Medical Policy:

Zoledronic Acid (Zometa, Reclast) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.113	January 2, 2025	January 1, 2020

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Length of Authorization

Zometa:

- Hypercalcemia of Malignancy: Coverage is provided for up to 2 doses for 12 months and may NOT be renewed.
- All other indications: Coverage is provided for 12 months and may be renewed.

Reclast:

- Prevention of osteoporosis in post-menopausal women: Coverage is provided for 24 months and may be renewed.
- All other indications: Coverage is provided for 12 months and may be renewed.
- Fracture risk reduction following alternative osteoporosis class therapy: Coverage will be provided for 12 months and may NOT be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

Zometa:

Indication	Max Units
Hypercalcemia of malignancy	4 billable units per 7 days x 2 doses only
Multiple myeloma & bone metastases from solid tumors, osteopenia/osteoporosis in systemic mastocytosis	4 billable units every 21 days
Prevention of bone loss in breast cancer	4 billable units every 168 days (6 months)
Prevention of bone loss in prostate cancer & Prevention or treatment of osteoporosis in prostate cancer	4 billable units every 84 days (3 months)
Langerhans Cell Histiocytosis	4 billable units every 28 days

Reclast:

Indication	Max Units
Paget's Disease	5 billable units for 2 doses
Prevention of osteoporosis in post-menopausal women	5 billable units every 730 days (24 months)
Fracture risk reduction following alternative osteoporosis class therapy	5 billable units for 1 dose
Treatment of osteoporosis/Treatment and prevention of glucocorticoid-induced osteoporosis	5 billable units every 84 days (3 months)

Guideline

I. INITIAL APPROVAL CRITERIA

1. Zometa

Coverage is provided in the following conditions:

Hypercalcemia of malignancy †

-Patient has an albumin-corrected serum calcium level of ≥ 12 mg/dL

Multiple myeloma †

Bone metastases from solid tumors †

Prevention of skeletal related events in men with castration-recurrent prostate cancer ‡

Prevention of bone loss associated with aromatase inhibitor therapy for breast cancer in post-menopausal women or premenopausal women on adjuvant ovarian suppression ‡

Prevention of bone loss associated with androgen deprivation therapy in men with prostate cancer ‡

Treatment of osteopenia/osteoporosis in patients with systemic mastocytosis ‡

Langerhans Cell Histiocytosis ‡

- Patient has multifocal bone disease **OR** unifocal isolated bone disease

2. Reclast

Coverage is provided in the following conditions:

Treatment and prevention of postmenopausal osteoporosis †

- Patient experienced severe intolerance, ineffective response±, or has contraindications* to oral bisphosphonate therapy; **OR**
- Patient had a prior fragility fracture or is at especially high fracture risk

Treatment to increase bone mass in men with osteoporosis †

- Patient experienced severe intolerance, ineffective response±, or has contraindications* to oral bisphosphonate therapy; **OR**
- Patient had a prior fragility fracture or is at especially high fracture risk

Treatment and prevention of glucocorticoid-induced osteoporosis †

- Patient experienced severe intolerance, ineffective response±, or has contraindications* to oral bisphosphonate therapy; **OR**
- Patient had a prior fragility fracture or is at especially high fracture risk

Treatment of Paget's disease of bone in men and women †

- Serum alkaline phosphatase is two times or higher than the upper limit of the age-specific reference range; **OR**
- Patient is symptomatic; **OR**
- Patient is at risk for complications from their disease

± Ineffective response is defined as one or more of the following:
○ Decrease in T-score in comparison with baseline T-score from DXA scan ○ Patient has a new fracture while on bisphosphonate therapy
*** Examples of contraindications to oral bisphosphonate therapy include the following:**
○ Documented inability to sit or stand upright for at least 30 minutes ○ Documented pre-existing gastrointestinal disorder such as inability to swallow, Barrett's esophagus, esophageal stricture, dysmotility, or achalasia ○ Surgical anastomoses are present in the GI tract after certain types of bariatric surgery (e.g.,Roux-en-Y gastric bypass)

