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FUTURE Local Coverage Article: Zoledronic Acid (e.g., Zometa ®, Reclast®) – Related to LCD L33394 (A52455)

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Please note: **Future Effective Date.**

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Contractor Information

Contractor Name	Contract Number	Contract Type	Jurisdiction
National Government Services, Inc.	13202	A and B and HHH MAC	J - K

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Article Information

General Information

FUTURE

Article ID
A52455

Original ICD-9 Article ID
A46096

Article Title
Zoledronic Acid (e.g., Zometa ®, Reclast®) – Related to LCD L33394

Jurisdiction
New York - Downstate

Original Effective Date
10/01/2015

Revision Effective Date
10/01/2015

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

This article defines coding and coverage for zoledronic acid including on and off-label indications. National Government Services Local Coverage Determination (LCD) "Coverage of Drugs and Biologicals for Label and Off-Label Uses" (accessible via www.NGSMedicare.com or www.cms.gov/medicare-coverage-database) provides criteria for coverage of off-label indications based on the American Hospital Formulary Services (AHFS), Clinical Pharmacology, NCCN Drugs and Biologics Compendium and/or Thomson Micromedex DrugDex® compendium. Providers may request approval for additional off-label indications by submitting this request in writing with supporting medical literature.

Abstract:

Zoledronic acid marketed under the brand name Zometa® (4mg/5ml) is an FDA approved intravenous bisphosphonate drug for treatment of patients with hypercalcemia of malignancy. Approximately 10% of cancer patients experience elevated serum calcium levels which overload the kidneys' processing capability, leading to complications such as dehydration, generalized muscle weakness, fatigue, nausea, and confusion. This drug has been shown in clinical trials to normalize the serum calcium concentrations in 88.4% of patients tested.

Zoledronic acid marketed under the brand name Reclast® (5mg/100ml) is FDA approved for the treatment of Paget's disease of bone in men and women.

Indications:

Zoledronic acid is considered reasonable and necessary for the treatment of:

- Hypercalcemia of malignancy;
- Multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy.
- Monoclonal gammopathy of uncertain significance, with osteopenia or osteoporosis.
- Paget's disease to induce remission in symptomatic individuals, or in asymptomatic individuals at risk for complications from the disease, or when asymptomatic with alkaline phosphatase levels at least twice the upper limit of the age specific normal reference range;
- Osteoporosis, in men;
- Patients at high risk of fracture defined as recent low-trauma hip fracture;
- Glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months; and,
- Osteoporosis in post-menopausal women

Note: Zoledronic acid is FDA approved for the prevention of osteoporosis in postmenopausal women. However preventative services other than those payable by statute are excluded from coverage. Since prevention of osteoporosis is not covered by statute, National Government Services does not cover zoledronic acid for the prevention of osteoporosis in postmenopausal women who do not have documented osteopenia. This service should be submitted with the appropriate CPT/HCPCS code with the -GY modifier. Using the –GY modifier will result in denial of Medicare payment for this service.

Indications expanded by this Article:

Zoledronic acid is considered reasonable and necessary for the treatment of:

- Osteoporosis or osteopenia secondary to the endocrine management (including aromatase inhibitors) of breast cancer or prostate cancer.
- Osteopenia in postmenopausal women.

Limitations:

1. Zoledronic acid is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other biphosphonates.
2. Zoledronic acid is contraindicated in pregnant or breast feeding patients or those who may become pregnant.

Utilization:

1. For hypercalcemia of malignancy (HCM), the albumin-corrected serum calcium level must be at least 12 mg/dl.
2. Infusion time for zoledronic acid is under 1 hour. Therefore, the administration time reported should not exceed one hour.
3. The dose and frequency of administration should be consistent with the FDA approved package insert, for example:
    - Treatment for osteoporosis, one infusion annually
    - Treatment of osteoporosis secondary to endocrine management of breast cancer patients, one infusion every six months
    - Osteoporosis secondary to endocrine management for prostate cancer patients, one infusion per 3 months
    - Treatment of Paget’s disease, re-treatment with zoledronic acid may be considered in patients who have relapsed, based on increases in serum alkaline phosphatase, or in those patients who failed to achieve normalization of their serum alkaline phosphatase, or in those patients with symptoms, as dictated by medical practice.

