CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 70	**Date: MAY 11, 2007**
	Change Request 5521

Subject: Bone Mass Measurements (BMMs)

I. SUMMARY OF CHANGES: Manualizes conditions for coverage issued in the Federal Register (FR) Interim Final Rule (63 FR 34320) on June 24, 1998, and changes issued in the FR Final Rule (71 FR 69624) on December 1, 2006.

New / Revised Material
Effective Date: January 1, 2007
Implementation Date: July 2, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. 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 is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	15/Table of Contents
N	15/80.5/Bone Mass Measurements (BMMs)
N	15/80.5.1/Background
N	15/80.5.2/Authority
N	15/80.5.3/Definition
N	15/80.5.4/Conditions for Coverage
N	15/80.5.5/Frequency Standards
N	15/80.5.6/Beneficiaries Who May be Covered
N	15/80.5.7/Noncovered BMMs
N	15/80.5.8/Claims Processing
N	15/80.5.9/National Coverage Determinations (NCDs)

III. FUNDING:
No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-02	Transmittal: 70	Date: May 11, 2007	Change Request: 5521

SUBJECT: Bone Mass Measurements (BMMs)

Effective Date: **January 1, 2007**

Implementation Date: July 2, 2007

I. GENERAL INFORMATION

A. Background: On June 24, 1998, CMS published an Interim Final Rule with Comment Period (IFC) in the **Federal Register** entitled "Medicare Coverage of and Payment for Bone Mass Measurements." This IFC implemented section 4106 of the BBA by establishing 42 CFR 410.31, Bone Mass Measurement: Conditions for Coverage and Frequency Standards. This new regulation defined BMM and individuals qualified to receive a BMM, established conditions for coverage under the "reasonable and necessary" provisions of 1862(a)(1)(A) of the Social Security Act, and established frequency standards governing when qualified individuals would be eligible for a BMM.

B. Policy: On December 1, 2006, CMS published the CY 2007 Physician Fee Schedule final rule, which included changes to 42 CFR 410.31. Complete coverage instructions for BMMs can be found in chapter 15, section 80.5 of Pub.100-02, Medicare Benefit Policy Manual. Claims processing instructions can be found in chapter 13, section 140 of Pub.100-04, Claims Processing Manual.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5521.1	Effective for dates of service on and after January 1, 2007, contractors shall pay BMM claims for dual-energy x-ray absorptiometry (CPT procedure code 77080) when this procedure is used to monitor osteoporosis drug therapy.	X		X	X							
5521.1.1	Contractors shall accept/allow CPT procedure code 77080 when billed with the following ICD-9-CM diagnoses codes or any of the other valid ICD-9-CM diagnoses codes that are recognized by Medicare contractors as appropriate for BMMs.	X		X	X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	• 733.00, • 733.01, • 733.02, • 733.03, • 733.09, • 733.90, or • 255.0.											
5521.2	Effective for dates of service on and after January 1, 2007, contractors shall not pay BMM claims when a procedure other than dual-energy x-ray absorptiometry (CPT procedure code 77080) is used to monitor osteoporosis drug therapy.	X		X	X							
5521.2.1	Contractors shall deny CPT procedure codes 77078, 77079, 77081, 77083, 76977 and G0130 when billed with ICD-9-CM diagnosis codes 733.00, 733.01, 733.02, 733.03, 733.09, 733.90, or 255.0.	X		X	X							
5521.3	Effective for dates of service on or after January 1, 2007, contractors shall not pay BMM claims for single photon absorptiometry.	X		X	X							
5521.3.1	Contractors shall deny CPT procedure code 78350. **Note: CPT procedure code 78350 is non-covered in the 2007 MPFSDB.**	X		X	X							
5521.4	Contractors shall advise physicians and hospitals that they will be liable for noncovered BMMs unless they issue an appropriate advance beneficiary notice (ABN) as required in 5521.8.	X		X	X							
5521.4.1	Contractors shall advise physicians and hospitals to include the following language in the ABN form: "Items or Service" Section: Insert name of the denied procedure. "Because" Section: **"**As specified in chapter 15, section 80.5 of Pub.100-02, Medicare Benefit Policy	X		X	X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	Manual, Medicare will not pay for this test as it is not reasonable and necessary for Medicare beneficiaries undergoing bone mass measurement."											
5521.5	Contractors shall use the following messages when denying BMM claims as specified in BRs 5521.2 and 5521.3 and an ABN was issued. Medicare Summary Notice (MSN) # 16.10: "Medicare does not pay for this item or service." Or "Medicare no paga por este articulo o servicio." (Spanish Version) Claim Adjustment Reason Code 50: "These are non-covered services because this is not deemed a "medical necessity" by the payer". Remittance Advice Remark Code M38: "The patient is liable for the charges for this service as you informed the patient in writing before the service was furnished that we would not pay for it, and the patient agreed to pay." Group code PR: "Patient Responsibility." MSN# 36.1: "Our records show that you were informed in writing, before receiving the service, that Medicare would not pay. You are liable for this charge. If you do not agree with this statement, you may ask for a review." (English version) or "Nuestros archivos indican que usted fue informado por escrito, antes de recibir el servicio, que Medicare no pagaría. Usted es	X			X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	responsable por esta cantidad. Si usted no está de acuerdo, usted puede pedir una revisión." (Spanish version)											
5521.5.1	Contractors shall use the following messages when denying BMM claims as specified in BRs 5521.2 and 5521.3 and an ABN was issued. MSN# 36.1: "Our records show that you were informed in writing, before receiving the service, that Medicare would not pay. You are liable for this charge. If you do not agree with this statement, you may ask for a review." (English version) or "Nuestros archivos indican que usted fue informado por escrito, antes de recibir el servicio, que Medicare no pagaría. Usted es responsable por esta cantidad. Si usted no está de acuerdo, usted puede pedir una revisión." (Spanish version) Claim Adjustment Reason Code 50: "These are non-covered services because this is not deemed a "medical necessity" by the payer". Remittance Advice Remark Code M38: "The patient is liable for the charges for this service as you informed the patient in writing before the service was furnished that we would not pay for it, and the patient agreed to pay." Group code PR: "Patient Responsibility."	X		X								

