

UPON ENROLMENT, A KYOWA KIRIN CARES™ CASE MANAGER WILL:

- Partner with and remain dedicated to your patient throughout the treatment journey
- Contact the patient or caregiver to review insurance coverage and support Program offerings

GETTING STARTED: STEPS FOR ENROLMENT IN KYOWA KIRIN CARES™*

Below are the steps for ensuring a complete enrolment in the Program so your patient can access the Program's suite of support services.

✓ OBTAIN PATIENT CONSENT*

The patient or the patient's legal representative's signature or the patient's verbal consent (confirmed with them in writing) is required to allow third parties to share personal health information with Kyowa Kirin

✓ SELECT PREFERRED PATIENT COMMUNICATION METHOD

Ask your patient and/or the patient's legal representative about how they will prefer to communicate with their Kyowa Kirin Cares Case Manager and their preferred time to contact them, as well as if a message can be left

✓ SPECIFY PRESCRIPTION FOR PrCRYSVITAM[™] (burosumab injection) [hereinafter "CRYSVITA"]

Ensure the physician provides a signature, date, contact information, and fax as necessary for the pharmacist to obtain a legally compliant prescription and to process the prescription

✓ PRESCRIBER INFORMATION

Provide contact details

*If the patient wants to opt out of the patient consent section, inform the Kyowa Kirin Cares team verbally on the phone or in writing to the email address below.

PATIENT AUTHORIZATION/CONSENT TO COLLECT, USE AND SHARE PERSONAL INFORMATION (the "Authorization")

I have been scripted by my physician a product for which Kyowa Kirin (as defined below) is the manufacturer (the "Product").

I understand that the Kyowa Kirin Cares Patient Support Program ("Program") for Healthcare Providers (as defined below) and patients is sponsored by Kyowa Kirin Canada, Inc., which is a subsidiary of Kyowa Kirin Inc. (a U.S. Company), the parent corporation being Kyowa Kirin Co., Ltd. (a Japanese company), together with their affiliated companies, their assigns, vendors, agents, collaboration partners, and representatives including providers of alternate sources of funding for prescription drug costs, and other service providers are herein collectively referred to as "Kyowa Kirin". I understand that the Program is administered by a third party service provider on behalf of Kyowa Kirin Canada, Inc. (the "Service Provider"). The current Service Provider is Innomar Strategies Inc. I understand that other Service Providers may be appointed by Kyowa Kirin to administer the Program and/or process my personal information from time to time.

By signing this Authorization, I authorize and consent to each of my prescribers, pharmacists, including any specialty pharmacy that receives my prescription for my medication and other healthcare providers (together "Healthcare Providers") and each of my health insurers (including any public or private payor) (together, "Insurers") to disclose my personal information and personal health information, including but not limited to medical records, information related to my medical condition and treatment, my lab values, my financial information, my health insurance coverage, my name, address, telephone number, insurance plan and or group numbers (together, "Personal Health Information") to Kyowa Kirin and its Service Providers supporting the services under the Program, for the purposes described below.

Specifically, I authorize and consent to the disclosure of my Personal Health Information to Kyowa Kirin and its Service Providers, and authorize Kyowa Kirin and its Service Providers to collect, use disclose, and exchange my Personal Health Information as described above with my Healthcare Providers and Insurers, for purposes of the Program, in order to:

- Manage and administer the Program, including to 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.
- Communicate with my Healthcare Providers and Insurers about benefits, coverage and medical care, including compliance with Product treatments and any legal reporting obligations.

- Locate a specialty pharmacy of my choice that can fill my prescription and facilitate dispensing of my prescription by such pharmacy.
- Provide me with educational materials, information, and services related to my treatment experience with my medication and my condition and as applicable work with third parties to provide community resources and referrals.
- Contact me and leave messages (including through telephonic and electronic means) about my use of my medication and my medical care, the Program and its services, or to obtain additional information to fulfill its legal obligations including adverse drug event reporting obligations.
- Verify, investigate, assist with, and coordinate my coverage for my medication with my Insurers.
- Coordinate prescription fulfillment.
- Conduct surveys, data analytics, market research, and other internal business activities related to the Program, my medication, and other Kyowa Kirin products and programs.
- As otherwise required or permitted by law, including to report adverse drug events to health authorities and to monitor product complaints.

