Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
IV Biphosphonate and Monoclonal Antibodies for Treatment of Osteoporosis and Other: Denosumab (Prolia®, Jubbonti®, Wyost®, Xgeva®), Ibandronate IV (Boniva®)	MP-RX-FP-123-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of denosumab products (Prolia, Xgeva, and their interchangeable products Jubbonti and Wyost), a monoclonal antibody approved by the Food and Drug Administration (FDA) for:

- The treatment of postemenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men at high risk for fracture and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer (Prolia and Jubbonti).
- The prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors, treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and teatment of hypercalcemia of malignancy refractory to bisphosphonate therapy (Xgeva and Wyost).

This document also addresses the use of Ibandronate inj (Boniva®), a bisphosphonate approved by the Food and Drug Administration (FDA) for the treatment of osteoporosis in postemenopausal women.

Background Information

The American College of Endocrinology (AACE/ACE) (2020) osteoporosis treatment guidelines stratify initial treatment based on risk status. For those at high risk/no prior fractures, initial therapy options include bisphosphonates (alendronate, risedronate, or zoledronic acid) or denosumab. For those at very high risk/prior fractures, initial therapy options are denosumab, abaloparatide, teriparatide, romosozumab, or zoledronic acid. The Endocrine Society osteoporosis guideline update (2020) recommends initial therapy with bisphosphonates (alendronate, risedronate, zoledronic acid, or ibandronate) or alternatively denosumab for those at high risk.

Osteoporosis may be diagnosed by bone mineral density (BMD) testing indicating a T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population. It also may be clinically diagnosed based on a history of a fragility fracture (low trauma fracture).

Higher risk for fracture may be defined as:

1. History of osteoporotic fracture; **OR**

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2. Multiple risk factors for fractures, including but not limited to:
   - Prior low-trauma fracture as an adult
   - Advanced age
   - Low bone mineral density (T-score -1.0 to-2.5)
   - Low body weight (<57.6kg)
   - Family history of osteoporosis
   - Use of glucocorticoids, (daily dosage equivalent to 5mg or greater prednisone for at least 3 months)
   - Current cigarette smoking
   - Excessive alcohol consumption (3 or more drinks per day)
   - Secondary osteoporosis (such as rheumatoid arthritis)
   - Early menopause
   - Height loss of kyphosis
   - Fall risk and low calcium intake; **OR**

3. Failure or intolerance to other osteoporosis therapies: A failure of other osteoporosis therapies, otherwise known as refractory disease, may be defined as a decline in BMD while on therapy (>5%) or a fragility fracture while on therapy.

AACE/ACE (2020) recommends obtaining a baseline axial (lumber spine and hip; 1/3 radius if indicated) dual-energy X-ray absorptiometry (DXA) and after treatment initiation, repeat DXA every 1 to 2 years until findings are stable. Depending on clinical circumstances, follow-up DXA every 1 to 2 years or less frequently can be continued thereafter. Successful response to osteoporosis therapy is considered when BMD is stable or increasing with no evidence of new fractures or vertebral fracture progression.

Black box warnings on Prolia and Jubbonti address severe hypocalcemia in patients with advanced kidney disease. It is recommended that prior to treatment, these patients should be supervised by a healcare provider with expertise in the diagnosis and management of chronic kidney disease with mineral bone disorder

Products in this document include:

- Prolia (denosumab) and Jubbonti (denosumab-bbdz)
- Xgeva (denosumab) and Wyost (denosumab-bbdz)
- Boniva (ibandronate IV)

Clinical Criteria:

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B vs D Criteria: Prolia and Xgeva drugs included in this PA are subject to B vs D evaluation. Medication must be furnished "incident to" physician service provided and usually not self-administered to be covered by Medicare and to be eligible to be evaluated through part B. If not, medication must be evaluated through part D.

Prolia (Denosumab) or Jubbonti (denosumab-bbdz)

Approved Indication (s)

A. Treatment of postmenopausal women with osteoporosis at high risk for fracture.
B. Treatment to increase bone mass in men with osteoporosis.
C. Treatment of Glucocorticoid-Induced Osteoporosis.
D. Treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer.
E. Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer.

