Local Coverage Determination (LCD):
Drugs and Biologicals: Zoledronic Acid (L30035)

Contractor Name
Cahaba Government Benefit Administrators®, LLC

Document Information

LCD ID
L30035

LCD Title
Drugs and Biologicals: Zoledronic Acid

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Original Effective Date
For services performed on or after 05/04/2009

Revision Effective Date
For services performed on or after 01/01/2014

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy

- Title XVIII of the Social Security Act, Section 1833 (e). This section states that no payment shall be made to any provider for any claims that lack the necessary information to process the claim.
• Title XVIII of the Social Security Act, section 1861 (s) and (t). These sections outline coverage for drugs and biologicals and services and supplies.

• Title XVIII of the Social Security Act, section 1862(a)(1)(A). This section allows coverage and payment for only those services that are considered to be reasonable and medically necessary, i.e., reasonable and necessary are those tests used in the diagnosis and management of illness or injury or to improve the function of a malformed body part.

• Medicare Benefit Policy Manual (Pub. 100-02), Chapter 15, Section 50.

• Medicare Claims Processing Manual (Pub. 100-04), Chapter 17, Section 20.

• Medicare Program Integrity Manual (Pub. 100-08), Chapter 13. Local Coverage Determinations.

<table>
<thead>
<tr>
<th>Coverage Guidance</th>
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<tbody>
<tr>
<td>Coverage Indications, Limitations, and/or Medical Necessity</td>
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</table>

**Indications**

Zoledronic acid is indicated for the treatment of:

1. Acute Hypercalcemia of malignancy;
2. Multiple myeloma;
3. 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;
4. Drug-induced osteopenia, secondary to androgen-deprivation therapy in prostate cancer patients (prophylaxis);
5. Cancer treatment-induced bone loss in breast cancer;
6. Pagets disease;
7. Post-Menopausal (Senile) Osteoporosis;
8. Osteoporosis in men; and
9. Glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months *(Effective 3/13/2009).*

**Limitations**

1. The safety and efficacy of zoledronic acid in the treatment of hypercalcemia associated with hyperparathyroidism or with other non-tumor-related conditions has not been established.
2. Osteonecrosis of the jaw has been reported. All patients should have a routine oral exam prior to treatment.

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

999x Not Applicable

**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 policy
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 policy
should be assumed to apply equally to all Revenue Codes.

99999 Not Applicable

**CPT/HCPCS Codes**

**Group 1 Paragraph:** N/A

**Group 1 Codes:**

J3489 INJECTION, ZOLEDRONIC ACID, 1 MG

**ICD-9 Codes that Support Medical Necessity**

**Group 1 Paragraph:** The correct use of an ICD-9-CM code listed in the “ICD-9 Codes that Support Medical
Necessity” section does not guarantee coverage of a service. The service must be reasonable and necessary
in the specific case and must meet the criteria specified in this LCD.

ICD-9 codes must be coded to the highest level of specificity. Consult the ‘Official ICD-9-CM Guidelines for
Coding and Reporting’ in the current ICD-9-CM book for correct coding guidelines. This LCD does not take
precedence over the Correct Coding Initiative (CCI).

**Group 1 Codes:**

140.0 - MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - UNSPECIFIED LEUKEMIA,
208.92 IN RELAPSE
209.00 - MALIGNANT CARCINOID TUMOR OF THE SMALL INTESTINE, UNSPECIFIED PORTION -
209.36 MERKEL CELL CARCINOMA OF OTHER SITES
209.70 - SECONDARY NEUROENDOCRINE TUMOR, UNSPECIFIED SITE - SECONDARY MERKEL
209.75 CELL CARCINOMA
209.79 SECONDARY NEUROENDOCRINE TUMOR OF OTHER SITES
275.42 HYPERCALCEMIA
731.0 OSTEITIS DEFORMANS WITHOUT BONE TUMOR
733.00 OSTEOPOROSIS UNSPECIFIED
733.01 SENILE OSTEOPOROSIS
733.09 OTHER OSTEOPOROSIS
733.90 DISORDER OF BONE AND CARTILAGE UNSPECIFIED

ICD-9 Codes that DO NOT Support Medical Necessity

Paragraph: Any ICD-9-CM code that is not listed in the "ICD-9 Codes that Support Medical Necessity" section of this LCD.

