# Kyowa Kirin Cares Prescription & Enrollment Form

**Phone:** 833-KK-CARES (833-552-2737) | **Fax:** 833-552-3299 | **Email:** patientsupport@kyowakirincares.com | **Hours:** M–F, 8AM to 8PM ET

= Patient = HCP

## Patient Information

First Name: _____ MI: _____ Last Name: _____ DOB: ____/____/____

Address: _____ City: _____ State: _____ ZIP: _____

Last 4 SSN: _____ US Resident: ☐ Yes ☐ No Gender: ☐ Male ☐ Female Hearing impaired: ☐ Yes ☐ No

Cell Phone: (____)_____ Home Phone: (____)_____ Email: _____

OK to Text?: ☐ *By checking this box, I confirm this is my phone number and agree to subscribe to the Kyowa Kirin Cares Text Message program. I understand the number of texts I receive may vary based on the progress of my enrollment. Full Text Message Program terms and conditions: https://www.kyowakirincares.com/SMS_Terms.pdf*

Preferred Contact Method: ☐ Text ☐ Cell Phone ☐ Home Phone ☐ Email Best Time to Call: ☐ Morning ☐ Afternoon ☐ Evening

If patient is a minor, please complete Legal Guardian information:

Legal Guardian Name (First and Last): _____ Relationship to patient: _____

Legal Guardian Phone: (____)_____ Legal Guardian Email: _____

## Additional Authorized Care Partner(s)

Name: _____

Relationship to Patient: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: (____)_____ Email: _____

Name: _____

Relationship to Patient: _____

Address: _____

City: _____ State: _____ ZIP: _____

Phone: (____)_____ Email: _____

## Insurance Information

☐ Provide copies of all medical and prescription cards—front and back (primary and secondary, supplemental coverage)

☐ Patient does not have health insurance

## Prescriber Information

First Name: _____ Last Name: _____ HCP Tax ID: _____

Office/Clinic/Institution Name: _____ State License #: _____ NPI #: _____

Address: _____ City: _____ State: _____ ZIP: _____

Office Phone: (____)_____ Fax: (____)_____ Office Email: _____

Office Contact Name/Title: _____

Office Contact Phone: (____)_____ Office Contact Email: _____

Preferred Product Procurement (select one): ☐ Specialty Pharmacy ☐ Buy and Bill

Desired Site of Care:

☐ Home Injection (see patient home address) including RN visit to provide education related to therapy, disease state, and nurse administration of CRYSVITA® (burosumab-twza)

☐ Physician Office (see provider office address)

☐ Alternate Medical Facility

Facility Name:_____ Facility Address:_____

☐ Facility to Home (first dose at facility and remainder at home administered by HCP)

Facility Name:_____ Facility Address:_____

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## CRYSVITA® (burosumab-twza) Prescription Information: Select ICD-10-CM code below and type of prescription

☐ XLH: E83.31 (familial hypophosphatemia)
☐ TIO: M83.8 (other adult osteomalacia)
☐ E83.39 (other disorders of phosphorus metabolism)
☐ Other _____

Subcutaneous injection only and should be administered by a health care provider. How Supplied: 10 mg/mL single-dose vial, 20 mg/mL single-dose vial, 30 mg/mL single-dose vial.

| CRYSVITA Prescription | Date Weight Taken | Patient Weight (in kg) | Initial Dose Prescribed | Total Calculated Dose | Frequency | Days Supply | Refills |
|---|---|---|---|---|---|---|---|
| ☐ XLH<br>☐ TIO | | X | ☐ 0.4 mg/kg (Pediatric TIO)<br>☐ 0.5 mg/kg (Adult TIO)<br>☐ 0.8 mg/kg (Pediatric XLH ≥10 kg)<br>☐ 1 mg/kg (Adult XLH or Pediatric XLH less than 10 kg) | | ☐ Every 2 weeks SQ<br>☐ Every 4 weeks SQ | | |

