

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 90	Date: July 25, 2008
	Change Request 6138

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

I. SUMMARY OF CHANGES: 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.

This addition/revision is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW / REVISED MATERIAL

EFFECTIVE DATE: MARCH 19, 2008

IMPLEMENTATION DATE: August 25, 2008

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	1/Table of Contents
R	1/190.11/Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management – (Effective March 19, 2008)

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. 100-03	Transmittal: 90	Date: July 25, 2008	Change Request: 6138
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SUBJECT: Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management

Effective Date: March 19, 2008

Implementation Date: August 25, 2008

I. GENERAL INFORMATION

A. Background: The 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.

Currently, Medicare's national coverage determination (NCD) at 190.11 of the NCD Manual limits coverage of home PT/INR monitoring to anticoagulation management for patients with mechanical heart valves who are on warfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a) and 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;
2. The patient must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
3. Self-testing with the device should not occur more frequently than once a week.

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, 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

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6138.1	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	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	atrial fibrillation, or venous thromboembolism, in accordance with section 190.11, Pub.100-03, NCD Manual, and chapter 32, section 60, Pub. 100-04, Medicare Claims Processing Manual.										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6138.2	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:

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, Tracey Herring (supplier claims), 410-786-7169, tracey.herring@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 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):*

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.

Medicare National Coverage Determinations Manual

Chapter 1, Part 3 (Sections 170 – 190.34)

Coverage Determinations

Table of Contents

(Rev. 90, 07-25-08)

190.11 – Home Prothrombin Time/*International Normalized Ratio (PT/INR)*
Monitoring for Anticoagulation Management – *(Effective March 19, 2008)*

190.11 - Home Prothrombin Time/*International Normalized Ratio (PT/INR)* Monitoring for Anticoagulation Management – *Effective March 19, 2008*
(Rev.90, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

A. General

Use of the International Normalized Ratio (INR) *or prothrombin time (PT) - standard measurement for reporting the blood's clotting time* - allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's *PT (extrinsic or tissue-factor dependent coagulation pathway)* compared to the mean *PT* for a group of normal individuals. Maintaining patients within *his/her prescribed* therapeutic range minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events. Patient self-testing and self-management through the use of a home INR monitor may be used to improve the time in therapeutic rate (TTR) for select groups of patients. Increased TTR leads to improved clinical outcomes and reductions in thromboembolic and hemorrhagic events.

Warfarin (also prescribed under other trade names, e.g., Coumadin®) is a self-administered, oral anticoagulant (blood thinner) medication that affects the vitamin K-dependent clotting factors II, VII, IX and X. It is widely used for various medical conditions, and has a narrow therapeutic index, meaning it is a drug with less than a 2-fold difference between median lethal dose and median effective dose. For this reason, since October 4, 2006, it falls under the category of a Food and Drug Administration (FDA) "black-box" drug whose dosage must be closely monitored to avoid serious complications. A PT/INR monitoring system is a portable testing device that includes a finger-stick and an FDA-cleared meter that measures the time it takes for a person's blood plasma to clot

B. Nationally Covered Indications

For services furnished on or after *March 19, 2008*, 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.

C. Nationally Non-Covered Indications

N/A

D. Other

1. *All other indications for home PT/INR monitoring not indicated as nationally covered above remain at local Medicare contractor discretion.*
2. *This national coverage determination (NCD) is distinct from, and makes no changes to, the PT clinical laboratory NCD at section 190.17 of Publication 100-03 of the NCD Manual.*

(This NCD last reviewed March 2008.)