Other Uses

A. N/A

Xgeva (Denosumab) or Wyost (denosumab-bbdz)

Approved Indication (s)

A. Prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors.
B. Treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
C. Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

Other Uses

A. N/A

Ibandronate (Boniva)

Approved Indication

A. Treatment of postmenopausal osteoporosis

Other Uses

A. Bone metastasis (Micromedex Category IIb; Lexi-Drugs Level of Evidence A): Ibandronate, whether administered intravenously or orally, demonstrated a notable decrease in the occurrence of skeletal-related events (SRE) and bone pain scores over 96 weeks, according to a comprehensive review involving 10 studies comprising 3473 patients with metastatic bone disease or multiple myeloma.

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Specifically, the risk ratio (RR) for SRE reduction was 0.8 (95% CI, 0.71 to 0.9; based on 4 studies involving 1099 patients), while the weighted mean difference in bone pain score was -0.41 (95% CI, -0.56 to -0.27; based on 2 studies involving 876 patients) when compared to a placebo.

In comparison with zoledronate, ibandronate showed similar rates of SRE occurrence (RR, 1.02; 95% CI, 0.82 to 1.26; based on 2 studies involving 1454 patients). However, differences in study design hindered a direct comparison of changes in bone pain scores from baseline.

SREs, encompassing hypercalcemia, pathological fracture, bone-related radiotherapy or surgery, and spinal cord compression, were significantly reduced with ibandronate. However, there was a higher incidence of abdominal pain associated with ibandronate compared to placebo, alongside similar risks of diarrhea, nausea, and renal toxicity.

Compared to zoledronate, ibandronate exhibited a significantly lower risk of fever or influenza-like symptoms and renal toxicity. However, risks of anorexia, fatigue, and jaw necrosis were comparable between the two medications.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J0897	Injection, denosumab, 1 mg [Prolia, Xgeva]
J3590	Unclassified biologics [when specified as Jubbonti or Wyost]
Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg (Effective 10/1/2024)
J1740	Injection, ibandronate sodium, 1 mg

ICD-10	Description
C00.0-C39.9	Malignant neoplasm
C40.00-C41.9	Malignant neoplasm of bone and articular cartilage
C43.0-C60.9	Malignant neoplasms
C61	Malignant neoplasm of prostate
C62.00-C75.9	Malignant neoplasms
C76.0-C76.8	Malignant neoplasm of other and ill-defined sites
C79.51	Secondary malignant neoplasm of bone
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms
D48.0	Neoplasm of uncertain behavior of bone and articular cartilage [specified as GCTB
E83.52	Hypercalcemia
M81.0-M81.8	Osteoporosis without current pathological fracture
M85.80-M85.9	Other specified disorders of bone density and structure [osteopenia]
N95.1	Menopausal and female climacteric states
Z08	Encounter for follow-up examination after completed treatment for malignant neoplasm
Z51.11-Z51.12	Encounter for antineoplastic chemotherapy and immunotherapy
Z78.0	Postmenopausal status NOS
M80.0	Age-related osteoporosis with current pathological fracture
N95.9	Unspecified menopausal and perimenopausal disorder
Z79.51-Z79.52	Long term (current) use of steroids
Z79.811	Long term (current) use of aromatase inhibitors
Z79.899	Other long term (current) drug therapy [prophylactic drug therapy]
Z85.00-Z85.45	Personal history of malignant neoplasms
Z85.46	Personal history of malignant neoplasm of prostate
Z85.47-Z85.59	Personal history of malignant neoplasms
Z85.810-Z85.9	Personal history of malignant neoplasms
Z87.310	Personal history of (healed) osteoporosis fracture
M80.00XA- M80.88XS	Osteoporosis with current pathological fracture

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria:

B vs D Criteria: Prolia and Xgeva drugs included in this PA are subject to B vs D evaluation. Medication must be furnished "incident to" physician service provided and usually not self-administered to be covered by Medicare and to be eligible to be evaluated through part B. If not, medication must be evaluated through part D.

