CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1663	**Date: JANUARY 8, 2009**
	Change Request 6313

NOTE: CR 6313 rescinds and replaces CR6138 released on July 25, 2008. Please see BR 6313.2 for additional ICD-9-CM codes inadvertently omitted. All other information remains the same.

Subject: Correction to Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management

I. SUMMARY OF CHANGES: Adds ICD-9-CM diagnosis codes that were inadvertently omitted from original implementation.

New / Revised Material
Effective Date: March 19, 2008
Implementation Date: February 9, 2009

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-*Only One Per Row.*

R/N/D	Chapter / Section / Subsection / Title
R	32/60.4.1/Allowable Covered Diagnosis Codes
R	32/60.5.2/Applicable Diagnosis Codes for Carriers

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted 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.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1663	Date: January 8, 2009	Change Request: 6313

NOTE: CR 6313 rescinds and replaces CR6138 released on July 25, 2008. Please see BR 6313.2 for additional ICD-9-CM codes inadvertently omitted. All other information remains the same.

SUBJECT: Correction to Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management

Effective Date: March 19, 2008

Implementation Date: February 9, 2009

I. GENERAL INFORMATION

A. Background: The prothrombin time (PT) test is an in-vitro test to assess coagulation. PT testing and its normalized correlate, the International Normalized Ratio (INR), are the standard measurements for therapeutic effectiveness of warfarin therapy. Warfarin, Coumadin®, and others, are self-administered, oral anticoagulant, or blood thinner, medications that affect a person's Vitamin K-dependent clotting factors.

The Centers for Medicare & Medicaid Services (CMS) received a formal, complete, written request for reconsideration to expand the population eligible for coverage of home PT/INR monitoring to patients on warfarin. This revised NCD is a result of that request.

B. Policy: Effective for claims with dates of service on and after March 19, 2008, CMS revised its NCD on Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management as follows:

Medicare will cover the use of home PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a) and all of the following requirements must be met:

1. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device; and,
2. The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home; and,
3. The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and,
4. Self-testing with the device should not occur more frequently than once a week.

NOTE: Applicable HCPCS Codes G0248, G0249, and G0250 will continue to be used for claims processing purposes for PT/INR. With the July 2008 OCE and Medicare Physician Fee Schedule updates (MPFS), the descriptors of these codes will change to reflect the revised coverage policy. The new descriptors reflect the expanded NCD criteria and are effective back to March 19, 2008. See below:

Long Descriptor G0248: Demonstration, prior to initial use, of home INR monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results, and documentation of patient ability to perform testing prior to its use

Short Descriptor G0248: Demonstrate use home INR mon

Long Descriptor G0249: Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week

Short Descriptor G0249: Provide INR test mater/equip

Long Descriptor G0250: Physician review, interpretation, and patient management of home INR testing for a patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes face-to-face verification by the physician that the patient uses the device in the context of the management of the anticoagulation therapy following initiation of the home INR monitoring; not occurring more frequently than once a week

Short Descriptor G0250: MD INR test revie inter mgmt

NOTE: Test materials continue to include 4 tests. Frequency of reporting requirements shall remain the same.

NOTE: Porcine valves are not included in this NCD, so Medicare will not make payment on Home INR Monitoring for patients with porcine valves unless covered by local Medicare contractors.

