

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 \geq 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 postmenopausal 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 \geq 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 \pm , 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 \pm , 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 \pm , 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); ◻ 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 |

ZOLEDRONIC ACID (Zometa®, Reclast®) Prior Auth Criteria

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| 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=gAAAAAAAAAAAAAA == | |
| Jurisdiction(s): 5, 8 | NCD/LCD Document (s): A56907 |
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56907&bc=gAAAAAAAAAAAAAA | |
| Jurisdiction(s): N | NCD/LCD Document (s): L33270 |
| https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33270&bc=gAAAAAAAAAAAAAA == | |
| Jurisdiction(s): N | NCD/LCD Document (s): A57603 |
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A57603&bc=gAAAAAAAAAAAAAA | |

| 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. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |

ZOLEDRONIC ACID (Zometa®, Reclast®) Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

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Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|---------------------|--------------------------------------|-------------------------|
| 15 | KY, OH | CGS Administrators, LLC |