☐ Pharmacy is to dispense supplies needed for administration ☐ No known drug allergies (NKDA)

**Vial Size and Quantity**

☐ Pharmacist to select strengths used based on dose unless otherwise stated: _____ Special Instructions: _____

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

☐ Substitution Permitted

I certify that the information in this Prescription & Enrollment Form is complete and accurate to the best of my knowledge. By signing this Prescription & Enrollment Form*, I certify that I have prescribed CRYSVITA (burosumab-twza) based on my professional judgment of medical necessity, and that I will supervise the patient's medical treatment. I authorize the release of medical and/or other patient information relating to CRYSVITA therapy to agents, and service providers of Kyowa Kirin (including but not limited to AllCare Plus Pharmacy, LLC and CRYSVITA-dispensing pharmacies) to use and disclose as necessary for fulfillment of the prescription and to furnish any information on this form to the insurer of the above-named patient for the purpose of verifying benefit eligibility and obtaining coverage authorization.

**Prescriber Signature:** _____ **Date:** _____

Original signature is required. *If required by applicable law, please attach copies of all prescriptions on official state prescription forms.

## Prescription Reference Information

### X-linked hypophosphatemia (XLH) dosing regimens:

**Pediatric XLH (6 months to less than 18 years of age):**

- For patients who weigh less than 10 kg, starting dose regimen is 1 mg/kg of body weight rounded to the nearest 1 mg, administered every 2 weeks
- For patients who weigh 10 kg and greater, 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.

| Body Weight (kg) | 10–14 | 15–18 | 19–31 | 32–43 | 44–56 | 57–68 | 69–80 | 81–93 | 94–105 | 106 and greater |
|---|---|---|---|---|---|---|---|---|---|---|
| Starting Dose (mg) | 10 | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 |
| First Dose Increase to (mg) | 15 | 20 | 30 | 40 | 60 | 70 | 90 | 90 | 90 | 90 |
| Second Dose Increase to (mg) | 20 | 30 | 40 | 60 | 80 | 90 | 90 | 90 | 90 | 90 |

**Adult XLH (18 years of age and older):** 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.

### Tumor-Induced Osteomalacia (TIO) associated with phosphaturic mesenchymal tumors dosing regimens:

**Pediatric TIO (2 years to less than 18 years of age):** Starting dose is 0.4 mg/kg of body weight rounded to the nearest 10 mg every 2 weeks. Dose may be increased up to 2 mg/kg not to exceed 180 mg, administered every 2 weeks.

| Body Weight (kg) | 10–14 | 15–18 | 19–31 | 32–43 | 44–56 | 57–68 | 69–80 | 81–93 | 94–105 | 106 and greater |
|---|---|---|---|---|---|---|---|---|---|---|
| Starting Dose (mg) | 5 | 5 | 10 | 10 | 20 | 20 | 30 | 30 | 40 | 40 |
| First Dose Increase to (mg) | 10 | 10 | 20 | 30 | 40 | 50 | 60 | 70 | 80 | 90 |
| Second Dose Increase to (mg) | 15 | 20 | 25 | 40 | 50 | 70 | 80 | 100 | 110 | 130 |
| Third Dose Increase to (mg) | 20 | 25 | 30 | 50 | 70 | 90 | 100 | 120 | 140 | 160 |

The table shows a dose increase up to 1.5 mg/kg. Further dose increases to a maximum of 2 mg/kg not to exceed 180 mg, administered every 2 weeks, should be calculated by the physician.