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5521.5.2	Contractors shall use the following messages when denying BMM claims as specified in BRs 5521.2 and 5521.3 and an ABN was NOT issued. MSN # 16.10: "Medicare does not pay for this item or service. (English Version) Or "Medicare no paga por este articulo o servicio." (Spanish Version) Claim Adjustment Reason Code 50: "These are non-covered services because this is not deemed a "medical necessity" by the payer". Remittance Advice Remark Code M27: "The patient has been relieved of liability of payment of these items and services under the limitation of liability provision of the law. You, the provider, are ultimately liable for the patient's waived charges, including any charges for coinsurance, since the items or services were not reasonable and necessary or constituted custodial care, and you knew or could reasonably have been expected to know, that they were not covered. You may appeal this determination. You may ask for an appeal regarding both the coverage determination and the issue of whether you exercised due care. The appeal request must be filed within 120 days of the date you receive this notice. You must make the request through this office." Group code CO: "Contractual Obligations." MSN# 36.2: "It appears that you did not know that we	X			X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	would not pay for this service, so you are not liable. Do not pay your provider for this service. If you have paid your provider for this service, you should submit to this office three things: (1) a copy of this notice, (2) your provider's bill, and (3) a receipt or proof that you have paid the bill. You must file your written request for payment within 6 months of the date of this notice. Future services of this type provided to you will be your responsibility." (English version) or "Aparentemente, usted no sabia que nosotros no pagamos por este servicio, por lo tanto usted no es responsable. Si usted le pagó al proveedor por este servicio debe enviarnos lo siguiente: (1) Copia de esta notificación; (2) Factura del proveedor; (3) El recibo o prueba de que usted le pagó. Debe enviar su petición por escrito dentro de 6 meses de la fecha de esta notificación. Servicios de este tipo prestados en el futuro serán su responsabilidad." (Spanish Version)											
5521.5.3	Contractors shall use the following messages when denying BMM claims as specified in BRs 5521.2 and 5521.3 and an ABN was NOT issued. MSN# 36.2: "It appears that you did not know that we would not pay for this service, so you are not liable. Do not pay your provider for this service. If you have paid your provider for this service, you should submit to this office three things: (1) a copy of this notice, (2) your provider's bill, and (3) a receipt or proof that you have paid the bill. You must file your written request for payment within 6 months of the date of this notice. Future services of this type provided to you will be your responsibility." (English version)	X		X								

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
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Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5521.6	Contractors shall advise physicians and hospitals of these payment changes via the MLN Matters Article as required in 5521.8.	X		X	X							
5521.7	Contractors shall not search for and adjust claims that have been paid prior to the implementation date. However contractors shall adjust claims brought to their attention.	X		X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MMAAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5521.8	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN 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 shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X							

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s):

Coverage: Bill Larson at william.larson@cms.hhs.gov or 410-786-4639.
FI Claims: Bill Ruiz at william.ruiz@cms.hhs.gov or 410-786-9283.
Carrier Claims: Tom Dorsey at thomas.dorsey@cms.hhs.gov or 410-786-7434.

