Zoledronic acid:
Zometa®; Reclast®
(Intravenous)

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I. Length of Authorization

Zometa:

- 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 (unless otherwise specified).

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Zometa

Indication	Quantity Limit
Hypercalcemia of malignancy	4 mg bottle/vial per 7 days
Multiple myeloma, bone metastases from solid tumors, & osteopenia/osteoporosis in systemic mastocytosis	4 mg bottle/vial every 21 days
Prevention of bone loss in breast cancer	4 mg bottle/vial every 168 days (6 months)
Prevention of bone loss in prostate cancer & Prevention or treatment of osteoporosis in prostate cancer	4 mg bottle/vial every 84 days (3 months)
Langerhans Cell Histiocytosis	4 mg bottle/vial every 28 days

Reclast

Indication	Quantity Limit

Prevention of osteoporosis in post-menopausal women	5 mg solution every 730 days (24 months)
All other indications	5 mg solution every 365 days (12 months)

B. Max Units (per dose and over time) [HCPCS Unit]:

Zometa

Indication	Max Units
Hypercalcemia of malignancy	4 billable units per 7 days
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
Prevention of osteoporosis in post-menopausal women	5 billable units every 730 days (24 months)
All other indications	5 billable units every 365 days (12 months)

III. Initial Approval Criteria [1,2]

Universal Criteria

- Reclast/Zometa should not be used in combination with one another, other bisphosphonates, denosumab, romosozumab, or parathyroid hormone analogs/related peptides; **AND**
- Patient does not have hypocalcemia (supplement adequately with calcium and vitamin D); **AND**

Zometa [1,3,4,6,8,10-14,19-22,27, 28, 29]

- Patient must have a CrCl ≥ 30 mL/min; **AND**

Coverage is provided in the following conditions:

Hypercalcemia of malignancy † Φ

Multiple myeloma †

Bone metastases from solid tumors † (in conjunction with standard antineoplastic therapy)

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 ‡ [27,28]

Langerhans Cell Histiocytosis ‡ [29]

Reclast [2,3,5,7-9,15-18,23-26]

- Patient must have a CrCl ≥ 35 mL/min and no evidence of acute renal impairment; **AND**

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

Note: patients discontinuing treatment with denosumab due to a reduction in fracture risk (i.e., no longer high or very high risk) require subsequent antiresorptive therapy in order to prevent accelerated bone mineral density loss and increase in fracture risk. Coverage is provided for ***one*** *administration for this use prior to temporary discontinuation of intravenous antiresorptive therapy*

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

Prevention or treatment of osteoporosis in men with prostate cancer during androgen deprivation therapy ‡

± 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

† FDA Approved Indication(s); ‡ Compendia recommended indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,2,27]

Coverage can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in the initial criteria section; **AND**
- 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

- Disease response as indicated by the following:
  - Osteoporosis indications:
    - Absence of fractures; **OR**
    - Increase in bone mineral density compared to pretreatment baseline; **AND**
      - 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: 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)

Zometa

- Disease response as indicated by the following:

- Bone metastases/MM: absence/delay in skeletal-related events (e.g., pathologic fracture, radiation therapy to bone, surgery to bone, or spinal cord compression)
- Hypercalcemia of Malignancy: corrected serum calcium ≤ 11.5 mg/dL
- 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
- Langerhans Cell Histiocytosis:
  - Improvement in bone pain; **OR**
  - Improvement/resolution in active bone lesions compared to pretreatment baseline

V. Dosage/Administration

Zometa

Indication	Dose
Hypercalcemia of malignancy	4 mg IV x 1 dose, may be repeated after 7 days if serum calcium does not return to normal
Prevention of aromatase inhibitor-induced bone loss in breast cancer	4 mg IV every 6 months
Prevention of androgen deprivation-induced bone loss in prostate cancer	4 mg IV every 3 months
Multiple myeloma & bone metastases from solid tumors	4 mg IV every 3 to 4 weeks OR 4 mg every 12 weeks
Treatment of osteopenia/osteoporosis in systemic mastocytosis	4 mg IV every 3 to 4 weeks
Langerhans Cell Histiocytosis	4 mg IV every month

*decrease dose based upon CrCl (mL/min): 3.5 mg for CrCl 50-60; 3.3 mg for CrCl 40-49; 3 mg for CrCl 30-39

Reclast

Indication	Dose
Active Paget's Disease	5 mg IV x 1 dose
Prevention of osteoporosis in post-menopausal women	5 mg IV every 2 years
Prevention of glucocorticoid-induced osteoporosis	5 mg IV every year
Treatment of osteoporosis	5 mg IV every year

Prevention of androgen deprivation-induced bone loss in prostate cancer	5 mg IV every year

VI. Billing Code/Availability Information

HCPCS Code:

- J3489 - Injection, zoledronic acid, 1 mg; 1 billable unit = 1 mg

NDC*:

- Zometa 4 mg/100 mL single-use ready-to-use bottle: 00078-0590-XX (obsolete)
- Zometa 4 mg/5 mL single-use vial of concentrate: 00078-0387-XX (obsolete)
- Reclast 5 mg/100 mL ready-to-infuse solution: 00078-0435-XX

**Generics available from various manufacturers*

VII. References

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2. Reclast [package insert]. East Hanover, NJ; Novartis Pharmaceuticals; April 2020. Accessed February 2021.
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Appendix 1 – Covered Diagnosis Codes

Zometa

ICD-10	ICD-10 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
C50.011-C50.929	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.00-C7A.8	Malignant neuroendocrine tumors
C7B.00-C7B.8	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

ICD-10	ICD-10 Description
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
C90.10	Plasma cell leukemia not having reached remission
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse
C90.20	Extramedullary plasmacytoma not having reached remission
C90.21	Extramedullary plasmacytoma in remission
C90.22	Extramedullary plasmacytoma in relapse
C90.30	Solitary plasmacytoma not having reached remission
C90.31	Solitary plasmacytoma in remission
C90.32	Solitary plasmacytoma in relapse
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell leukemia, in relapse
C96	Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.2	Malignant mast cell neoplasm
C96.20	Malignant mast cell neoplasm, unspecified
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
C96.7	Other specified malignant neoplasms of lymphoid, haematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
D00-D09	In situ neoplasms
D10-D36	Benign neoplasms, except benign neuroendocrine tumors
D3A.00-D3A.8	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
D47.02	Systemic mastocytosis

ICD-10	ICD-10 Description
D48	Neoplasm of uncertain behavior of other and unspecified sites
D49.0-D49.9	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: M85.80, M85.851, M85.852, M89.9 or M94.9 plus Z85.46

Prevention of aromatase inhibitor induced bone loss in breast cancer:

- Primary code: M85.80, M85.851, M85.852, M89.9 or M94.9 plus: Z85.3

Reclast

ICD-10	ICD-10 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
M85.859	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

ICD-10	ICD-10 Description
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: M85.80, M85.851, M85.852, M89.9 or M94.9 plus Z85.46

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD):

Zometa & Reclast

Jurisdiction(s): 5, 8	**NCD/LCD Document (s):** L34648
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34648&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): 5, 8	**NCD/LCD Document (s):** A56907
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56907&bc=gAAAAAAAAAAA	

Jurisdiction(s): N	**NCD/LCD Document (s):** L33270
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33270&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): N	**NCD/LCD Document (s):** A57603
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57603&bc=gAAAAAAAAAAA	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC