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# CMS Manual System

## Pub. 100-02 Medicare Benefit Policy

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

Transmittal 26

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	7/50.4/Medical Supplies (Except for Drugs and Biologicals Other Than Covered Osteoporosis Drugs) and the Use of Durable Medical Equipment
N	7/50.4.3/Covered Osteoporosis Drugs

**III. FUNDING:** Medicare contractors shall implement these instructions within their current operating budgets.

**IV. ATTACHMENTS:**

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

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

# Medicare Benefit Policy Manual

## Chapter 7 - Home Health Services

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*(Rev. 26, 11-05-04)*

### [Crosswalk to Old Manuals](#)

50.4 - Medical Supplies (Except for Drugs and Biologicals *Other Than Covered Osteoporosis Drugs*) and the Use of Durable Medical Equipment

*50.4.3 – Covered Osteoporosis Drugs*

**50.4 - Medical Supplies (Except for Drugs and Biologicals *Other Than Covered Osteoporosis Drugs*) and the Use of Durable Medical Equipment**  
*(Rev.26, Issued 11-05-04, Effective: 01-01-05, Implementation: 04-04-05)*

**50.4.3 – Covered Osteoporosis Drugs**

*(Rev. 26, Issued 11-05-04, Effective: 01-01-05, Implementation: 04-04-05)*

*Sections 1861(m) and 1861(kk) of the Act provide for coverage of FDA approved injectable drugs for the treatment of osteoporosis. These drugs are expected to be provided by an HHA to female beneficiaries who are currently receiving services under an open home health plan of care, who meet existing coverage criteria for the home health benefit and who meet the criteria listed below. These drugs are covered on a cost basis when provided by an HHA under the circumstances listed below.*

*The home health visit (i.e., the skilled nurse's visit) to administer the drug is covered under all fee-for-service Medicare (Part A or Part B) home health coverage rules (see section 30 above). Coverage of the drug is limited to female beneficiaries who meet each of the following criteria:*

- 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 she 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.*

*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.*

*For instructions on billing for covered osteoporosis drugs, see Pub. 100-04, Medicare Claims Processing Manual, Chapter 10, Section 90.1.*