**Adult TIO (18 years of age and older):** Starting dose is 0.5 mg/kg rounded to the nearest 10 mg, administered every 4 weeks. Dose may be increased up to 2 mg/kg not to exceed 180 mg, administered every 2 weeks.

| | Starting Dose | First Dose Increase† | Second Dose Increase† | Third Dose Increase† | Fourth Dose Increase | Fifth Dose Increase (maximum dose) |
|---|---|---|---|---|---|---|
| **If serum phosphorus 2 weeks post-dose adjustment is below lower limit of normal*** | 0.5 mg/kg every 4 weeks | Increase to 1 mg/kg every 4 weeks OR 0.5 mg/kg every 2 weeks | Increase to 1.5 mg/kg every 4 weeks‡ OR 0.75 mg/kg every 2 weeks | Increase to 2 mg/kg every 4 weeks‡ OR 1 mg/kg every 2 weeks | Increase to 1.5 mg/kg not to exceed 180 mg every 2 weeks | Increase to 2 mg/kg not to exceed 180 mg every 2 weeks |

*Rounded to the nearest 10 mg. Do not adjust CRYSVITA more frequently than every 4 weeks.
†For those individuals not reaching a serum phosphorus greater than the lower limit of the normal range, physicians may consider dividing total dose administered every 4 weeks and administering every 2 weeks.
‡In patients with high body weight, if the calculated dose is greater than 180 mg every 4 weeks, move to a divided dose of every 2 weeks.

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## Patient Authorization

By signing this Authorization, I authorize each of my prescribers, pharmacists, including any specialty pharmacy that receives my prescription for CRYSVITA® (burosumab-twza) and other healthcare providers (together "Healthcare Providers") and each of my health insurers (together, "Insurers") to disclose my Protected Health Information, including but not limited to medical records, information related to my medical condition and treatment, my health insurance coverage, my name, address, telephone number, Social Security number, insurance plan and or group numbers (together, "Protected Health Information") to Kyowa Kirin, its affiliated companies, Ultragenyx, vendors, agents, collaboration partners, and representatives (together, "Kyowa Kirin") including providers of alternate sources of funding for prescription drug costs, and other service providers supporting Kyowa Kirin Cares Support Services (the "Program") for Healthcare Providers and patients for the purposes described below.

Specifically, I authorize disclosure of my Protected Health Information in order to:

I. Enroll me in, and contact me about the Program, including online support, financial assistance services, co-pay assistance, specialist services, and compliance and persistency services

II. Communicate with my Healthcare Providers and Insurers about benefits, coverage and medical care, including compliance with Product treatments

III. Locate a specialty pharmacy that can fill my prescription and facilitate dispensing of my prescription by such pharmacy

IV. Provide me with educational materials, information and services related to my treatment experience with CRYSVITA and my condition

V. Contact me and leave messages about my use of CRYSVITA and my medical care

VI. Verify, investigate, assist with, and coordinate my coverage for CRYSVITA with my Insurers

VII. Coordinate prescription fulfillment

VIII. Conduct surveys, data analytics, market research and other internal business activities related to the Program, CRYSVITA, and other Kyowa Kirin products and programs

IX. Contact me as otherwise required or permitted by law

I understand that pharmacies that ship my medication may be paid to share this information with the Program to help provide the offerings requested for me. Once my Protected Health Information has been disclosed to Kyowa Kirin, I understand that federal privacy laws no longer protect the information. However, Kyowa Kirin agrees to protect my Protected Health Information by using and disclosing it only for the purposes described in this Authorization or as permitted by law.

I understand that I may refuse to sign this Authorization. My choice about whether to sign will not change the way my Healthcare Providers or Insurers treat me, but I will not have access to the Program and the services provided by Kyowa Kirin under the Program. If I refuse to sign the Authorization, or revoke my authorization later, I understand that this means I will not be able to participate or receive assistance from the Program.

This Authorization will last for a period of five (5) years (unless earlier termination is required by applicable state law). I understand that I may cancel this Authorization at any time in the future, except to the extent that actions have been taken in reliance on the Authorization, by mailing a request to 510 Carnegie Center Dr, Suite 600, Princeton, NJ 08540, via fax at 833-552-3299, or by calling 833-552-2737. I understand that revoking this Authorization will end further uses and disclosure of my Protected Health Information by the parties identified above except to the extent those uses and disclosures have been made in reliance upon this Authorization as permitted by applicable law. I am entitled to receive a copy of this Authorization.

