Welcome to **Kyowa Kirin Cares**

Enroll your patients who have been prescribed CRYSVITA so they can access available support.

Begin the process at kyowakirincares.com:

Download the Kyowa Kirin Cares CRYSVITA enrollment form, fill it out with your patient's information, and fax it to 833-529-3299.

Kyowa Kirin Cares helps to get your patients from prescription to therapy quickly and seamlessly.

Once you enroll, a Case Manager will assist your patients with information regarding access and reimbursement options.

Upon receiving the completed enrollment form, Kyowa Kirin Cares will begin the benefits investigation (BI) process for the patient.

Within two business days, you will be informed of the status of the BI. If CRYSVITA is covered by the patient's insurance, you will receive a summary of the BI. If a prior authorization or exception is required, a Case Manager will call to inform you of next steps.

Patient Access Liaisons (PALs) can help navigate diagnostic documentation required for insurance coverage.

Contact Kyowa Kirin Cares by calling 833-KK-CARES (833-552-2737).

Kyowa KIRIN cares
ACCESS • ASSISTANCE • UNDERSTANDING

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

A Case Manager can help your patients navigate their access options

Commercial insurance

- Kyowa Kirin offers co-pay assistance for eligible commercially insured patients
- Review the co-pay assistance terms and conditions to determine if your patients with commercial insurance qualify[a,b]

Government insurance

- Kyowa Kirin does not offer co-pay assistance for patients with federal or state government insurance such as Medicare, Medicaid and Tricare
- A Case Manager may be able to provide patients with government insurance with information about other available co-pay assistance programs

No insurance

- Kyowa Kirin offers a Patient Assistance Program for eligible uninsured patients[c]
- Download the application to review the terms and conditions and determine if your patients without insurance qualify[d]

[a] Patients must be US residents with an active primary commercial plan; patients with federal or state government insurance such as Medicare, Medicaid, and Tricare are not eligible for co-pay assistance. Other terms and conditions may apply.
[b] Commercially insured patients do not need to participate in Kyowa Kirin Cares to be eligible for co-pay assistance.
[c] Patients who do not meet the Patient Assistance Program coverage criteria and have special circumstances of financial and/or medical hardship, as determined in accordance with Kyowa Kirin Cares criteria, can request that an exception be made for them. The decision to grant an exception is based on an individual's unique circumstances and is made solely at the discretion of Kyowa Kirin.
[d] Patients must be US residents with no active medical or pharmacy benefit coverage and an annual gross income ≤400% of the federal poverty level, as confirmed by documented proof of income.

Kyowa Kirin Cares works with you to give your patients ongoing support

CRYSVITA® burosumab-twza injection 10, 20, 30 mg/mL

A dedicated Case Manager will be available to:

- Answer questions about the treatment experience
- Answer general questions about CRYSVITA
- Provide external resources, when applicable
- Support patients throughout their treatment journey

Questions? Call 833-KK-CARES (833-552-2737)
Monday through Friday, 8 AM to 8 PM (ET)

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

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

Important Safety Information continued on next page.

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

Important Safety Information (cont)

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

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

Important Safety Information continued on next page.

CRYSVITA®
burosumab-twza
Injection 10, 20, 30 mg/mL

Important Safety Information (cont)

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%)
- Postmarketing experience reported in CRYSVITA-treated pediatric XLH patients: blood phosphorus increased

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.

[1]CRYSVITA. Prescribing Information. Kyowa Kirin Inc. Princeton, NJ.

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