



**Mineral Deficiency Drugs**  
**Crysvita (burosumab-twza) J0584,**  
**Parsabiv (etelcalcetide) J0606, Miacalcin**  
**(calcitonin salmon) J0630**  
**Prior Authorization Request**  
**Medicare Part B Form**

*Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

<input type="checkbox"/>	<b>Standard Request– (72 Hours)</b>	<input type="checkbox"/>	<b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

**MEMBER INFORMATION**

\*Name: \_\_\_\_\_ \*ID#: \_\_\_\_\_ \*DOB: \_\_\_\_\_

**PRESCRIBER INFORMATION**

\*Name: \_\_\_\_\_ MD FNP DO NP PA \*Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ \*Fax: \_\_\_\_\_

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

\*Name: \_\_\_\_\_ Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ Fax: \_\_\_\_\_

**PROCEDURE / PRODUCT INFORMATION**

HCP Code	Name of Drug	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Self-administered       Provider-administered       Home Infusion

Chart notes attached. **Other important information:** \_\_\_\_\_

**Diagnosis: ICD10:** \_\_\_\_\_ **Description:** \_\_\_\_\_

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

**Parsabiv - New Start or Initial Request: (Clinical documentation required for all requests)**

- Diagnosis of secondary hyperparathyroidism with chronic kidney disease.
- Patient is on dialysis.
- All of the following:
  - History of failure, contraindication, or intolerance to one phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.); and
  - History of failure, contraindication, or intolerance to one vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.); and
  - History of failure of maximum tolerated dosage, adverse reaction, or contradiction to Sensipar (cinacalcet hydrochloride) and
  - Patient is not receiving Parsabiv (etelcalcetide) in combination with Sensipar (cinacalcet hydrochloride);
- Prescribed by or in consultation with an endocrinologist or nephrologist;

**Crysvita - New Start or Initial Request: (Clinical documentation required for all requests)**

- Diagnosis of XLH, confirmed by one of the following:
  - Genetic testing (e.g., confirmed PHEX gene mutation in patient or first-degree relative)
  - Elevated Serum fibroblast growth factor 23 (FGF23) level > 30 pg/mL
  - All of the following biochemical findings associated with XLH
    - Serum phosphate < 3.0 mg/dL (0.97 mmol/L)
    - Serum creatinine (SCr) below age adjusted upper limit of normal (ULN)
    - Serum 25(OH)D ≥ 16 ng/mL
- Patient's epiphyseal plate has fused
- Fasting serum phosphorus is below the normal range for age
- Prescribed by or in consultation with an endocrinologist or specialist experienced in the treatment of metabolic bone disorders;

**Miacalcin - New Start or Initial Request: (Clinical documentation required for all requests)**

- Diagnosis of Hypercalcemia
  - Hypercalcemia documented/confirmed by labs and clinical testing
- Diagnosis of osteoporotic vertebral fracture
  - Osteoporotic spinal compression fracture has been verified on imaging with correlating clinical signs and symptoms suggesting an acute injury; and
  - The date of imaging must be 0 to 5 days after an identifiable event or onset of symptoms and within 4 weeks of the medication request; and
  - Member has a contraindication, intolerance, or ineffective response to standard analgesic therapy (e.g., non-steroidal anti-inflammatory drug (NSAID), acetaminophen); and
  - Member cannot tolerate or has a contraindication to intranasal calcitonin; and
  - Member is neurologically intact.
- Diagnosis of Paget's Disease
  - Member has symptomatic disease (e.g., bone pain, bone deformity, fracture, hearing loss);
  - Member has failed prior treatment with or is intolerant to injectable bisphosphonate (e.g., zoledronic acid (Reclast), pamidronate).
- Diagnosis of Postmenopausal osteoporosis
  - Member is greater than 5 years postmenopausal; and
  - Member has a history of fragility fractures, or has a pre-treatment T-score less than or equal to -2.5, or member has osteopenia (i.e., pre-treatment T-score greater than -2.5 and less than -1) with a high pre-treatment FRAX fracture probability (See Appendix B);
  - Member has failed prior treatment, or has a clinical reason to avoid oral bisphosphonate
  - Member has failed prior treatment with or is intolerant to previous injectable osteoporosis therapy (e.g., zoledronic acid [Reclast], denosumab [Prolia], etc);
  - Member has failed prior treatment or has a contraindication to intranasal calcitonin

**Continuation Requests: (Clinical documentation required for all requests)**

- Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_  
\_\_\_\_\_

**ACKNOWLEDGEMENT**

**Request By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

## Prior Authorization Group –Mineral Deficiency Drugs PA

### Drug Name(s):

<b>CRYSVITA</b>	<b>BUROSUMAB-TWZA</b>
<b>PARSABIV</b>	<b>ETELCALCETIDE</b>
<b>MIACALCIN</b>	<b>CALCITONIN SALMON</b>

### Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
  - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
  - Quantity limits and Tiering will be determined by the Plan.

### Exclusion Criteria:

N/A

### Prescriber Restrictions:

- Endocrinologist or Nephrologist

### Coverage Duration:

Approvals will be for 12 months

### FDA Indications:

#### Crysvita

- Familial x-linked hypophosphatemic vitamin D refractory rickets
- Tumor-induced osteomalacia

#### Miacalcin

- Hypercalcemia
- Paget's disease
- Postmenopausal osteoporosis

#### Parsabiv

- Chronic kidney disease stage 5 on dialysis - Secondary hyperparathyroidism

### Off-Label Uses:

#### Miacalcin

- Cancer pain; Adjunct
- Fracture of bone; Prophylaxis - Osteoporosis
- Osteoporosis due to corticosteroid

### Age Restrictions:

Safety and efficacy have not been established in patients younger than 18 years

### Other Clinical Considerations:

N/A

### Resources:

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/D96880/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYNC/D81A83/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932052&contentSetId=100&title=Etelcalcetide&serviceTitle=Etelcalcetide&brandName=Parsabiv&UserMdxSearchTerm=Parsabiv&=&null#](https://www.micromedexsolutions.com/micromedex2/librarian/CS/D96880/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/D81A83/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932052&contentSetId=100&title=Etelcalcetide&serviceTitle=Etelcalcetide&brandName=Parsabiv&UserMdxSearchTerm=Parsabiv&=&null#)

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).



## Part B Prior Authorization Guidelines

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/90179D/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYN/C/8C0B4A/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932462&contentSetId=100&title=Burosumab-twza&servicesTitle=Burosumab-twza&brandName=Crysvita&UserMdxSearchTerm=Crysvita&=null](https://www.micromedexsolutions.com/micromedex2/librarian/CS/90179D/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN/C/8C0B4A/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932462&contentSetId=100&title=Burosumab-twza&servicesTitle=Burosumab-twza&brandName=Crysvita&UserMdxSearchTerm=Crysvita&=null)

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/6C7189/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DUPLICATIONSHIELDSYN/C/AB2C47/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=099515&contentSetId=100&title=Calcitonin+%28Salmon%29&servicesTitle=Calcitonin+%28Salmon%29&brandName=Miacalcin&UserMdxSearchTerm=miacalcin&=null](https://www.micromedexsolutions.com/micromedex2/librarian/CS/6C7189/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYN/C/AB2C47/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=099515&contentSetId=100&title=Calcitonin+%28Salmon%29&servicesTitle=Calcitonin+%28Salmon%29&brandName=Miacalcin&UserMdxSearchTerm=miacalcin&=null)

CLINICAL / CMS  
ONLY