The personal information and health insurance I have provided on this form is complete and accurate to the best of my knowledge. I will update my information promptly if any of the information reflected on this form changes by contacting the Program at 833-552-2737.

Patient Name: _____

Patient or Legal Guardian Signature: _____ Date: _____

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## What is CRYSVITA® (burosumab-twza)?

CRYSVITA is a prescription medicine used to treat:

- Adults and children 6 months of age and older with X-linked hypophosphatemia (XLH)
- Adults and children 2 years of age and older with fibroblast growth factor 23 (FGF23)–related hypophosphatemia in tumor-induced osteomalacia (TIO) when the tumor cannot be located or removed

## Important Safety Information

**You should not take CRYSVITA if:**

- You take an oral phosphate supplement and/or a specific form of vitamin D supplement (such as calcitriol, paricalcitol, doxercalciferol, calcifediol)
- Your phosphorus levels from a blood sample are within or above the normal range for age
- You have kidney problems

**What is the most important information you should know about CRYSVITA?**

- Some patients developed allergic reactions (e.g., rash and hives) while taking CRYSVITA. Your doctor will monitor you for symptoms of an allergic reaction while you are taking CRYSVITA
- High levels of phosphorus in the blood have been reported in some patients taking CRYSVITA. This may be related to a risk of high calcium levels in the kidneys. Your doctor will collect blood samples to monitor your levels
- Administration of CRYSVITA may result in reactions at the injection site, such as hives, reddening of the skin, rash, swelling, bruising, pain, severe itching of the skin, and collection of blood outside of a blood vessel (i.e., hematoma)
- If you are taking CRYSVITA for TIO, your doctor will have you stop your CRYSVITA treatment temporarily if you are undergoing treatment for your tumor (e.g., surgical removal of the tumor or radiation therapy)

**What are the possible side effects of CRYSVITA?**

- Adverse reactions that were seen in children with XLH are:
  - Fever
  - Injection site reaction
  - Cough
  - Vomiting
  - Pain in arms and legs
  - Headache
  - Tooth abscess
  - Dental cavities
  - Diarrhea
  - Decreased vitamin D levels
  - Toothache
  - Constipation
  - Muscle pain
  - Rash
  - Dizziness
  - Nausea
- Adverse reactions that were seen in adults with XLH are:
  - Back pain
  - Headache
  - Tooth infection
  - Restless legs syndrome
  - Decreased vitamin D levels
  - Dizziness
  - Constipation
  - Muscle spasms
  - Phosphorus levels increased in the blood
- Narrowing of the spaces within the spine is common in adults with XLH, and pressure on the spinal cord has been reported in adults taking CRYSVITA. It is not known if taking CRYSVITA worsens the narrowing of the spaces within the spine or the pressure on the spinal cord
- Adverse reactions that were seen in adults with TIO are:
  - Tooth abscess
  - Muscle spasms
  - Dizziness
  - Constipation
  - Injection site reaction
  - Rash
  - Headache

**Before taking CRYSVITA, tell your doctor about all of your medications (including supplements) and medical conditions, including if you:**

- Are taking oral phosphate and/or active vitamin D (such as calcitriol, paricalcitol, doxercalciferol, calcifediol)
- Are pregnant, think you may be pregnant, or plan to become pregnant. There is not enough experience to know if CRYSVITA may harm your unborn baby. Report pregnancies to the Kyowa Kirin, Inc. Adverse Event reporting line at 1-844-768-3544
- Are breastfeeding or plan to breastfeed. There is not enough experience to know if CRYSVITA passes into your breast milk. Talk with your doctor about the best way to feed your baby while you receive CRYSVITA

**While taking CRYSVITA, tell your doctor if you experience:**

- An allergic reaction such as rash or hives
- A rash, swelling, bruising, or other reaction at the injection site
- New or worsening restless legs syndrome

These are not all the possible side effects of CRYSVITA. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Kyowa Kirin, Inc. at 1-844-768-3544.

For important risk and use information, please click to see the full Prescribing Information.