

MLN Matters Number: MM3524

Related Change Request (CR) #: 3524

Related CR Release Date: November 5, 2004

Effective Date: January 1, 2005

Related CR Transmittal #: 26 and 358

Implementation Date: Medicare systems changes: April 4, 2005;
Regional Home Health Intermediary (RHHI) actions: December 6, 2004

Inclusion of Forteo as a Covered Osteoporosis Drug and Clarification of Manual Instructions Regarding Osteoporosis Drugs

Note: This article was updated on April 6, 2013, to reflect current Web addresses. All other information remains unchanged.

Provider Types Affected

Home health agencies (HHAs) and providers

Provider Action Needed



STOP – Impact to You

Effective for dates of service on or after January 1, 2005, Medicare may cover teriparatide (generic name for the brand name Forteo) when provided by an HHA to female beneficiaries who meet the criteria established in the Medicare Benefit Policy Manual, Section 50.4.3 and the coverage criteria for the home health benefit established in the Medicare Benefit Policy Manual, Section 30.



CAUTION – What You Need to Know

Teriparatide is paid on a cost basis and is subject to deductible and coinsurance (as is the calcitonin-based osteoporosis drug).



GO – What You Need to Do

To ensure accurate claims processing, please review the information summarized below and stay current with CMS announcements pertaining to Food and Drug Administration (FDA) approved injectable drugs for osteoporosis.

Disclaimer

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Background

Sections 1861(m) and 1861(kk) of the Social Security Act (SSA) provide for coverage of FDA-approved injectable drugs for osteoporosis provided by a home health agency (HHA) to female beneficiaries who meet the coverage criteria for the home health benefit and who also meet the criteria established in the *Medicare Benefit Policy Manual*, Section 50.4.3., namely:

- The individual is eligible for Medicare Part B coverage of home health services (the nursing visit to perform the injection may be the individual's qualifying service);
- The individual sustained a bone fracture that a physician certifies was related to post-menopausal osteoporosis; and
- The individual's physician certifies that the individual is unable to learn the skills needed to self-administer the drug or is otherwise physically or mentally incapable of administering the drug and that her family or caregivers are unable or unwilling to administer the drug.

Initially, calcitonin was the only FDA-approved injectable drug for osteoporosis. The FDA has approved the drug teriparatide (brandnamed Forteo) for use in treating osteoporosis. The drug should be billed using HCPCS code J3110, effective January 1, 2005.

Like the calcitonin-based osteoporosis drug, teriparatide is paid on a cost basis and is subject to deductibles and coinsurance.

The home health visit (i.e., the nurse's visit) to administer the drug is covered under Medicare (Part A or Part B) home health coverage rules. This drug is considered part of the home health benefit under Part B. Therefore, Part B deductible and coinsurance apply regardless of whether home health visits for the administration of the drug are covered under Part A or Part B.

The administration of the drug is included in the charge for the skilled nursing visit billed under bill type 32X or 33X, as appropriate. The cost of the drug is billed under bill type 34X, using revenue code 0636. Additional billing instructions include the following:

- Drugs with the ingredient teriparatide should be billed using HCPCS code J3110 (defined as 10mcg). Providers should report one unit in FL46 for each 10 mcg dose provided during the billing period.
- Drugs that have the ingredient calcitonin are billed using HCPCS code J0630 (defined as up to 400 units). The provider should calculate the units for FL46 of the bill as follows:
 - 100-400 units furnished - enter 1 in FL46

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- 401-800 units furnished - enter 2 in FL46
- 801-1200 units furnished - enter 3 in FL46
- 1201-1600 units furnished - enter 4 in FL46
- 1601-2000 units furnished - enter 5 in FL46
- 2001-2400 units furnished - enter 6 in FL46
- All other osteoporosis drugs that are FDA-approved and are awaiting an HCPCS code must use the miscellaneous code of J3490 until a specific HCPCS code is approved for use.

These codes are paid on a reasonable cost basis, using the provider's submitted charges to make initial payments, which are subject to annual cost settlement.

Implementation

It is important to note that Medicare systems will not be able to process the J3110 claims until April 4, 2005. Therefore, while providers may bill for this drug for dates of service on or after January 1, 2005, the RHHI will suspend such claims received on or before April 5, 2005. However, once the Medicare systems can process the claims, your RHHI will process the claims and pay any interest due as a result of holding the claim.

Additional Information

The official instructions, including the revision to the Medicare Benefit Policy Manual regarding this change can be found online at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R358CP.pdf> and <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R26BP.pdf> on the CMS website.

If you have questions regarding this issue, you may also contact your intermediary/RHHI at their toll free number, which may be found online at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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