Prolia (Denosumab) or Jubbonti (denosumab-bbdz)

A. Criteria For Initial Approval

For the treatment of Osteoporosis in men, postmenopausal women, and glucocorticoid-induced osteoporosis

i. Individual is 18 years of age or older

AND

ii. Individual meets one of the following diagnostic criteria of osteoporosis:

- A. Individual is a male or postmenopausal female with any of the following:
  - a. A diagnosis of osteoporosis based on the Tscore (defined as a bone mineral density (BMD) Tscore of ≤ -2.5); **OR**
  - b. A clinical diagnosis of osteoporosis based on history of a low trauma fracture (fragility fracture).

OR

- B. Individual has glucocorticoid-induced osteoporosis with any of the following:
  - a. A bone mineral density (BMD) T-score of ≤ -2.5) while initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for a least 6 months); **OR**
  - b. A clinical diagnosis of osteoporosis based on history of a low trauma fracture (fragility fracture) while initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for a least 6 months).

AND

iii. Individual is at high risk of fracture, defined as having **ONE OR MORE** of the following criteria:

- A. Individual has had at least one osteoporotic (minimal trauma) fracture; **OR**
- B. Individual has two or more of the following risk factors for osteoporotic fracture;
  1. Age between 40-90

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2. Body Mass Index (BMI) (less than 21 kg/m^2)
3. History of fragility fracture
4. Cigarette smoking
5. Prior fracture
6. Rheumatoid Arthritis
7. Secondary osteoporosis (e.g., type 1 diabetes, osteogenesis imperfecta in adults, longstanding hyperthyroidism, hypogonadism, premature menopause [before age 40], chronic malabsorption and chronic liver disease
8. Exposed to ≥5 mg/day of prednisolone for ≥3 mo (or equivalent doses of other glucocorticoids)
9. Alcohol use of greater than 2 medium glasses of wine or beer per day
10. Hip fracture in mother or father; **OR**

C. Individual has failed, is intolerant to or has a medical contraindication to other available osteoporosis therapies (for example, bisphosphonates).

<u>To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer</u>

i. Patient is a postmenopausal (natural or induced) female; **AND**
ii. Patient is receiving adjuvant aromatase inhibitor therapy (e.g. anastrazole, exemestane, letrozole) for treatment of breast cancer.

<u>To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer</u>

i. Individual is a male with a diagnosis of nonmetastatic prostate cancer; **AND**
ii. Individual is a receiving androgen deprivation therapy (e.g. leuprolide, goserelin, histerelin); **AND**
iii. Individual is at high risk of fracture, defined as having **ANY** of the following criteria:
    A. Individual has had at least one osteoporotic (minimal trauma) fracture; **OR**
    B. Individual has one or more of the following risk factors for osteoporotic fracture;
        1. Age between 40-90
        2. Body Mass Index (BMI) (less than 21 kg/m2)
        3. History of fragility fracture
        4. Cigarette smoking
        5. Prior fracture
        6. Rheumatoid Arthritis

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7. Secondary osteoporosis (e.g., type 1 diabetes, osteogenesis imperfecta in adults, longstanding hyperthyroidism, hypogonadism, premature menopause [before age 40], chronic malabsorption and chronic liver disease
8. Exposed to ≥5 mg/day of prednisolone for ≥3 mo (or equivalent doses of other glucocorticoids)
9. Alcohol use of greater than 2 medium glasses of wine or beer per day
10. Hip fracture in mother or father

B. Criteria For Continuation of Therapy

i. There is confirmation of clinically significant response to therapy (including but not limited to confirmation of no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction); **AND**

ii. If individual has been on therapy ≥ 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.

