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# CMS Manual System

## Pub. 100-04 Medicare Claims Processing

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Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

Transmittal 358

Date: NOVEMBER 5, 2004

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CHANGE REQUEST 3524

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

**I. SUMMARY OF CHANGES:** This transmittal adds a new section to restore to Medicare's Internet-based manuals details of coverage of osteoporosis drugs formerly contained in the Home Health Agency Manual, section 460.

**NEW/REVISED MATERIAL - EFFECTIVE DATE\*:** January 1, 2005

**IMPLEMENTATION DATES:** Systems changes: April 4, 2005.

RHHI actions: December 6, 2004

*Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)**  
**(R = REVISED, N = NEW, D = DELETED)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	10/90.1/Osteoporosis Injections as HHA Benefit

**III. FUNDING:** No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2005 operating budgets.

**IV. ATTACHMENTS:**

X	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

\*Unless otherwise specified, the effective date is the date of service.

# Attachment - Business Requirements

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

## I. GENERAL INFORMATION

**A. Background:** Sections 1861(m) and 1861(kk) of the Social Security Act provide for coverage of Food and Drug Administration (FDA) approved injectable drugs for osteoporosis provided by a home health agency (HHA) to female beneficiaries who meet certain criteria. Initially, the only FDA approved injectable drug for osteoporosis was calcitonin. The FDA has approved the drug teriparatide (brand named Forteo) for use in treating osteoporosis. A new HCPCS code for teriparatide will be effective January 1, 2005.

**B. Policy:** Effective for dates of service on or after January 1, 2005, Medicare may cover teriparatide when provided by an HHA to female beneficiaries who meet the criteria established in Pub. 100-02, Medicare Benefit Policy Manual, section 50.4.3 and the coverage criteria for the home health benefit established in Pub. 100-02, Medicare Benefit Policy Manual, section 30. Like the calcitonin based osteoporosis drug, teriparatide is paid on a cost basis and is subject to deductible and coinsurance. The drug may be billed using HCPCS code J3110. Additionally, Medicare systems must make changes to accept a miscellaneous code to prepare for future situations in which an osteoporosis drug is approved by the FDA but has not yet received an HCPCS code.

**C. Provider Education:** A Medlearn Matters provider education article related to this instruction will be available at [www.cms.hhs.gov/medlearn/matters](http://www.cms.hhs.gov/medlearn/matters) shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article must be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.

## II. BUSINESS REQUIREMENTS

*"Shall" denotes a mandatory requirement*

*"Should" denotes an optional requirement*

Require ment Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3524.1	RHHIs shall instruct providers to submit claims for Forteo for dates of service on or after January 1, 2005, using HCPCS code J3110 (Injection, teriparatide, 10 mcg) on type of bill 34X.		X							
3524.2	RHHIs shall instruct providers to submit claims for FDA approved osteoporosis drugs not described by a specific HCPCS code using HCPCS code J3490 on type of bill 34X.		X							
3524.3	Medicare systems shall accept HCPCS codes J3110 and J3490 on type of bill 34X.		X			X				
3524.4	Medicare systems shall make payment on a cost basis on HCPCS codes J3110 and J3490 when reported on type of bill 34X.					X				
3524.5	Medicare systems shall apply Part B deductible and 20% coinsurance to payments for HCPCS codes J3110 and J3490 when reported on type of bill 34X.					X				
3524.6	RHHIs shall suspend claims with HCPCS J3110 for dates of service on or after January 1, 2005, which are received before April 5, 2005 (i.e., before Medicare systems changes can be made to process them).		X							
3524.6.1	RHHIs shall release suspended claims with HCPCS J3110 after Medicare systems changes have been made to process them, paying any applicable interest due.		X							
3524.6.2	RHHIs shall annotate claims with HCPCS J3110 for dates of service on or after January 1, 2005, which are received before April 5, 2005, with condition code 15.		X							

