UnitedHealthcare®

Reimbursement Policy

Zoledronic Acid (Zometa® & Reclast®)

Policy Number	ZOL07012013RP	**Approved By**	UnitedHealthcare Medicare Reimbursement Policy Committee	**Current Approval Date**	08/27/2014

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy d006Fes not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network

physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Summary

Overview

Zoledronic acid (Reclast® and Zometa®) is a bisphosphonic acid, which is an inhibitor of osteoclastic bone resorption. Zoledronic acid binds to the bone matrix, which decreases osteoclastic activity, prevents bone resorption and skeletal calcium release induced by various stimulatory factors released by tumors. Zoledronic acid is currently available under the brand names Zometa ® and Reclast ®.

Zometa ® is indicated for the treatment of:

- Acute Hypercalcemia of malignancy;
- Multiple myeloma;
- Bone metastases from solid tumors in conjunction with standard antineoplastic therapy, including bone metastases from multiple myeloma, breast carcinoma, prostate carcinoma, and other solid tumors. Note: Prostate cancer should have progressed after treatment with at least one hormonal therapy;
- Drug-induced osteopenia, secondary to androgen-deprivation therapy in prostate cancer patients (prophylaxis); and
- Cancer treatment-induced bone loss in breast cancer.

Reclast ® is indicated for the treatment of:

- Pagets disease;
- Post-Menopausal (Senile) Osteoporosis;
- Osteoporosis in men; and
- Glucocorticoid - induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months

Zometa Guidelines

Zometa®

- An indication that the patient is not on any other bisphosphonate medication(s)
- Documentation to support that the drug was administered per IV route by a healthcare professional with a dosage amount not exceeding 4 mg administered for no less than 15 minutes
- An indication that the renal status of the patient has been monitored

Zometa® for Hypercalcemia of Malignancy

- An indication that the patient has an albumin-corrected serum calcium of ≥ 12 mg/dL (3.0 mmol/L)
- The date of the last treatment must be indicated

Zometa® for Multiple Myeloma and Metastatic Bone Lesions of Solid Tumors

- An indication that for the patient with a creatinine clearance of > 60 mL/min, a 4 mg IV infusion over no less than 15 minutes was administered every 3-4 weeks by a healthcare provider
- An indication that the patient was coadministered oral calcium supplements of 500 mg and a multiple vitamin containing 400 IU of vitamin D per day

Zoledronic Acid (Zometa® & Reclast®)

Reclast Guidelines

Reclast® - All patients

- An indication that the patient received adequate hydration prior to treatment
- An indication that the patient has a creatinine clearance of ≥35 mL/min or better
- Documentation to support that the drug was administered one time in a year per IV route by a healthcare professional with 5 mg Reclast® infused IV over no less than 15 minutes given over a constant infusion rate with a 10 mL normal saline flush of the IV line following the infusion

Reclast® for Glucocorticoid-Induced Osteoporosis in Men and Women (must meet above criteria also)

- An indication that the patient is either initiating or continuing to take system glucocorticoids in a daily dosage of 7.5 mg or greater of prednisone and who are expected to remain on glucocorticoids for at least 12 months
- An indication that the patient is taking at least 1200 mg calcium and 800-1000 IU vitamin D per day

Reclast® for Women or Men with Osteoporosis

- An indication that the patient is taking at least 1200 mg calcium and 800-1000 IU vitamin D per day

Reclast® for Paget's Disease

An indication that the patient has been instructed to take 1500 mg elemental calcium daily in divided doses (750 mg two times per day, or 500 mg three times per day) and 800 IU vitamin D per day, particularly in the 2 weeks following the administration of Reclast®

An indication that the patient has one of the following:

- An elevated serum alkaline phosphatase of two times or higher than the upper limit of the age-specific normal reference range, or
- The patient is symptomatic, or
- The patient is at risk for complications from the disease, to induce remission (normalization of serum alkaline phosphotase) prior to treatment with Reclast®

Reclast® for Re-Treatment of Paget's Disease

- An indication that the patient is experiencing a relapse based on serum alkaline phosphatase, or
- An indication that the patient has failed to achieve normalization of their serum alkaline phosphatase, or
- An indication that the patient has symptoms as dictated by current standard medical practice.

Utilization Guidelines

Zometa®

- Zometa® contains the same active ingredient found in Reclast®. A patient that is already receiving Zometa® should not be treated with Reclast®.
- A single dose of Zometa® should not exceed 4mg and must be given intravenously for no less than 15 minutes.
- Retreatment with Zometa® 4 mg may be considered if serum calcium does not return to normal or remain normal after treatment.
- It is recommended that a minimum of 7 days elapse before re-treatment to allow for full response to the initial dose.
- Renal function must be carefully monitored in all patients receiving Zometa® and possible deterioration in renal function must be assessed prior to re-treatment with Zometa®

Reclast®

- Reclast® contains the same active ingredient found in Zometa®. A patient that is already receiving Zometa® should not be treated with Reclast®.
- Patients must receive adequate hydration prior to the administration of Reclast®
- For patients with creatinine clearance ≥35 mL/min the recommended dose of Reclast® is 5 mg infused intravenously **once a year** over no less than 15 minutes given over a constant infusion rate with a 10 mL normal saline flush of the IV line following the infusion

Zoledronic Acid (Zometa® & Reclast®)

CPT / HCPCS Codes

Code	Description
J3487	Injection, zoledronic acid (Zometa), 1 mg (Invalid for Medicare Purposes as of 06/30/2013)
J3488	Injection, zoledronic acid (Reclast), 1 mg (Invalid for Medicare Purposes as of 06/30/2013)
J3489	Injection, zoledronic acid, 1 mg (Effective 01/01/14)
Q2051	Injection, zoledronic acid, not otherwise specified, 1 mg (Effective 07/01/2013-12/31/2013)

References Included (but not limited to):

CMS LCD(s)

Numerous LCDs

CMS Article(s)

Numerous Articles

CMS Transmittals

Transmittal 2695, Change Request 8286, Dated 05/02/2013 (Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes – July 2013 Update)

Transmittal 2708, Change Request 8291, Dated 05/17/2013 (July Update to the Calendar Year (CY) 2013 Medicare Physician Fee Schedule Database (MPFSDB))

Transmittal 2717, Change Request 8328, Dated 05/31/2013 (July 2013 Update of the Ambulatory Surgical Center (ASC) Payment System)

UnitedHealthcare Reimbursement Policies

Discarded Drugs and Biologicals

UnitedHealthcare Medical Policies

Maximum Dosage

MLN Matters

Article MM8286, Quarterly Healthcare Common Procedure Coding System (HCPCS) Drug/Biological Code Changes – July 2013 Update

Article MM8291, July Update to the Calendar Year (CY) 2013 Medicare Physician Fee Schedule Database (MPFSDB)

Article MM8328, July 2013 Update of the Ambulatory Surgical Center (ASC) Payment System

Others

About Zometa® (Zoledronic Acid) 4 mg/5 mL Injection, Zometa® Website

Medicare Program Integrity Manual, Chapter 3 Verifying Potential Errors and Taking Corrective Actions, CMS Website

Reclast® (Zoledronic Acid), Novartis Pharmaceuticals Website

History

Date	Revisions
08/27/2014	Annual review
12/23/2013	Administrative udpates
07/24/2013	New policy created and presented to MRPC for approval