticist / endo / nephro prescriber required
BCBS	Yes	Some plans require conventional therapy trial first (adult XLH)
Medicare (LCD)	Doc	FDA-labeled indication + biochemistry; lifelong for XLH

Universal PA musts: confirmed XLH/TIO dx · serum phosphate (low) · serum FGF23 (high) · specialist prescriber · documented oral phosphate + active vit D washout ≥1 wk · for TIO, imaging workup (PET-CT / DOTATATE).

ADMINISTRATION

CODE	WHEN
96372	Primary — therapeutic SC injection, non-chemo
96401	NOT appropriate — Crysvita is not chemo
96365 / 96413	NOT appropriate — Crysvita is SC only, never IV

Self-admin at home: after training; specialty pharmacy distributes drug; no admin code billed by practice

MODIFIERS

- **JZ** — when calculated dose matches vial(s) with no waste (60 mg adult = 30+30 vials)
- **JW** — required when partial-vial waste (frequent in pediatrics: 28 mg child uses 30 mg vial → JW for 2 units)
- One of JZ or JW required on every J0584 claim (CMS 7/1/2023)
- Modifier 25 on E/M for same-day titration assessment

MEDICARE REIMBURSEMENT (Q2 2026)

FIELD	VALUE
ASP + 6%	\$498.716 / mg (eff. 4/1 – 6/30/2026)
60 mg adult dose	\$29,922.96 (60 × \$498.716)
90 mg max dose	\$44,884.44 (90 × \$498.716)
Annual XLH adult (60 mg q4wk × 13)	~\$388,998
Annual XLH max (90 mg q4wk × 13)	~\$583,498

Among the highest per-mg drugs in the Medicare catalog at ~\$499/mg. Lifelong therapy. Precise unit counting + JW waste documentation matters more than for typical biologics.

SITE OF CARE

SETTING	POS	NOTES
Endo / nephro / genetics office	11	Preferred — SC fits cleanly
Pediatric specialty clinic	11	Preferred for XLH peds titration
Hospital outpatient	22	Acceptable for academic centers
Patient home (self-admin)	12	After training; specialty pharm bills drug

PATIENT ASSISTANCE — ULTRACARE

- **Phone: 1-888-756-8657** (UltraCare)
- **Crysvita Co-Pay Program:** commercial \$0 first dose, ongoing copay support
- **Ultragenyx PAP:** free drug for uninsured / underinsured
- **Foundations:** PAN, HealthWell, NORD — verify quarterly for open XLH/rare disease funds
- **Web:** ultracare-us.com / crysvita.com

W&P (no boxed): hypersensitivity (rash/urticaria), hyperphosphatemia (monitor q2wk × 1 mo, then q4wk), restless leg syndrome, injection-site reactions. Rotate sites: arm / abdomen / thigh / buttock.