Documentation:

1. Physician order;
2. Medication administration record; and

3. Clinical records documenting the conditions being treated.
4. For hypercalcemia of malignancy (275.42), the medical record must document the underlying malignancy and the rationale for the use of zoledronic acid.

Coding Information:

Infusion of fluids for hydration (e.g., saline) can be reported on the same day as zoledronic acid, using the appropriate hydrating solution and infusion codes. All codes must be reported on the same claim.

For claims submitted to the Part B MAC:

Zoledronic acid should be billed using therapeutic/diagnostic administration codes and is payable in the following places of service: office (11), nursing facility for patients not in a Part A stay (32), independent clinic (49), and state or local public health clinic (71), only when supplied as an "incident to" service by the physician.

Sources of Information:

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- United States Pharmacopoeia (USP), Volume I; Drug Information for the Health Care Professional, 2007.

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Coding Information

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Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

011x	Hospital Inpatient (Including Medicare Part A)
013x	Hospital Outpatient
085x	Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the article services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph:
HCPCS codes J3487, J3488 and Q2051 were deleted 12/31/2013

Group 1 Codes:

J3489	INJECTION, ZOLEDRONIC ACID, 1 MG

ICD-10 Codes that are Covered

Group 1 Paragraph: N/A

Group 1 Codes:

Show entries: 100

Search: **Search By:** ⊙ **Description** ○ **Code** SEARCH GROUP

ICD-10 CODE	DESCRIPTION
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
E83.52	Hypercalcemia
M80.051A	Age-related osteoporosis with current pathological fracture, right femur, initial encounter for fracture
M80.052A	Age-related osteoporosis with current pathological fracture, left femur, initial encounter for fracture
M80.851A	Other osteoporosis with current pathological fracture, right femur, initial encounter for fracture
M80.852A	Other osteoporosis with current pathological fracture, left femur, initial encounter for fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.6	Localized osteoporosis [Lequesne]
M81.8	Other osteoporosis without current pathological fracture
M84.451A	Pathological fracture, right femur, initial encounter for fracture
M84.452A	Pathological fracture, left femur, initial encounter for fracture
M84.459A	Pathological fracture, hip, unspecified, initial encounter for fracture
M84.551A	Pathological fracture in neoplastic disease, right femur, initial encounter for fracture
M84.552A	Pathological fracture in neoplastic disease, left femur, initial encounter for fracture
M84.559A	Pathological fracture in neoplastic disease, hip, unspecified, initial encounter for fracture
M84.651A	Pathological fracture in other disease, right femur, initial encounter for fracture
M84.652A	Pathological fracture in other disease, left femur, initial encounter for fracture
M84.659A	Pathological fracture in other disease, hip, unspecified, initial encounter for fracture
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
M88.821	Osteitis deformans of right upper arm
M88.822	Osteitis deformans of left upper arm
M88.831	Osteitis deformans of right forearm
M88.832	Osteitis deformans of left forearm
M88.841	Osteitis deformans of right hand
M88.842	Osteitis deformans of left hand
M88.851	Osteitis deformans of right thigh
M88.852	Osteitis deformans of left thigh
M88.861	Osteitis deformans of right lower leg
M88.862	Osteitis deformans of left lower leg
M88.871	Osteitis deformans of right ankle and foot
M88.872	Osteitis deformans of left ankle and foot
M88.88	Osteitis deformans of other bones
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

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ICD-10 Codes that are Not Covered

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Revision History Information

Please note: The Revision History information included in this Article prior to 06/20/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 06/20/2013 will display as a row in the Revision History section of the Article and numbering will begin with "R2".

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/01/2015	R1	Updated to include revisions made since April 2014.

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Associated Documents

Related Local Coverage Document(s)

Article(s)
A52855 - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses - Supplemental Instructions Article
LCD(s)
L33394 - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

Updated on 03/09/2015 with effective dates 10/01/2015 - N/A
Updated on 04/02/2014 with effective dates 10/01/2015 - N/A

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Keywords

N/A

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