Post-Implementation Contact(s): Regional Office

VI. FUNDING

A. *For Fiscal Intermediaries, Carriers, and the Durable Medical Equipment Regional Carrier (DMERC)*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. Medicare Administrative Contractors:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Benefit Policy Manual

Chapter 15 - Covered Medical and Other Health Services

Table of Contents

(Rev. 70, 05-11-07)

80.5 - Bone Mass Measurements (BMMs)
(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

80.5.1 - Background
(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

*On June 24, 1998, CMS published an Interim Final Rule with Comment Period (IFC) in the **Federal Register** entitled "Medicare Coverage of and Payment for Bone Mass Measurements." This IFC implemented section 4106 of the Balanced Budget Act of 1997 by establishing conditions for coverage and frequency standards thereby providing uniform coverage under Medicare Part B. It was effective July1, 1998.*

On December 1, 2006, CMS published the CY 2007 Physician Fee Schedule final rule. This rule implemented several changes effective January 1, 2007, which are reflected below.

80.5.2 - Authority
(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Definitions can be found in sections 1861(s)(15) and (rr)(1) of the Social Security Act (the Act). Conditions for coverage and frequency standards can be found in 42 CFR 410.31. Denials as not reasonable and necessary can be found at §1862(a)(1)(A) of the Act, 42 CFR 410.31(e), and 42 CFR 411.15(k).

80.5.3 - Definition
(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

BMM means a radiologic, radioisotopic, or other procedure that meets all of the following conditions:

- *Is performed to identify bone mass, detect bone loss, or determine bone quality.*
- *Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system that has been cleared for marketing for BMM by the Food and Drug Administration (FDA) under 21 CFR part 807, or approved for marketing under 21 CFR part 814.*
- *Includes a physician’s interpretation of the results.*

80.5.4 - Conditions for Coverage

(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Medicare covers BMM under the following conditions:

1. *Is ordered by the physician or qualified nonphysician practitioner who is treating the beneficiary following an evaluation of the need for a BMM and determination of the appropriate BMM to be used.*

   A physician or qualified nonphysician practitioner treating the beneficiary for purposes of this provision is one who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results in the management of the patient. For the purposes of the BMM benefit, qualified nonphysician practitioners include physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives.

2. *Is performed under the appropriate level of physician supervision as defined in 42 CFR 410.32(b).*

3. *Is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in §80.5.6.*

4. *In the case of an individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy, is performed with a dual-energy x-ray absorptiometry system (axial skeleton).*

5. *In the case of any individual who meets the conditions of 80.5.6 and who has a confirmatory BMM, is performed by a dual-energy x-ray absorptiometry system (axial skeleton) if the initial BMM was not performed by a dual-energy x-ray absorptiometry system (axial skeleton). A confirmatory baseline BMM is not covered if the initial BMM was performed by a dual-energy x-ray absorptiometry system (axial skeleton).*

80.5.5 - Frequency Standards

(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Medicare pays for a screening BMM once every 2 years (at least 23 months have passed since the month the last covered BMM was performed).

When medically necessary, Medicare may pay for more frequent BMMs. Examples include, but are not limited to, the following medical circumstances:

- *Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.*

- *Confirming baseline BMMs to permit monitoring of beneficiaries in the future.*

80.5.6 - Beneficiaries Who May be Covered
(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

To be covered, a beneficiary must meet at least one of the five conditions listed below:

1. *A woman who has been determined by the physician or qualified nonphysician practitioner treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.*

   NOTE: *Since not every woman who has been prescribed estrogen replacement therapy (ERT) may be receiving an "adequate" dose of the therapy, the fact that a woman is receiving ERT should not preclude her treating physician or other qualified treating nonphysician practitioner from ordering a bone mass measurement for her. If a BMM is ordered for a woman following a careful evaluation of her medical need, however, it is expected that the ordering treating physician (or other qualified treating nonphysician practitioner) will document in her medical record why he or she believes that the woman is estrogen-deficient and at clinical risk for osteoporosis.*

2. *An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.*

3. *An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average of 5.0 mg of prednisone, or greater, per day, for more than 3 months.*

4. *An individual with primary hyperparathyroidism.*

5. *An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.*

80.5.7 - Noncovered BMMs
(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

The following BMMs are noncovered under Medicare because they are not considered reasonable and necessary under section 1862(a)(1)(A) of the Act.

- *Single photon absorptiometry (effective January 1, 2007).*
- *Dual photon absorptiometry (established in 1983).*

80.5.8 - Claims Processing

(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

For instructions concerning payment methodology, HCPCS coding, and Medicare summary notice and remittance advice messages, see chapter 13, section 140 of Pub. 100-04, Medicare Claims Processing Manual.

80.5.9 - National Coverage Determinations (NCDs)

(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

In addition to these conditions for coverage, CMS may determine through the NCD process that additional BMM systems are reasonable and necessary under section 1862(a)(1) of the Act for monitoring and confirming baseline BMMs.