I also understand that my personal information may be used and analysed by Kyowa Kirin and its Service Providers to improve the Program, to design and implement other patient programs, and for research purposes including the identification of trends such as patient use of the product, patient adherence to treatment regimens, and evaluating patient outcomes. Kyowa Kirin and its Service Providers may combine my personal information with the information of others who participate in the Program in order to generate anonymized and aggregated data that may be used by Kyowa Kirin and/or disclosed to third parties for research and reimbursement purposes. I understand that these uses of my personal information are optional and not required for my participation in the Program and that I can opt out of these uses by contacting the Program. I herein consent to said uses unless I opt out by contacting the Program.

I understand that I may refuse to sign this Authorization, and that I may withdraw consent to Kyowa Kirin's and its Service Provider's further collection, use and sharing of my Personal Health Information relating to all or any of the services or uses at any time by contacting the Program. My choice about whether to provide my consent or later revoke it will not change the way my Healthcare Providers or Insurers treat me, but may affect my ability to participate or receive assistance from the Program to the

extent that such consent(s) are required to administer or offer the Program. I understand that revoking my consent may not operate retroactively, for example, if my Personal Health Information has been combined with others of if Kyowa Kirin or its Service Providers are required by law to retain or disclose my personal information.

I also understand that if permitted by applicable law, I may contact the Program to exercise additional privacy rights, including the right to access, correct/rectify, or request deletion of my Personal Health Information, the right to obtain information about the processing of my Personal Health Information, and the right to request that my Personal Health Information be communicated or transferred to myself or a third-party in a structured and commonly used technological format, subject to such limitations as recognized in applicable law.

I understand that Kyowa Kirin and its Service Providers may transfer, process and store my Personal Health Information outside of the Province of Quebec and Canada (including in the United States), where my Personal Health Information may be accessible to foreign law enforcement and other authorities pursuant to a lawful request under the laws of that jurisdiction.

By acceptance of services under the Program, I herein agree that all information I (or my legal representative) provide to the Program is to my knowledge correct and complete. I understand and agree that I must notify Kyowa Kirin Cares at 833-KYOWA-CA immediately if any of the information I provide (including as applicable, my insurance status) changes during the Program enrollment period and that under NO circumstances may I or will I claim reimbursement from any third party (including any Insurers or any related third party) for any of the services or benefits provided to me under the Program. I understand that Kyowa Kirin reserves the right at any time without notice to modify or discontinue the Program and its criteria. I further herein agree and confirm that I will be solely responsible for making any requisite disclosures of receipt of any benefits under the Program to any public or third party payor.

For further information regarding Kyowa Kirin's and the Program's privacy program and practices, to withdraw consent, or to exercise other rights as may be available to me under applicable law, I understand that I can contact: 3470 Superior Court, Oakville, ON, L6L 0C4, via fax at 888- 355-1217, or by calling 833-596-9222. I am entitled to receive a copy of this Authorization.

My signature certifies that I have read and understand the above statements, and I agree to the outlined terms.

Patient Name (Print): _____ Patient or Patient's Legal Representative' Signature: _____ Date (DD/MM/YYYY): _____
Patient Signature: _____ For Patient Representative' – Relationship to Patient: _____

IMPORTANT: If health care provider is unable to obtain written consent from patient, please document when patient verbal consent was obtained. This will allow the Program to continue with processing this enrolment. Written consent will be obtained by the Program.

