

## Evidence Based Guideline

# Prothrombin Time Monitoring In The Home

**File Name:** prothrombin\_time\_monitoring\_in\_the\_home  
**Guideline Number:** EBG.DME0232  
**Origination:** 8/2002  
**Last Review:** 3/2008  
**Next Review:** 3/2010

### Description of Procedure or Service

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Warfarin (Coumadin) is an effective anticoagulant for the treatment and prevention of venous and arterial blood clots. Chronic warfarin therapy is recommended in all patients with mechanical heart valves and in some patients with chronic atrial fibrillation (i.e., patients with one high risk factor or more than one moderate risk factor). Patients with mechanical heart valves are frequently anticoagulated at higher levels than patients anticoagulated for other indications. This puts them at higher risk of complications from warfarin therapy. Appropriate levels of warfarin anticoagulation are monitored with periodic prothrombin time measurements, as measured by the International Normalized Ratio (INR). For example, an INR >3 results in a higher risk of serious hemorrhage, while an INR of 6 increases the risk of developing a serious bleed nearly 7 times that of someone with an INR below 3. In contrast, an INR below 2 is associated with an increased risk of stroke. Therefore, monitoring of the prothrombin time is recommended to ensure that the dose levels are within the therapeutic range.

There are at least 3 sites/methods of monitoring anticoagulation:

- Physician's office (80%) - usually once a month
- Anticoagulation clinics (20%) - usually once every 2-3 weeks
- Home prothrombin time monitors (<5%)

There are several different devices approved by the U.S. Food and Drug Administration (FDA) that may be purchased by the patient for in-home monitoring of chronic anticoagulant therapy. The FDA approval for all of these devices was based on the demonstration that appropriately trained patients could generate INR test results comparable to laboratory measures. The clinical impact of home prothrombin time monitoring is related to improved warfarin management. Specifically, home prothrombin time monitoring permits more frequent monitoring and self-management of warfarin therapy with the ultimate goal of 1) increasing the time that the anticoagulation is within a therapeutic INR range (intermediate health outcome); and 2) decreasing the incidence of thromboembolic or hemorrhagic events (final health outcome). Home self-monitoring is typically associated with some form of self-management of warfarin therapy. In some cases, the patient may be supplied with treatment algorithms and instructed to alter the dose based on the results of self-monitoring. In other cases, the patient may be instructed to telephone in the results of the self-monitoring and receive further telephonic instructions on warfarin dose.

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Prothrombin Time Monitoring in the Home may be appropriate for the following patients:

1. Patients with mechanical heart valves, or
2. Patients requiring anticoagulation similar to levels as mechanical heart valve, (i.e., an INR of greater

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- than 3), or
3. Patients with chronic atrial fibrillation or deep venous thrombosis.
  4. Before initiation of at-home monitoring, patients must have undergone anticoagulation management for at least 3 months.

### Medical Evidence regarding Prothrombin Time Monitoring in the Home indicates it is not recommended in the following situations:

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Prothrombin Time Monitoring in the Home is not recommended for any condition other than those listed above.

### Benefits Application

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Education or demonstration related to the use of the Prothrombin Time Monitoring is considered incidental to the office visit or the provision of the materials and equipment. Additional reimbursement is not warranted for these services.

Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: G0248, G0249, G0250*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

### Medical Term Definitions

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not applicable

### Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual. 1.01.14; 5/15/02

ECRI, TARGET Report #753, October 2001

Specialty Matched Consultant Advisory Panel - 8/2004

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Hambleton J. (Aug-Oct 2003). Home monitoring of anticoagulation. *J Thromb Thrombolysis*, 16(1-2), 39. Retrieved on July 8, 2004 from [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=14760210](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14760210).

Cheung DS, Heizer D, Wilson J, Gage BF. (Set-Oct 2003). Cost-savings analysis of using a portable coagulator for monitoring homebound elderly patients taking warfarin. *Am J Geriatr Cardiol*, 12(5), 283-7. Retrieved on July 8, 2004 from [http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list\\_uids=12963852](http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=12963852).

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.14, 10/09/03

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.14, 10/10/06

Brown A, Wells P, Jaffey J, McGahan L, Poon M-C, Cimon K, Campbel K. Point-of-care monitoring devices for long-term oral anticoagulation therapy: clinical and cost effectiveness [Technology report no 72]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2007

## Policy Implementation/Update Information

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8/02 Original policy issued.

10/02 System coding changes.

9/9/04 Specialty Matched Consultant Advisory Panel review 8/23/2004 with no changes made to policy criteria. References added. Policy guidelines added to clarify reasons for providing coverage for only patients with mechanical heart valves. Benefits Application and Billing/Coding sections updated for consistent policy language.

3/16/06 Specialty Matched Consultant Advisory Panel review 2/27/06. No changes to policy criteria. Policy number added to Key Words.

4/21/08 Revisions made to the When Covered section. Deleted the statement regarding 3 months of anticoagulant use from Item 1. Added Item 3, "patients with chronic atrial fibrillation or deep venous thrombosis" and added Item 4, "Before initiation of at-home monitoring, patients must have undergone anticoagulation management for at least 3 months." References updated. Specialty Matched Consultant Advisory Panel review 3/13/08. No change to policy statement.

Medical Policy changed to Evidence Based Guideline.

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.