**SAMPLE LETTER FOR DENIAL APPEAL**

***Please Note: This letter is intended as an example for your consideration and may not include all the information necessary to support your appeal. 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 appeal. 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.***

[PRESCRIBER LETTERHEAD]

(Date)

(Payer name)

ATTN: APPEALS

(Type in payer name)

(Type in payer address)

**Patient:** (Type in patient’s first and last name)

**Subscriber ID#**: (Type in insurance ID#)

**Subscriber Group #**: (Type in insurance group#)

**Re:** Crysvita® (Burosumab-twza) injection for subcutaneous use

**Dates of Service:** (Include all denied dates of service)

Dear Appeals Reviewer:

I am writing to request appeal of the above denial(s) of Crysvita® (Burosumab-twza) injection for my patient [patient name]. I understand from your denial letter that the denialswere based on [denial reason]. I would like to address [that reason/those reasons] now.

The FDA approved the use of CRYSVITA for the treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients 6 months of age and older and 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.

Please see the enclosed documentation demonstrating the medical necessity of Crysvita for my patient, (type in patient name). (He/she) has [X-linked hypophosphatemia (XLH) / hypophosphatemia in tumor induced osteomalacia (TIO)]. I would appreciate prompt review of this information for authorization of Crysvita.

**Patient’s Clinical History**

[Patient’s name] is a [age] year old [male/female] who was diagnosed in [date] with [stage of

disease] [MF/SS]. Systemic treatment options for patients with MF/SS are limited.

[He/She] underwent [describe treatment to date].

􀀀 [Be sure to include diagnosis and dates]

􀀀 [Past treatments]

􀀀 [Test results that indicate failure of past treatment]

􀀀 [Social & family information (especially if young patient)]

[i.e. young children or grandchildren, contributes to the well-being of the family, part-time

work, volunteer work]

# 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 X-linked hypophosphatemia (XLH) / hypophosphatemia in tumor induced osteomalacia (TIO)] , 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.

**Summary**

In summary, I am requesting appeal of the denial(s) of Product therapy for my patient, [Patient Name]. [He/She] was diagnosed with X-linked hypophosphatemia (XLH) / hypophosphatemia in tumor induced osteomalacia (TIO)] with few treatment options. I am requesting that you reconsider coverage based on the information above. I am readily available at my office phone [MD phone#] to address any questions or concerns you might have regarding this appeal.

Thank you for your time and consideration.

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

Sincerely,

(Physician’s name and credentials)

Suggested Enclosures

USPI

Relevant clinical/chart notes