Physician attestation if consent is verbal: ☐ Patient consented verbally

Consent obtained by: ☐ Patient ☐ Patient's Legal Representative
Name (Last, First): _____

Physician Name (Last, First): _____

Physician Title: ☐ MD ☐ RN ☐ Other (specify) _____

Date (DD/MM/YYYY): _____ Physician Signature: _____

By providing my email address, I agree to receive, electronically, communications from Innomar acting on behalf of Kyowa Kirin Co., Ltd. containing information and updates relating to my enrolment in the Kyowa Kirin Cares Program. I understand that I may withdraw my consent to such communications at any time by providing notice to Innomar Strategies Inc., c/o Kyowa Kirin Cares Program, 3470 Superior Court, Oakville, ON, L6L 0C4, or via email at KKcares@innomar-strategies.com.

PATIENT INFORMATION: Be sure to choose your preferred contact method

First, Middle, Last Name _____
 Gender ☐ Female ☐ Male
 DOB (DD/MM/YYYY) _____
 Healthcare Card Number _____
 Street Address _____
 City _____ Province _____ Postal Code _____
 Home Phone (_____) _____ Work Phone (_____) _____
 Mobile Phone (_____) _____ Best Time to Contact _____
 Preferred Method of Contact ☐ Home ☐ Work ☐ Mobile
 Can leave message ☐ Yes ☐ No
 Email _____
 Preferred Language ☐ English ☐ French ☐ Other _____
 Patient's Legal Representative Name (First and Last) _____

 Relationship to Patient _____
 Patient's Legal Representative Phone (_____) _____

PRESCRIBER INFORMATION:

First Name _____
 Last Name _____
 Street Address _____
 City _____ Province _____
 Postal Code _____ License # _____
 Office Phone (_____) _____ Fax (_____) _____
 Office Email _____
 Office Contact Name/Title _____
 Office Contact Phone (_____) _____

CRYSVITA PRESCRIPTION INFORMATION:

CRYSVITA Prescription	<input type="checkbox"/> X-linked hypophosphatemia <input type="checkbox"/> Positive PHEX variant test <input type="checkbox"/> Tumour-induced osteomalacia						
	Supplied as: 10 mg/mL single-dose vial, 20 mg/mL single-dose vial, 30 mg/mL single-dose vial. Subcutaneous Injection Only.						
<input type="checkbox"/> XLH <input type="checkbox"/> TIO	Date Weight Taken (DD/MM/YYYY)	Patient Weight (in kg)	Initial Dose Prescribed <input type="checkbox"/> 0.8 mg/kg (Pediatric XLH) <input type="checkbox"/> 1 mg/kg (Adult XLH) <input type="checkbox"/> 0.5 mg/kg (Adult TIO)	Total Calculated Dose XLH <input type="checkbox"/> Round down to the nearest 1 mg and min dose is 5 mg (Pediatric 6 months to <1 year) <input type="checkbox"/> Round to the nearest 10 mg and max dose is 90 mg (Pediatric ≥ 1 year and adult)	Frequency <input type="checkbox"/> Every 2 weeks (Pediatric XLH) <input type="checkbox"/> Every 4 weeks (Adult XLH and TIO)	Days' Supply (Limit: 28 days)	Refills
			$\text{Weight (kg)} \times \text{Initial dose (mg/kg)} = \text{Total dose (mg)}$	TIO <input type="checkbox"/> Rounded to the nearest 10 mg, up to a maximum dose of 2 mg/kg			
Other disorders of phosphorus metabolism _____ Other _____							
Prescriber Signature _____ Date (DD/MM/YYYY) _____							
Special Instructions _____							
Special Precautions (eg, Allergies) _____							

Consult the Product Monograph at <https://international.kyowa-kirin.com/share/ca/Crysvita-Product-Monograph.pdf> for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also by visiting www.international.kyowa-kirin.com.



CRYSVITA FOR X-LINKED HYPOPHOSPHATEMIA (XLH) AND TUMOUR-INDUCED OSTEOMALACIA (TIO)

Below is the information on CRYSVITA dosages and dose adjustment schedules for patients with XLH or TIO.

