

Evidence Based Guideline

Prothrombin Time Monitoring in the Home

File Name:	prothrombin_time_monitoring_in_the_home
Origination:	8/2002
Last CAP Review:	10/2011
Next CAP Review:	10/2012
Last Review:	4/2012

Description of Procedure or Service

Patients who are prescribed chronic warfarin anticoagulation need ongoing monitoring that has generally taken place in a physician's office or anticoagulation clinic. Home prothrombin monitoring with a U.S. Food and Drug Administration (FDA)-approved device is proposed as an alternative to office or laboratory-based testing.

Warfarin is an effective anticoagulant for the treatment and prevention of venous and arterial thrombosis. 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 prescribed anticoagulants at higher levels than patients given anticoagulants for other indications, which 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 result greater than 3 indicates a higher risk of serious hemorrhage, while an INR of 6 indicates an increased risk of developing a serious bleed nearly 7 times that of someone with an INR less than 3. In contrast, an INR less than 2 is associated with an increased risk of stroke. Therefore, monitoring of the prothrombin time is recommended to ensure that the prescribed dosing regimens result in INRs within the therapeutic range. Anticoagulation can be monitored: 1) in the physician's office (usually once a month), at an anticoagulation clinic (usually once every 2 to 3 weeks), or at home.

In order for home prothrombin time monitoring to be effective, patients need to be appropriately trained and able to generate INR test results comparable to laboratory measures. Moreover, 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 provide the results of the self-monitoring (e.g., on the telephone or internet) and receive instructions on warfarin dosage.

Regulatory Status

In January 2007, the CoaguChek XS System (patient self-testing) (Roche Diagnostics Corporation) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices, including the CoaguChek SX System (professional, cleared in 2006). Other than a labeling change, the device is identical to the professional version of the CoaguChek XS System. The patient self-testing system is intended for self-monitoring of prothrombin time in patients who are on a stable regimen of

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anticoagulation medications.

Previously, the ProTime Microcoagulation System (International Technidyne Corporation) was cleared for marketing by the FDA in 1995 for professional use and in 1997 for home use.

Related policies:

Pharmacogenetic Testing for Warfarin Dose

*****Note: This Evidence Based Guideline is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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At-home monitoring of chronic warfarin therapy is recommended in patients who require continuous anticoagulation for chronic medical conditions. These conditions include, but are not limited to, patients with mechanical heart valves and chronic atrial fibrillation.

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

Prothrombin time monitoring in the home is not recommended for any condition other than those listed above.

Benefits Application

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.

This evidence based guideline relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this guideline.

Billing/Coding/Physician Documentation Information

This guideline 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. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: G0248, G0249, G0250, 99363, 99364

Scientific Background and Reference Sources

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

ECRI, TARGET Report #753, October 2001

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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.

Cheung DS, Heizer D, Wilson J, Gage BF. (Set-Oct 2003). Cost-savings analysis of using a portable coagulometer 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.

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.14, 3/11/10

National Institutes of Health (NIH). Remote Home Prothrombin Time (PT)/International Normalized Ratio (INR) Monitoring and Patient Management System (vMetrics-AMS). Retrieved on September 21, 2010 from <http://clinicaltrials.gov/ct2/show/NCT00978445>

Specialty Matched Consultant Advisory Panel review 10/2010

Garcia-Alamino JM, Ward AM, Alonso-Coello P et al. Self-monitoring and self-management of oral anticoagulation. *Cochrane Database of Systematic Reviews* 2010; Issue 4. Art No: CD003839. Retrieved on April 7, 2011 from <http://onlinelibrary.wiley.com/doi/10.1111/j.1538-7836.2009.03497.x/full>

Matchar DB, Jacobson AK, Edson RG et al. The impact of patient self-testing of prothrombin time for managing anticoagulation: rationale and design of VA cooperative study #481- the Home INR study (THINRS). *J Thromb Thrombolysis* 2005; 19(3):163-72. Retrieved on April 7, 2011 from <http://onlinelibrary.wiley.com/doi/10.1111/j.1538-7836.2009.03497.x/full>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.14, 3/10/11

Specialty Matched Consultant Advisory Panel review 10/2011

Bloomfield HE, Krause A, Greer N, et al. Safe and Effective Anticoagulation in the Outpatient Setting: A Systematic Review of the Evidence. Department of Veterans Affairs. February 2011. Retrieved on April 11, 2011 from <http://www.ncbi.nlm.nih.gov/books/NBK54599/pdf/TOC.pdf>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.14, 3/8/12

Medical Director review 4/2012

Policy Implementation/Update Information

- 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

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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. (adn)

Medical Policy changed to Evidence Based Guideline. (adn)

6/22/10 Policy Guideline Number(s) removed (amw)

11/23/10 Specialty Matched Consultant Advisory Panel review 10/2010. Description section updated. References updated. (mco)

5/24/11 References updated. "Description" section updated. No changes to guideline statements. (mco)

11/8/11 Specialty Matched Consultant Advisory Panel review 10/2011. No changes to Guideline Statements. (mco)

5/1/12 CPT codes 99363 and 99364 added to "Billing/Coding" section. Description section updated. "When Recommended" section revised to state: "At-home monitoring of chronic warfarin therapy is recommended in patients who require continuous anticoagulation for chronic medical conditions. These conditions include, but are not limited to, patients with mechanical heart valves and chronic atrial fibrillation." References updated. Medical Director review 4/2012. (mco)

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.