NOTE: This NCD is distinct from, and makes no changes to, the PT clinical laboratory NCD at Pub. 100-03, section 190.17, of the NCD Manual.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6313.1	Effective for claims with dates of service on and after March 19, 2008, contractors shall process and pay for expanded home PT/INR monitoring for patients requiring chronic, oral anticoagulation management with warfarin because of a mechanical heart valve, chronic atrial fibrillation, or venous thromboembolism, in accordance with section 190.11 of Pub 100-03 of the NCD Manual.	X		X	X						
6313.2	Effective for claims with dates of service on and after March 19, 2008, contractors shall be aware that revised HCPCS codes G0248 and G0249 (effective March 19, 2008) will be used to process and pay for expanded home PT/INR monitoring services, along with ICD-9-CM: V43.3 (organ or tissue replaced by other means; heart valve), 289.81 (primary hypercoagulable state), 451.0-451.9 (includes 451.11, 451.19, 451.2, 451.80-451.84, 451.89) (phlebitis & thrombophlebitis), 453.0-453.3 (other venous embolism & thrombosis), 453.40-453.49 (includes 453.40-453.42, 453.8-453.9) (venous embolism and thrombosis of the deep vessels of	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	the lower extremity, and other specified veins/unspecified sites) 415.11-415.12, 415.19 (pulmonary embolism & infarction) or, 427.31 (atrial fibrillation (established) (paroxysmal)).										
6313.3	Effective for claims with dates of service on and after March 19, 2008, contractors shall be aware that revised HCPCS code G0250 (effective March 19, 2008) will be used to process and pay for expanded home PT/INR monitoring services, along with ICD-9-CM codes noted above in 6313.2.	X			X						
6313.4	Effective for claims with dates of service on and after March 19, 2008, contractors shall deny PT/INR monitoring services not delivered in accordance with section 190.11 of Pub 100-03 of the NCD Manual based on a reasonable and necessary determination.	X		X	X						
6313.4.1	When denying claims for home PT/INR monitoring services, contractors shall use the following messages: Medicare Summary Notice 15.20, "The following policies (NCD 190.11) were used when we made this decision." Claims Adjustment Reason Code 50," "Theses are non-covered services because this is not deemed a medical necessity by the payer." Remittance Advice Remark Code N386, "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have Web access, you may contact the contractor to request a copy of the NCD."	X		X	X						
6313.4.2	Denials are subject to appeal and Shared-System Maintainers (SSMs) shall allow for medical review override of denials for appeal purposes.	X		X	X						
6313.4.3	Contractors shall assign liability for the denied charges to the provider unless documentation of an Advance Beneficiary Notice (ABN) is present on the claim.	X		X	X						
6313.5	Contractors shall not search for claims but shall adjust inappropriately denied claims with dates of service	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	March 19, 2008, through the implementation date of this CR, that are brought to their attention.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6313.6	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 one 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

Section 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:
6313.2&3	Claims processed on and after March 19, 2008, and prior to the implementation date of this CR shall process using the current HCPCS descriptors.

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Kimberly Long (coverage), 410-786-5702, Kimberly.long@cms.hhs.gov, Pat Brocato-Simons (coverage), 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Cynthia Glover (practitioner claims), 410-786-2589, cynthia.glover@cms.hhs.gov, Melissa E. Dehn (Institutional Claims) 410-786-5721, melissa.dehn@cms.hhs.gov

Post-Implementation Contact(s): Appropriate CMS Regional Office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs) and Carriers*:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*:
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Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev. 1663, 01-08-09)

60.4.1 – Allowable Covered Diagnosis Codes

(Rev. 1663; Issued: 01-08-09; Effective Date: 03-19-08; Implementation Date: 02-09-09)

For services furnished on or after July 1, 2002, the applicable ICD-9-CM diagnosis code for this benefit is V43.3, organ or tissue replaced by other means; heart valve.

For services furnished on or after March 19, 2008, the applicable ICD-9-CM diagnosis codes for this benefit are:

V43.3 (organ or tissue replaced by other means; heart valve),
289.81 (primary hypercoagulable state),
451.0-451.9 (includes 451.11, 451.19, 451.2, 451.80-451.84, 451.89) (phlebitis & thrombophlebitis),
453.0-453.3 (other venous embolism & thrombosis),
453.40-453.49 (includes 453.40-453.42, 453.8-453.9) (venous embolism and thrombosis of the deep vessels of the lower extremity, and other specified veins/unspecified sites)
415.11-415.12, 415.19 (pulmonary embolism & infarction) or,
427.31 (atrial fibrillation (established) (paroxysmal)).

60.5.2 – Applicable Diagnosis Codes for Carriers

(Rev. 1663; Issued: 01-08-09; Effective Date: 03-19-08; Implementation Date: 02-09-09)

For services furnished on or after July 1, 2002, the applicable ICD-9-CM diagnosis code for this benefit is V43.3, organ or tissue replaced by other means; heart valve.

For services furnished on or after March 19, 2008, the applicable ICD-9-CM diagnosis codes for this benefit are:

V43.3 (organ or tissue replaced by other means; heart valve),
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451.0-451.9 (includes 451.11, 451.19, 451.2, 451.80-451.84, 451.89) (phlebitis & thrombophlebitis),
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