† FDA Approved Indication(s); **‡** Compendia recommended indication(s)

II. RENEWAL CRITERIA

Coverage can be renewed based on the following criteria:

1. Patient continues to meet the criteria identified above; **AND**
2. Absence of unacceptable toxicity from the drug (e.g., renal toxicity, osteonecrosis of the jaw, atypical femoral fractures, hypocalcemia, incapacitating pain in the bone/joint/muscle, etc.); **AND**

Reclast

1. Disease response as indicated by the following:
   A. Osteoporosis indications:
      i. Absence of fractures; **OR**
      ii. Increase in bone mineral density compared to pretreatment baseline **AND**

a. Patients who have received 3 years of bisphosphonate therapy should be re-evaluated with a DXA or serum marker for bone turnover [i.e., serum C-terminal crosslinking telopeptide (CTX)]; **AND**

b. Those patients at low-to-moderate risk of fractures should be considered for a temporary discontinuation of bisphosphonate for up to 5 years (re-assess risk at 2 to 4 year intervals to determine if earlier re-initiation is necessary)

B. Paget's Disease: Patient previously experienced therapeutic response to treatment (i.e., normalization of serum alkaline phosphatase (SAP) or a reduction of ≥ 75% from baseline in total SAP excess (defined as the difference between the measured level and midpoint of normal range); **AND**

i. Patient is having a relapse of disease based on increases in SAP; **OR**

ii. Patient has symptomatic disease; **OR**

iii. Patients failed to achieve normalization of SAP

C. Fracture Risk Reduction Following Alternative Osteoporosis Class Therapy:

i. May not be renewed

Zometa

Disease response as indicated by the following:

A. Bone metastases/MM: absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression)

B. Hypercalcemia of Malignancy: May not be renewed

C. Breast Cancer (bone loss prevention), Prostate Cancer (bone loss prevention), and Systemic Mastocytosis:

i. Absence of fractures; **OR**

ii. Increase in bone mineral density compared to pretreatment baseline

D. Breast Cancer (risk reduction of distant metastasis):

i. Prevention of bone recurrence; **OR**

ii. Stabilization of disease from baseline; **OR**

iii. Absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression)

E. Langerhans Cell Histiocytosis:

i. Improvement in bone pain; **OR**

ii. Improvement/resolution in active bone lesions compared to pretreatment baseline

Limitations/Exclusions

Reclast/Zometa is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

Code	Description
J3489	Injection, zoledronic acid, 1 mg

Applicable NDCs

Code	Description
00078-0590-XX	Zometa 4 mg/100 mL single-use ready-to-use bottle
00078-0387-XX	Zometa 4 mg/5 mL single-use vial of concentrate
00078-0435-XX	Reclast 5 mg/100 mL ready-to-infuse solution
00409-4229-01	Zoledronic acid 4 mg/100 mL single use IV vial

ICD-10 Diagnoses

Zometa:

Code	Description
C00-C14	Malignant neoplasms of lip, oral cavity and pharynx
C15-C26	Malignant neoplasms of digestive organs
C30-C39	Malignant neoplasms of respiratory and intrathoracic organs
C40-C41	Malignant neoplasms of bone and articular cartilage
C43-C44	Melanoma and other malignant neoplasms of skin
C45-C49	Malignant neoplasms of mesothelial and soft tissue
C50-C50	Malignant neoplasms of breast
C51-C58	Malignant neoplasms of female genital organs
C60-C63	Malignant neoplasms of male genital organs
C64-C68	Malignant neoplasms of urinary tract
C69-C72	Malignant neoplasms of eye, brain and other parts of central nervous system
C73-C75	Malignant neoplasms of thyroid and other endocrine glands
C7A-C7A	Malignant neuroendocrine tumors
C7B-C7B	Secondary neuroendocrine tumors
C76-C80	Malignant neoplasms of ill-defined, other secondary and unspecified sites
C81	Hodgkin lymphoma
C82	Follicular lymphoma
C83	Non-follicular lymphoma
C84	Mature T/NK-cell lymphomas
C85	Other specified and unspecified types of non-Hodgkin lymphoma
C86	Other specified types of T/NK-cell lymphoma
C88	Malignant immunoproliferative diseases and certain other B-cell lymphomas
C90.00	Multiple myeloma not having reached remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having reached remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having reached remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having reached remission
C90.32	Solitary plasmacytoma in relapse
C96	Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue
D00-D09	In situ neoplasms
D10-D36	Benign neoplasms, except benign neuroendocrine tumors
D3A-D3A	Benign neuroendocrine tumors
D37	Neoplasm of uncertain behavior of oral cavity and digestive organs