Codes:
XX000* Not Applicable

Associated Information

Documentation Requirements

1. Medical records should indicate the order, the route of administration, amount of medication, and the clinical information supporting the indication for use and the frequency of its usage.

2. All coverage criteria must be clearly documented in the patient’s medical record and made available to Medicare upon request.

3. Documentation must support CMS 'signature requirements' as described in the Medicare Program Integrity Manual (Pub. 100-08), Chapter 3.

Utilization Guidelines

The dose and frequency of administration should be consistent with the FDA approved package insert.

Sources of Information and Basis for Decision

- Consultation with Cahaba GBA Part A, Part B, representatives to the Intermediary Advisory Committee, the Carrier Advisory Committee and other Medicare Contractors.

- FDA approved package insert.

- NCCN Drugs and Biologicals Compendium

- Reclast.com

- Zometa.com

Please note: The Revision History information included in this LCD prior to 1/24/2013 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 1/24/2013 will display as a row in the Revision History section of the LCD and numbering will begin with "R2".
<table>
<thead>
<tr>
<th>Revision History Date</th>
<th>Revision History Number</th>
<th>Revision History Explanation</th>
<th>Reason(s) for Change</th>
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<tbody>
<tr>
<td>01/01/2014</td>
<td>R4</td>
<td>What's New Posted: December 2013</td>
<td>Revisions Due To CPT/HCPCS Code Changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effective Date: January 1, 2014</td>
<td>Other (Updated Sources of Information)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>This LCD was updated as a result of the Annual CPT/HCPCS Update for 2014. The code revisions reflect services which are currently addressed in the LCD and do not further restrict the current coverage. The following revision was made:</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Q2051 is invalid after December 31, 2013 and is being removed from the LCD. J3489 is effective January 1, 2014 and is being added to the LCD</td>
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<tr>
<td></td>
<td></td>
<td>Updated Sources of Information to remove: AHFS 2007, FDA approval letter NDA 21-817 for Reclast®, and NCCN Drugs and Biologicals Compendium, 2008. as these are outdated.</td>
<td></td>
</tr>
<tr>
<td>07/01/2013</td>
<td>R3</td>
<td>What's New Posted: July 2013</td>
<td>Revisions Due To CPT/HCPCS Code Changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effective Date: July 1, 2013</td>
<td>Other (LCD Clarification)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HCPCS codes J3487 (Injection, zoledronic acid (Zometa), 1 mg) and J3488 (Injection, zoledronic acid (Reclast), 1 mg) were replaced with one new HCPCS code, Q2051 (Injection, zoledronic acid, not otherwise specified, 1mg), effective July 1, 2013, to appropriately identify and pay for both the brand and generic forms of zoledronic acid.</td>
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<td>To that effect, this LCD is being further clarified. Brand names for zoledronic acid are being removed from the LCD, and the ‘Indications’, ‘Limitations’ and ‘ICD-9 Codes that Support Medical Necessity’ sections are being revised accordingly.</td>
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</tr>
<tr>
<td>07/01/2013</td>
<td>R2</td>
<td>What's New Posted Date: June 2013</td>
<td>Revisions Due To CPT/HCPCS Code Changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effective Date: July 1, 2013</td>
<td>Other (LCD Clarification)</td>
</tr>
</tbody>
</table>
As communicated in CMS Change Request 8286, effective for claims with dates of service on or after July 1, 2013, HCPCS codes J3487 (Injection, Zoledronic Acid (Zometa®), 1mg) and J3488 (Injection, Zoledronic Acid (Reclast®), 1mg) will no longer be payable for Medicare and will be removed from this LCD. Effective for claims with dates of service on or after July 1, 2013, HCPCS code Q2051 (Injection, Zoledronic Acid, not otherwise specified, 1mg) will be payable for Medicare and will be added to this LCD.

