CRYSVITA® (burosumab-twza) Prescription & KKCares Enrollment Form

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

= Patient = HCP

Once pages 1, 2, and 3 of the enrollment form are fully completed and signed, please email or fax to Kyowa Kirin Cares.

Patient Information

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

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

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

Preferred Language: _____

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

Legal Guardian Name (First and Last): _____ DOB: ___/___/_____

Relationship to patient: _____

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

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)

Primary Medical Insurance: _____ Phone: (_____)_____ Member ID #: _____

Group #: _____ Subscriber Name: _____ DOB: ___/___/_____

Secondary Medical Insurance: _____ Phone: (_____)_____ Member ID #: _____

Group #: _____ Subscriber Name: _____ DOB: ___/___/_____

Pharmacy Insurance: _____ Phone: (_____)_____ Insurance ID #: _____

Group #: _____ BIN: _____ PCN: _____ Subscriber Name: _____ DOB: ___/___/_____

☐ Patient does not have health insurance

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Patient First and Last Name: _____ DOB: ___/___/_____

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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:_____

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.

Date Weight Taken (mm/dd/yyyy)	Patient Weight (in kg)	Initial Dose Prescribed (**please check one**):	Total Calculated Dose = patient weight x initial dose prescribed	Frequency	Days Supply	Refills
___/___/_____		☐ 0.8 mg/kg (Pediatric XLH ≥10 kg) ☐ 1 mg/kg (Adult XLH or Pediatric XLH less than 10 kg ☐ 0.4 mg/kg (Pediatric TIO) ☐ 0.5 mg/kg (Adult TIO)		☐ Every 2 weeks SQ ☐ 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.

HCP Sign **Prescriber Signature:** _____ **Date:** ___/___/_____

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

Common Diagnostic Tests (Optional)

Payers may require diagnostic testing. You may consider checking the applicable tests that have been completed and the date of completion, or are in progress.

☐ Clinical signs/symptoms	Date: ___/___/_____	☐ In progress	☐ TmP/GFR	Date: ___/___/_____	☐ In progress
☐ Serum phosphorus test	Date: ___/___/_____	☐ In progress	☐ X-ray	Date: ___/___/_____	☐ In progress
☐ *PHEX* genetic test	Date: ___/___/_____	☐ In progress	☐ Serum creatinine test	Date: ___/___/_____	☐ In progress
☐ FGF23 serum test	Date: ___/___/_____	☐ In progress	☐ Serum 1,25$(OH)_2$D test	Date: ___/___/_____	☐ In progress

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Patient First and Last Name: _____ DOB: ___/___/_____

Once pages 1, 2, and 3 of the enrollment form are fully completed and signed, please email or fax to Kyowa Kirin Cares.

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, insurance plan and or group numbers (together, "Protected Health Information") to Kyowa Kirin, its affiliated companies, 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. 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.

☐ *If I check this box, I also authorize the use of my information for Kyowa Kirin marketing activities, Patient Ambassador activities, and consent to receive marketing and promotional communications from Kyowa Kirin, including information about opportunities to participate in market research.* ***Checking this box is not a requirement of receiving Kyowa Kirin medicine or Kyowa Kirin Cares services.***

By signing below, I acknowledge that I have read and agree to the Patient Authorization:

Patient or Legal Guardian Name (Print): _____

Patient Sign Patient or Legal Guardian Signature: _____ Date: ___/___/_____

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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. Please note, there is no dosing chart for adult patients with XLH.

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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Indication

CRYSVITA® (burosumab-twza) is a fibroblast growth factor 23 (FGF23) blocking antibody indicated for:

- The treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older
- The treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients 2 years of age and older

Important Safety Information

CONTRAINDICATIONS

CRYSVITA is contraindicated:

- In concomitant use with oral phosphate and/or active vitamin D analogs (e.g., calcitriol, paricalcitol, doxercalciferol, calcifediol) due to the risk of hyperphosphatemia
- When serum phosphorus is within or above the normal range for age
- In patients with severe renal impairment or end stage renal disease because these conditions are associated with abnormal mineral metabolism

WARNINGS AND PRECAUTIONS

Hypersensitivity

- Hypersensitivity reactions (e.g., rash, urticaria) have been reported in patients with CRYSVITA. Discontinue CRYSVITA if serious hypersensitivity reactions occur and initiate appropriate medical treatment

Hyperphosphatemia and Risk of Nephrocalcinosis

- Increases in serum phosphorus to above the upper limit of normal may be associated with an increased 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
- Patients with TIO who undergo treatment of the underlying tumor should have dosing interrupted and adjusted to prevent hyperphosphatemia

Hypercalcemia

- Increases in serum calcium have been reported in patients treated with CRYSVITA. Patients with risk factors such as pre-existing hyperparathyroidism, prolonged immobilization, dehydration, hypervitaminosis D, or renal impairment, are at higher risk of hypercalcemia. Monitor these patients for serum calcium and parathyroid hormone levels before and during CRYSVITA treatment for moderate to severe hypercalcemia. In patients with moderate to severe hypercalcemia, CRYSVITA should not be administered until hypercalcemia is adequately managed

Injection Site Reactions

- Administration of CRYSVITA may result in local injection site reactions. Discontinue CRYSVITA if severe injection site reactions occur and administer appropriate medical treatment

ADVERSE REACTIONS

Pediatric Patients

- Adverse reactions reported in 10% or more of CRYSVITA-treated pediatric XLH patients across three studies are: pyrexia (55%, 44%, and 62%), injection site reaction (52%, 67%, and 23%), cough (52%), vomiting (41%, 48%, and 46%), pain in extremity (38%, 46%, and 23%), headache (34% and 73%), tooth abscess (34%, 15%, and 23%), dental caries (31%), diarrhea (24%), vitamin D decreased (24%, 37%, and 15%), toothache (23% and 15%), constipation (17%), myalgia (17%), rash (14% and 27%), dizziness (15%), and nausea (10%)

Adult Patients

- Adverse reactions reported in more than 5% of CRYSVITA-treated adult XLH patients and in at least 2 patients more than placebo in one study are: back pain (15%), headache (13%), tooth infection (13%), restless legs syndrome (12%), vitamin D decreased (12%), dizziness (10%), constipation (9%), muscle spasms (7%), and blood phosphorus increased (6%)
- 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
- Adverse reactions reported in more than 10% of CRYSVITA-treated adult TIO patients in two studies are: tooth abscess (19%), muscle spasms (19%), dizziness (15%), constipation (15%), injection site reaction (15%), rash (15%), and headache (11%)

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 Kyowa Kirin, Inc. Adverse Event reporting line at 1-844-768-3544
- There is no information regarding the presence of CRYSVITA in human milk or the effects of CRYSVITA on milk production or the breastfed infant. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for CRYSVITA and any potential adverse effects on the breastfed infant from CRYSVITA or from the underlying maternal condition

PATIENT COUNSELING INFORMATION

- Advise patients not to use any oral phosphate and/or active vitamin D analog products
- Instruct patients to contact their physician if hypersensitivity reactions, injection site reactions, and restless legs 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 Kyowa Kirin, Inc. at 1-844-768-3544.

For important risk and use information, please see the full Prescribing Information for CRYSVITA.