C. Authorization Duration

A. Initial Approval Duration: 1 year
B. Reauthorization Approval Duration: 1 year

Xgeva (denosumab) or Wyost (denosumab-bbdz)

A. Criteria For Approval

i. Individual is 18 years of age or older; **AND**
ii. Individual is using for the prevention of skeletal-related events with one of the following conditions:
A. Multiple myeloma; **OR**
B. Bone metastases from solid tumor other than prostate cancer; **OR**
C. Bone metastases from castration resistant/recurrent prostate cancer;

OR

iii. Individual is 18 years of age or older; **AND**
iv. Individual is using for the treatment of hypercalcemia of malignancy (defined as an albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L)); **AND**
v. Patient is refractory to recent (within last 30 days) treatment with intravenous bisphosphonate therapy (such as pamidronate or zoledronic acid)

OR

vi. Individual has diagnosis of localized or metastatic giant cell tumor of the bone (GCTB); **AND**
A. The patients condition is unresectable; **OR**

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B. Surgical resection is likely to result in severe morbidity;
AND
C. Individual is 18 years of age or older; **OR**
D. Individual is a skeletally mature adolescent (defined by at least one mature long bone [for example; closed epiphyseal growth plate of the humerus])

B. Criteria For Continuation of Therapy

I. There is documentation of clinically significant response to therapy.

C. Authorization Duration

I. Initial Approval Duration: 1 year
II. Reauthorization Approval Duration: 1 year

Ibandronate IV (Boniva)

A. Criteria For Initial Approval

i. The patient has a diagnosis of postmenopausal osteoporosis defined as
   a. A bone mineral density (BMD) Tscore ≤ -2.5; **OR**
   b. A clinical diagnosis based on history of a low trauma fracture (fragility fracture) or osteoporotic fracture;

AND

ii. Patient has experienced treatment failure, or contraindication, or adverse side effects, to oral or self-administered drugs for osteoporosis, as evidenced by **ANY** of the following:
   a. Patient has a diagnosis of esophageal stricture, achalasia, or other severe esophageal dysmotility disorder; **OR**
   b. Patient has a history of severe malabsorption making use of oral bisphosphonates ineffective; **OR**
   c. Patient has an inability to stand or sit upright for 60 minutes; **OR**
   d. Patient has documented adverse effects following the initiation of treatment of the oral form of the medication that required the withdrawal of the oral form of the medication.

OR

iii. The patient has pain related to cancer with bone metastasis (Compendia; Lexi-Drugs Level of Evidence A; Micromedex IIb);

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B. Criteria For Continuation of Therapy

i. There is confirmation of clinically significant response to therapy (including but not limited to confirmation of no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction)

C. Authorization Duration

i. Initial Approval Duration: 1 year
ii. Reauthorization Approval Duration: 1 year

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for ibandronate i.v. may not be approved when the above criteria are not met and for all other indications.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Dosage
Prolia (denosumab) 60 mg/1 mL prefilled syringe or vial	60 mg SC or IV every 6 months
Jubbonti (denosumab-bbdz) 60 mg/1 mL prefilled syringe	60 mg (1 prefilled syringe) every 6 months
Xgeva (denosumab) 120 mg/1.7 mL vial*	120mg (1 vial) SC every 4 weeks
Wyost (denosumab-bbdz) 120 mg/1.7 mL vial*	120mg (1 vial) SC every 4 weeks
Boniva (Ibandronate) 1 MG/1 ML	Osteoporosis: 3mg IV every 3 months

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Exceptions
*Xgeva (denosumab) or Wyost (denosumab-bbdz): **For Giant Cell Tumor and Hypercalcemia of Malignancy**: Only during the first month of therapy, two (2) additional 120 mg doses (to be administered on Days 8 and 15) will be approved.

Reference Information

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3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
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5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2022. Updated periodically.
6. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
7. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221.
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10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

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11. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, The Journal of Clinical Endocrinology & Metabolism, Volume 105, Issue 3, March 2020, Pages 587-594.
12. Stopeck AT, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: a randomized, double-blind study. J Clin Oncol. 2010 ;28 :1-10

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Select Review	Wording update, add Jubbonti and Wyost criteria and quantity limit. Coding Reviewed: Added HCPCS J3590 Unclassified biologics when specified as Jubbonti or Wyost. Effective 10/1/24 added HCPCS Q5136 [Jubbonti/Wyost].	11/18/2024	12/17/2024
Policy Inception	New Medical Policy Creation	3/25/2024	6/28/2024
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Revised: 09/26/2024