XLH DOSING REGIMENS:

Pediatric XLH (6 months to < 1 year of age): For patients with a body weight ≥ 6 kg, starting dose regimen is 0.8 mg/kg of body weight, rounded down to the nearest 1 mg, administered every 2 weeks. The minimum starting dose is 5 mg.

Dose increase: If serum phosphorus is below the reference range for age, the dose may be increased stepwise in 0.4 mg/kg intervals up to a maximum of 1.2 mg/kg, administered every two weeks. The calculated dose should be rounded to the nearest 1 mg.

Pediatric XLH (1 year to 18 years of age): 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
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



Measure fasting serum phosphorus every 4 weeks for the first 3 months of treatment, and thereafter as appropriate.



Continue treatment with the same dose if serum phosphorus is within the lower limit of the reference range for age.



If serum phosphorus is below the reference range for age, dose may be increased stepwise in 0.4 mg/kg intervals up to a maximum of 2 mg/kg administered every 2 weeks. Do not adjust the CRYSVITA dose more frequently than every 4 weeks.



Maintain serum phosphorus within the reference range for age by following the dose adjustment schedule.



Check patient weight periodically to ensure proper total dose for patient weight is being administered.

DOSE DECREASE FOR ALL PEDIATRIC PATIENTS:



Withhold the next dose and reassess the serum phosphorus level in 4 weeks if serum phosphorus is above the reference range for age.






Confirm that serum phosphorus is below the reference range for age.

Once serum phosphorus is below the reference range for age	Restart	Reassess	Adjust
	Restart treatment at half the dose level previously administered.	Reassess serum phosphorus level 4 weeks after dose adjustment.	If serum phosphorus level is below the reference range for age, the dose can be gradually increased according to instructions.

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.

TIO DOSING REGIMEN:

Adult TIO (18 years of age and older): Starting dose is 0.5 mg/kg every 4 weeks.[‡] Dose may be increased stepwise up to a maximum of 2 mg/kg, administered every 2 weeks.[§]

Starting Dose	0.5 mg/kg every 4 weeks
	Assess fasting serum phosphorus on a monthly basis, measured 2 weeks post-dose, for the first 3 months of treatment, and thereafter as appropriate.
	Continue with the same dose if serum phosphorus is within the normal range.
	Maintain serum phosphorus within the reference range by following the dose adjustment schedule.

If serum phosphorus 2 weeks post-dose adjustment is below lower limit of normal*	First Dose Increase [¶]	Second Dose Increase [¶]	Third Dose Increase [¶]	Fourth Dose Increase	Fifth Dose Increase (maximum dose)
	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 every 2 weeks.	Increase to 2 mg/kg every 2 weeks.

If serum phosphorus is above the normal range	Withhold	Confirm	Decrease Dose	Reassess	Adjust Dose
	Withhold the next dose and reassess the serum phosphorus level in 4 weeks.	Confirm serum phosphorus below the reference range.	Restart at approximately half the initial starting dose administered every 2 weeks.	Reassess the serum phosphorus level 2 weeks after the dose adjustment.	If serum phosphorus is below the reference range after restarting the dose, the dose can be adjusted.

If patient undergoes treatment of the underlying tumour (i.e., surgical excision or radiation therapy)	Interrupt	Reassess	Restart
	Interrupt CRYSVITA treatment.	Reassess serum phosphorus after treatment is completed.	Restart CRYSVITA dose at the patient's initiation dose if serum phosphorus remains below the lower limit of normal.

Please consult the Product Monograph for complete dosing and administration instructions.



CRYSVITA is indicated for the treatment of:

- X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older.
- FGF23-related hypophosphatemia in tumour-induced osteomalacia (TIO) associated with tumours that cannot be curatively resected or localized in adult patients.

*Kyowa Kirin Cares Program™ herein referred to as "Program"

†NOTE: a patient's legal representative must be a person who is legally entitled and authorized to make decisions on behalf of the Patient with regard to their personal information (including Personal Health Information) and health care in cases where the Patient is not legally capable of doing so.

‡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 every 2 weeks.