D38	Neoplasm of uncertain behavior of middle ear and respiratory and intrathoracic organs
D39	Neoplasm of uncertain behavior of female genital organs
D40	Neoplasm of uncertain behavior of male genital organs
D41	Neoplasm of uncertain behavior of urinary organs
D42	Neoplasm of uncertain behavior of meninges
D43	Neoplasm of uncertain behavior of brain and central nervous system
D44	Neoplasm of uncertain behavior of endocrine glands
D48	Neoplasm of uncertain behavior of other and unspecified sites
D49-D49	Neoplasms of unspecified behavior
E83.52	Hypercalcemia
M80.80XA-M80.88XS	Other osteoporosis with current pathological fracture
M81.6	Localized osteoporosis
M81.8	Other osteoporosis without current pathological fracture
M85.80	Other specified disorders of bone density and structure, unspecified site
M85.851	Other specified disorders of bone density and structure, right thigh
M85.852	Other specified disorders of bone density and structure, left thigh
M85.859	Other specified disorders of bone density and structure, unspecified thigh
M85.9	Disorder of bone density and structure, unspecified
M89.9	Disorder of bone, unspecified
M94.9	Disorder of cartilage, unspecified
Z85	Personal history of malignant neoplasm

Dual coding requirements:

Prevention of bone loss in prostate cancer/ Prevention or treatment of osteoporosis in prostate cancer:

- Primary code: M89.9 or M94.9 plus Z85.46

Prevention of aromatase inhibitor induced bone loss in breast cancer:

- Primary code: M89.9 or M94.9 plus: Z85.3

Reclast:

Code	Description
C61	Malignant neoplasm of prostate
M80.00XA-M80.08XS	Age-related osteoporosis with current pathological fracture
M80.80XA-M80.88XS	Other osteoporosis with current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.6	Localized osteoporosis
M81.8	Other osteoporosis without current pathological fracture
M85.80	Other specified disorders of bone density and structure, unspecified site
M85.851	Other specified disorders of bone density and structure, right thigh
M85.852	Other specified disorders of bone density and structure, left thigh
	Other specified disorders of bone density and structure, unspecified thigh
M85.88	Other specified disorders of bone density and structure, other site
M85.89	Other specified disorders of bone density and structure, multiple sites
M85.9	Disorder of bone density and structure, unspecified
M88.0	Osteitis deformans of skull
M88.1	Osteitis deformans of vertebrae

M88.811	Osteitis deformans of right shoulder
M88.812	Osteitis deformans of left shoulder
M88.819	Osteitis deformans of unspecified shoulder
M88.821	Osteitis deformans of right upper arm
M88.822	Osteitis deformans of left upper arm
M88.829	Osteitis deformans of unspecified upper arm
M88.831	Osteitis deformans of right forearm
M88.832	Osteitis deformans of left forearm
M88.839	Osteitis deformans of unspecified forearm
M88.841	Osteitis deformans of right hand
M88.842	Osteitis deformans of left hand
M88.849	Osteitis deformans of unspecified hand
M88.851	Osteitis deformans of right thigh
M88.852	Osteitis deformans of left thigh
M88.859	Osteitis deformans of unspecified thigh
M88.861	Osteitis deformans of right lower leg
M88.862	Osteitis deformans of left lower leg
M88.869	Osteitis deformans of unspecified leg
M88.871	Osteitis deformans of right ankle
M88.872	Osteitis deformans of left ankle
M88.879	Osteitis deformans of unspecified ankle
M88.88	Osteitis deformans of other bone
M88.89	Osteitis deformans of multiple sites
M88.9	Osteitis deformans of unspecified bone
M89.9	Disorder of bone, unspecified
M94.9	Disorder of cartilage, unspecified
Z85.46	Personal history of malignant neoplasm of prostate

