CRYSVITA®
burosumab-twza

Injection for subcutaneous use

UltraCare™

UPON ENROLLMENT, AN ULTRACARE GUIDE WILL:

- Partner with and remain dedicated to your patient throughout the treatment journey
- Contact the patient or caregiver to review insurance coverage and support programs
- Assess the patient's eligibility for available financial assistance programs

GETTING STARTED: STEPS FOR SUCCESSFUL ENROLLMENT IN ULTRACARE

Below are the most critical steps for ensuring complete and timely enrollment in UltraCare so your patient can benefit fully from the program's suite of support services.

1 SELECT PREFERRED PATIENT COMMUNICATION METHOD

Ask your patient and/or caregiver about how they will prefer to communicate with their UltraCare Guide and the best time to contact them

2 VERIFY THE PATIENT'S INSURANCE

- Provide a copy of the front and back of all of the patient's **medical** and **prescription** insurance cards
- Indicate if the patient does not have health insurance (medical and pharmacy)

3 OBTAIN PATIENT CONSENT[a]

- The patient signature is required to allow third parties to share protected health information with Ultragenyx and to facilitate:
  - Benefits investigation
  - Prior authorization
  - Specialty pharmacy provider prescription transfer
  - Home infusion agency
  - Additional services provided by UltraCare, including insurance coverage, financial assistance, and patient support programs

4 SELECT SITE OF CARE (SOC)

- Choose your preferred SOC for the administration of the medication:
  - Home injection
  - Office administration
  - Outpatient hospital setting

5 SPECIFY PRESCRIPTION

- Patient weight (kg) × recommended starting dose = total initial dose (rounded to nearest 10 mg)
  - Pediatric: Recommended starting dose is 0.8 mg/kg of body weight (round to nearest 10 mg and max dose is 90 mg) every 2 weeks
  - Adult: Recommended starting dose is 1 mg/kg of body weight (round to the nearest 10 mg and max dose is 90 mg) every 4 weeks
- Ensure the physician provides a wet signature and date, which are necessary to process the prescription

[a] If the patient wants to opt out of the patient consent section, inform the UltraCare team verbally on the phone or in writing to the address on the next page.

INDICATION

CRYSVITA® (burosumab-twza) is indicated for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 1 year of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Do not use CRYSVITA with oral phosphate and active vitamin D analogs.
- Do not initiate CRYSVITA if serum phosphorus is within or above the normal range for age.
- CRYSVITA is contraindicated in patients with severe renal impairment or end stage renal disease.

WARNINGS AND PRECAUTIONS

Hypersensitivity

- Discontinue CRYSVITA if serious hypersensitivity reactions occur and initiate appropriate medical treatment.

Hyperphosphatemia and Risk of Nephrocalcinosis

- For patients already taking CRYSVITA, dose interruption and/or dose reduction may be required based on a patient's serum phosphorus levels.

Injection Site Reactions

- Discontinue CRYSVITA if severe injection site reactions occur and administer appropriate medical treatment.

ADVERSE REACTIONS

Pediatric Patients

- The most common adverse reactions (more than 10%) in pediatric XLH patients are: headache, injection site reaction, vomiting, pyrexia, pain in extremity, vitamin D decreased, rash, toothache, myalgia, tooth abscess, and dizziness.

Adult Patients

- The most common adverse reactions (more than 5% and in at least 2 patients more than placebo) in adult XLH patients are: back pain, headache, tooth infection, restless leg syndrome, vitamin D decreased, dizziness, constipation, blood phosphorus increased.
- Spinal stenosis is prevalent in adults with XLH and spinal cord compression has been reported. It is unknown if CRYSVITA therapy exacerbates spinal stenosis or spinal cord compression.

USE IN SPECIFIC POPULATIONS

- There are no available data on CRYSVITA use in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Serum phosphorus levels should be monitored throughout pregnancy. Report pregnancies to the Ultragenyx Adverse Event reporting line at 1-888-756-8657.
- There is no information regarding the presence of CRYSVITA in human milk, or the effects of CRYSVITA on milk production or the breastfed infant.

PATIENT COUNSELING INFORMATION

- Instruct patients to contact their physician if hypersensitivity reactions, injection site reactions, and restless leg syndrome induction or worsening of symptoms occur.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Ultragenyx at 1-888-756-8657.

Please see accompanying full Prescribing Information for a complete discussion of the risks associated with CRYSVITA.

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CRYSVITA®
burosumab-twza

UltraCare™

Toll-free Line: 888-756-8657 | **Fax:** 415-723-7474 | http://www.ultracaresupport.com
Email: UltraCare@ultragenyx.com | **Address:** 5000 Marina Boulevard, Brisbane, CA 94005

Patient Start Form

1 PATIENT INFORMATION: Be sure to choose your preferred contact method

First, Middle, Last Name _____
Gender ☐ Female ☐ Male
DOB (MM/DD/YYYY) _____ Last 4 Digits of Social Security # _____
Street Address _____
City _____ State _____ ZIP Code _____
Home Phone (____) _____ Work Phone (____) _____
Mobile Phone (____) _____ Best Time to Contact _____
Preferred Method of Contact ☐ Home ☐ Work ☐ Mobile ☐ Text ☐ Email
Preferred Language _____
Email _____
Caregiver Name (First and Last) _____
Relationship to Patient _____ Caregiver Phone (____) _____

2 INSURANCE INFORMATION: Be sure to provide copies of patient's MEDICAL and PRESCRIPTION cards

☐ Patient does not have health insurance ☐ Provide copies of all medical and prescription cards—front and back (primary and secondary, supplemental coverage) [No need to populate this section]

