***Please Note: This letter is intended as an example for your consideration and may not include all the information necessary to support your prior authorization request. Requirements will vary based on the health plan guidelines and patient benefit design. Please note the requesting provider is entirely responsible for ensuring the accuracy, adequacy, medical necessity, and supportability of all information required. Further, the requesting provider is solely responsible for submission to and follow-up with the health plan regarding this prior authorization request. Use of this document does not guarantee coverage or reimbursement and is not intended to be a substitute for or an influence on the independent medical judgment of the physician.***

*This template is provided by Kyowa Kirin Inc. for informational purposes only for patients and their physicians. Prescribers are not required to use Kyowa Kirin products in relation to or exchange for this template and should use their own medical judgement when determining patient treatment.*

[Healthcare Provider Letter Head]

Attention: Regarding:

[Medical Director Name] [Patient Name] Patient Insurance: [Patient’s Insurance Company] [Patient Date of Birth]

Address: [Insurance Policy Number][City, State, Zip Code] [Insurance Claim Number]

Request:

Authorization for treatment with [Drug Name] Diagnosis: [Diagnosis and ICD-10 Code] Dosage: [Dosing and Frequency]

[Date]

Dear [Medical Director Name]

I am writing on behalf of my patient, [Patient Name], to request authorization for and document the medical necessity of Crysvita (burosumab twza) for the treatment of [Drug's Indication].

This request is supported by the following information:

# Patient History: Diagnosis, Treatment, and Current Medical Condition

* [Patient's diagnosis, date of diagnosis]
* [Laboratory results and date]
* [Brief description of patient's current medical condition]
* [Patient's previous and current treatments/therapies]
* [Patient's response to those treatments/therapies]
* [If the patient has discontinued, include information on lack of response or tolerability]

# Rationale for Treatment With Crysvita

Based on the patient's medical history, [his/her] current medical condition, and evidence supporting the use of Crysvita for [Drug's Indication], I believe treatment with Crysvita at this time is warranted, appropriate, and medically necessary for this patient.

This therapy, Crysvita, will not be used in combination with oral phosphate and/or active vitamin D analogs, and when serum phosphorus is within the normal range for age, and in patients with severe renal impairment or end stage renal disease.

 I am enclosing the following supporting documentation for your review:

* Crysvita Indication and Important Safety Information
* Crysvita full Prescribing Information –

(To be attached - Crysvita\_Full\_Prescribing\_Information)

Please call my office at [telephone number] if you require any additional information or documentation to support the treatment authorization.

Sincerely,

[HealthCare Provider Name and Associated ID Numbers]

Enclosures

## **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.1
* 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**

# 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**](http://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 accompanying full [**Prescribing Information**](https://kkna.kyowakirin.com/wp-content/uploads/PI_Crysvita.pdf).