Dual coding requirement for prevention of bone loss in prostate cancer/ Prevention or treatment of osteoporosis in prostate cancer: Primary code: M89.9 or M94.9 plus Z85.46

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: Updated length of authorization and max units charts. Zometa: Hypercalcemia of malignancy † Updated statement to include > "Patient has an albumin-corrected serum calcium level of > 12 mg/dL" Renewal Criteria: Reclast Added: "Patients who have received 3 years of bisphosphonate therapy should be re-evaluated with a DXA or serum marker for bone turnover [i.e., serum C terminal crosslinking telopeptide (CTX)]; AND Those patients at low-to-moderate risk of fractures should be considered for a temporary discontinuation of bisphosphonate for up to 5 years (re-assess risk at 2 to 4 year intervals to determine if earlier re-initiation is necessary)" Paget's Disease: Updated the following statement: "normalization of serum alkaline phosphatase (SAP) or a reduction of ≥ 75% from baseline in total SAP excess (defined as the difference between the measured level and midpoint of normal range)" to: " Patient previously experienced therapeutic response to treatment (i.e., normalization of serum alkaline phosphatase (SAP) or a reduction of ≥ 75% from baseline in total SAP excess (defined as the difference between the

		measured level and midpoint of normal range); AND Patient is having a relapse of disease based on increases in SAP; OR Patient has symptomatic disease; OR Patients failed to achieve normalization of SAP" Renewal Criteria: Reclast: Added: "Fracture Risk Reduction Following Alternative Osteoporosis Class Therapy: May not be renewed" Renewal Criteria: Zometa Added: "Breast Cancer (bone loss prevention), Prostate Cancer (bone loss prevention), and Systemic Mastocytosis: Absence of fractures; OR Increase in bone mineral density compared to pretreatment baseline Breast Cancer (risk reduction of distant metastasis): Prevention of bone recurrence; OR Stabilization of disease from baseline; OR Absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression" Removed and reworded as above: "Prevention of bone loss/SRE in cancer patients/Osteoporosis or Osteopenia in Systemic Mastocytosis: Absence of fractures; OR Increase in bone mineral density compared to pretreatment baseline"
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: Max Units- updated chart Initial Criteria: Reclast: removed the following: Osteoporosis, Secondary prophylaxis in patients with recent low-trauma hip fracture† Prevention or treatment of osteoporosis in men with prostate cancer during androgen deprivation therapy ‡ Renewal Criteria: Zometa**:** Hypercalcemia of Malignancy: Removed "corrected serum calcium ≤ 11.5 mg/dL" Replaced with "May not be renewed"
EmblemHealth & ConnectiCare	5/02/2023	Annual Review: Under Zometa; Coverage is provided in the following conditions: Hypercalcemia of malignancy † Added "Patient has an albumin-corrected serum calcium level of > 12 mg/dL" Under Zometa; Coverage is provided in the following conditions: Added the following indications: "Treatment of osteopenia/osteoporosis in patients with systemic mastocytosis ‡ and Langerhans Cell Histiocytosis ‡" and criteria for Langerhans Cell Histiocytosis: "Patient has multifocal bone disease OR unifocal isolated bone disease" Add the following statement "Osteoporosis or Osteopenia in Systemic Mastocytosis" :to Zometa renewal criteria in the following section: "Prevention of bone loss/SRE in cancer patients/Osteoporosis or Osteopenia in Systemic Mastocytosis: -Absence of fractures; OR -Increase in bone mineral density compared to pretreatment baseline" Added Langerhans Cell Histiocytosis to Zometa renewal criteria.
EmblemHealth & ConnectiCare	1/19/2023	Transfer to New Template
EmblemHealth & ConnectiCare	7/15/2020	Added new NDC 00409-4229-01
EmblemHealth & ConnectiCare	01/01/2020	Annual Review

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