PRIMARY INSURANCE INFORMATION

Insurance Name_____ Insurance Phone (____) _____
Policyholder Name _____ Relationship to Patient _____
Group ID _____ Employer Name _____
Member ID _____

SECONDARY INSURANCE INFORMATION

Insurance Name_____ Insurance Phone (____) _____
Policyholder Name _____ Relationship to Patient _____
Group ID _____ Employer Name _____
Member ID _____

PRESCRIPTION CARD INFORMATION

Prescription Card Name_____ Prescription Phone (____) _____
Policyholder Name _____ Relationship to Patient _____
Member ID _____ BIN #_____
PCN # _____

3 PATIENT CONSENT TO SHARE PROTECTED HEALTH INFORMATION (PHI) AND SIGNATURE

I authorize each of my physicians and pharmacists (including any specialty pharmacies and other health care providers), and each of my health insurers, to disclose my PHI, including but not limited to medical records, information related to my medical condition and treatment, financial, lab values, insurance coverage information, my name, address, telephone number, and last 4 digits of Social Security number to Ultragenyx Pharmaceutical, Inc., and its agents, contractors, and assignees to use and disclose my PHI to enroll me in and contact me about UltraCare Patient Services, provide case management through telephone or electronic communications to assist with adherence to my medication regimen, and work with third parties to provide community resources and referrals. Third-party vendors, such as specialty pharmacies, may receive financial remuneration in exchange for data, product support services, reimbursement services, etc. This authorization expires one year from the date of execution, or one year after the date of my last prescription, whichever is later, unless a shorter period is required by state law. I understand I may refuse to sign this authorization and that my treatment, payment, enrollment, or eligibility for benefits, including my access to therapy, is not conditioned on my signing this authorization. I understand that revoking this authorization will not affect the ability to use and disclose PHI received prior to receipt of notification that I wish to discontinue my participation in the program. I understand I may revoke this authorization at any time verbally or by writing to the address listed at the top of this form. Once authorization has been revoked or expired, I understand my future PHI will not be disclosed. I understand that my PHI will not be used or disclosed for any other purposes, unless permitted by law, than for the purposes stated above. Information disclosed pursuant to this authorization or provided to a third-party may no longer be protected by federal privacy laws.

Patient Signature_____ **Date**_____
Parent/Guardian Signature (if patient is minor)_____ **Date**_____

4 PRESCRIBER INFORMATION: Be sure to choose your preferred site of care (SOC)

☐ Home Injection ☐ Office Administration ☐ Outpatient Hospital Setting
First and Last Name _____
Street Address _____
City _____ State _____ ZIP Code _____
Office Phone (_____) _____ Fax (_____) _____
Office Email _____
Office Contact Name/Title _____
Office Contact Phone (_____) _____
State License # _____ NPI # _____
☐ SOC is different from prescriber's location SOC Name_____
SOC Address _____

The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance with state-specific requirements could result in outreach to the prescriber.

5 CRYSVITA PRESCRIPTION INFORMATION: Select ICD-10 code and type of prescription

Pediatric XLH: Starting dose regimen is 0.8 mg/kg of body weight rounded to the nearest 10 mg, administered every 2 weeks. The minimum starting dose is 10 mg up to a maximum dose of 90 mg.
Adult XLH: Starting dose regimen is 1 mg/kg of body weight rounded to the nearest 10 mg up to a maximum dose of 90 mg, administered every 4 weeks.
How Supplied: 10 mg/mL single-dose vial, 20 mg/mL single-dose vial, 30 mg/mL single-dose vial.
Subcutaneous injection only.

☐ E83.31 (familial hypophosphatemia) ☐ E83.39 (other disorders of phosphorus metabolism) ☐ Other _____

CRYSVITA Prescription	Weight Date Taken	Patient Weight (in kg)	Initial Dose Prescribed	Total Calculated Dose (Round to the nearest 10 mg and max dose is 90 mg)	Frequency	Days Supply (Limit: 28 days)	Refills
		x	☐ 0.8 mg/kg (Pediatric) ☐ 1 mg/kg (Adult)		☐ Every 2 weeks (Pediatric) ☐ Every 4 weeks (Adult)		

☐ Prescriber: Please check here to authorize ancillary supplies such as needles and syringes as needed to administer the therapy.
☐ RN visit to provide education related to therapy, disease state, and nurse administration of CRYSVITA to include dosing and titration as per prescriber order.

Prescriber Signature _____ Date _____ (No Stamps) Dispense as Written
Prescriber Signature _____ Date _____ (No Stamps) Substitution Permitted

Fast Start Prescription (For AllCarePlus Pharmacy Only)	Weight Date Taken	Patient Weight (in kg)	Initial Dose Prescribed	Total Calculated Dose (Round to the nearest 10 mg and max dose is 90 mg)	Frequency	Days Supply	
		x	☐ 0.8 mg/kg (Pediatric) ☐ 1 mg/kg (Adult)		☐ Every 2 weeks (Pediatric) ☐ Every 4 weeks (Adult)		

Prescriber Signature _____ Date _____ (No Stamps) Dispense as Written
Prescriber Signature _____ Date _____ (No Stamps) Substitution Permitted

Fast Start: For all naive to commercial therapy, patients and product must be sent to the HCP for administration at office, and cost will not be passed along to patient.

Concurrent Medications (Attached List) Special Instructions _____
Special Precautions (eg, Allergies) _____

I authorize Ultragenyx to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by the patient utilizing their benefit plan. The prescriber is to comply with his/her state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc.

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