The 'Limitation' for osteonecrosis of the jaw was updated to reflect current product labeling.

Note: The ‘Documentation Requirements’ and ‘Utilization Guidelines’ sections were moved to ‘Associated Information’.

Revision 8

What’s New Posted Date: September 2011
Effective Date: October 1, 2011

This LCD was updated for J3487 based on the 2012 ICD-9 Coding Update. ICD-9 Codes 173.0-173.9 are invalid and replaced with 173.00-173.99.

Annual LCD Review: Template language in the 'ICD-9 Codes that Support Medical Necessity' section was clarified regarding correct coding guidelines (What’s New April 8, 2011). Added to Documentation Requirements: ‘Documentation must support CMS ‘signature requirements’ as described in the Medicare Program Integrity Manual (Pub. 100-08), Chapter 3. (Change Request 6698).

Revision 7

Posted What’s New Date: March 2011
Effective Date: April 1, 2011

ICD-9 diagnosis code 733.00 (Osteoporosis, unspecified) is being added to the list of ‘ICD-9 Codes that Support Medical Necessity’ for Reclast® (J3488) for coding osteoporosis in men.

Providers are encouraged to review this LCD to ensure compliance.

Revision 6

What's New Posted Date: August 2010
Effective Date: September 1, 2010

As the next step in the consolidation of J10 MAC LCDs, the Part A and Part B LCDs on the same topic will be consolidated into a single document effective September 1, 2010. These LCDs are identical in content; therefore, consolidation will not alter the content or coverage of the LCDs.

Retired Part A LCD L30003 will be incorporated into this Part B LCD effective September 1, 2010. For dates of service prior to September 1, 2010, please refer to the retired Part A LCD which can be accessed through ‘Related Documents’ found below.

Revision 5

Effective Date: January 1, 2010

The indications for Reclast® are being clarified. Reclast® is indicated for Postmenopausal Osteoporosis in Women and Osteoporosis in Men. The Indications section of the LCD will be updated; however, the list of ICD-9 Codes that Support
Medical Necessity will not change since ICD-9 Code 733.01 for Senile Osteoporosis is not gender specific.

Revision 4

**Posted:** What's New - Part B, September 2009  
**Effective Date:** October 1, 2009

This LCD was updated based on the 2010 ICD-9 Coding Update. The following ICD-9 codes were added for J3487: 209.31-209.36, 209.70-209.75, 209.79.

Revision 3

**Posted:** What's New - Part B, August 2009  
**Effective March 13, 2009**

This LCD was updated due to approval of a new indication for the use of Zoledronic Acid (Reclast®). For Reclast® (J3488), the *Indications and Limitations* section has been updated to include coverage for glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months. The following ICD-9 code has been added: 733.09.

**Note:** Due to the transition of Carrier Cahaba GBA to J10 MAC Part B Cahaba GBA, the above revision could not be made to previous versions of this LCD.

Revision 2

**Start Date of Notice Period:** July 14, 2009  
**Effective Date:** August 29, 2009

As part of the J10 MAC transition, LCD effective for contractor number 10302 – Tennessee Part B.
Revision 1

Start Date of Notice Period: June 17, 2009
Effective Date: August 1, 2009

As part of the J10 MAC transition, LCD effective for contractor number 10202 – Georgia Part B.

Original

Start Date of Notice Period: March 20, 2009
Effective Date: May 4, 2009

As part of the J10 MAC transition, LCD effective for contractor number 10102 – Alabama Part B.

08/27/2011 - This policy was updated by the ICD-9 2011-2012 Annual Update.

Attachments
N/A

Related Local Coverage Documents
LCD(s)
L30003 - (MCD Archive Site)

Related National Coverage Documents
N/A

Public Version(s)
Updated on 12/31/2013 with effective dates 01/01/2014 - N/A
Updated on 07/24/2013 with effective dates 07/01/2013 - 12/31/2013
Updated on 06/28/2013 with effective dates 07/01/2013 - N/A
Updated on 09/15/2011 with effective dates 10/01/2011 - 06/30/2013
Updated on 09/15/2011 with effective dates 10/01/2011 - N/A

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.