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)								
		F I	R H H I	C a r r i e r	D M E R C	Shared System Maintainers				Other
						F I S S	M C S	V M S	C W F	
3524.7	Medicare systems shall ensure that HCPCS codes J0630, J3110 or J3490 are not paid on type of bill 34X when a 34X claim has been paid for any of these HCPCS code for the same dates of service.					X			X	
3524.8	Medicare systems shall reject duplicate claims for osteoporosis drugs, as identified in requirement 3524.7, using reason code 18 (duplicate claim/service) on the remittance advice.		X			X				
3524.9	Medicare systems shall use Medicare Summary Notice 7.3 message for duplicate claims for osteoporosis drugs, as identified in requirement 3524.7.		X			X				
3524.10	RHHIs shall ensure HCPCS code J3490 is set up to suspend for manual intervention whenever it is received.		X							
3524.11	RHHIs shall reject claims for HCPCS code J3490 if they determine that a new osteoporosis drug has not been approved by the FDA effective for the submitted date of service.		X							

### III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

#### A. Other Instructions:

X-Ref Requirement #	Instructions
3524.1 through 3524.5	All coverage criteria for the home health benefit and for the osteoporosis drug must be met in order for claims for the drug to be paid.
3524.9	MSN message 7.3 is defined “This service/item is a duplicate of a previously processed service. No appeal rights are attached to the denial of this service except for the issue as to whether the service is a duplicate. Disregard the appeals information on this notice unless you are appealing whether the service is a duplicate.”

**B. Design Considerations: N/A**

**C. Interfaces: N/A**

**D. Contractor Financial Reporting /Workload Impact: N/A**

**E. Dependencies: N/A**

**F. Testing Considerations: N/A**

**IV. SCHEDULE, CONTACTS, AND FUNDING**

<p><b>Effective Date*:</b> January 1, 2005</p> <p><b>Implementation Date:</b> Systems changes: April 4, 2005. RHHI actions not dependent on systems changes: December 6, 2004.</p> <p><b>Pre-Implementation Contact(s):</b> Debra Gillespie, (410) 786 – 4631, <a href="mailto:dgillespie@cms.hhs.gov">dgillespie@cms.hhs.gov</a> (policy), Wil Gehne (410) 786-6148, <a href="mailto:wgehne@cms.hhs.gov">wgehne@cms.hhs.gov</a> (claims)</p> <p><b>Post-Implementation Contact(s):</b> Regional Offices</p>	<p><b>Medicare Contractors shall implement these instructions within their current operating budgets.</b></p>
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## 90.1 - Osteoporosis Injections as HHA Benefit

*(Rev. 358, Issued 11-05-04, Effective: 01-01-05, Implementation: 04-04-05)*

### A - Billing Requirements

*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. Drugs that have the ingredient calcitonin are billed using HCPCS code J0630. Drugs that have the ingredient teriparatide may be billed using HCPCS code J3110, if all existing guidelines for coverage under the home health benefit are met. 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.*

*HCPCS code J0630 is defined as up to 400 units. Therefore, the provider must calculate units for FL 46 of the bill as follows:*

<b>Units Furnished During Billing Period</b>	<b>Units of Service Entry on Bill</b>
100-400	1
401-800	2
801-1200	3
1201-1600	4
1601-2000	5
2001-2400	6

*HCPCS code J3110 is defined as 10 mcg. Providers should report 1 unit in FL 46 for each 10 mcg dose provided during the billing period.*

*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.*

*Coverage requirements for osteoporosis drugs are found in Pub. 100-02, Medicare Benefit Policy Manual, chapter 7, section 50.4.3. Coverage requirements for the home health benefit in general are found in Pub. 100-02, Medicare Benefit Policy Manual, chapter 7, section 30.*

### B - Denial Messages

If the claim for an osteoporosis drug is denied because it was not an injectable drug approved by the FDA, the FI shall use the appropriate message below on the MSN:

- MSN Message 6.2: "Drugs not specifically classified as effective by the Food and Drug Administration are not covered."

If the claim for an osteoporosis injection is denied because the patient did not meet the requirements for coverage, the FI shall use:

- MSN message 6.5, which reads, "Medicare cannot pay for this injection because one or more requirements for coverage were not met."

### **C - Edits**

If the service dates on the 34X claim fall within an HH PPS episode that is open for the beneficiary on CWF, CWF edits to assure that the provider number on the 34X claim matches the provider number on the episode file. This is to reflect that although the osteoporosis drug is paid separately from the HH PPS episode rate it is included in consolidated billing requirements (see §10.1.25 regarding consolidated billing).

*Claims are also edited to assure that the beneficiary is female and that the diagnosis code 733.01 (post-menopausal osteoporosis) is present.*