



# Medical Policy

**Subject:** Prothrombin Time Self-Monitoring Devices  
**Policy #:** DME.00001      **Current Effective Date:** 03/09/2007  
**Status:** Reviewed      **Last Review Date:** 06/08/2006

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## Description/Scope

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Prothrombin time self-monitoring devices are battery-operated devices used to monitor blood-clotting rates by patients in the home. Home prothrombin time monitoring permits more frequent monitoring and self-management of anticoagulant therapy (e.g., warfarin) with the ultimate goal of increasing the time that the anticoagulation is within a therapeutic INR (International Normalized Ratio) range and decreasing the incidence of thromboembolic or hemorrhagic events. The most common indication for chronic warfarin therapy is in patients with mechanical heart valves and to a lesser extent, those patients with atrial fibrillation who are post cerebrovascular accident or transient ischemic attack. Examples of self-monitoring prothrombin time systems include, but may not be limited to: Prottime Microcoagulation System by International Technidyne Corp.®, Coaguchek PST System by Roche Diagnostic Corp.®, Avocet by Avocet Medical Incorporated®, Rubicon Prothrombin Time Monitoring System by Lifescan®, Thrombolytic Assessment System (TAS)®, and Biotrack 512 System®.

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## Policy Statement

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### Medically Necessary:

Home prothrombin time monitoring with the use of INR devices is considered **medically necessary** for individuals who meet *all* of the following criteria:

- Require long term (> 1 year) anticoagulation with warfarin; and
- Require a least weekly determinations of INR values; and
- A treating physician prescribes the monitor and the home testing. (See attachment A “Prothrombin Time Self-Monitoring Devices – Medical Review Sheet” for reference/guidance purposes.)

Note: Patients and/or caregivers who undertake self-monitoring must demonstrate the technical skill and willingness to use the monitor, and the ability to comprehend the basic aspects of oral anticoagulation control, including the risks. Patient and/or caregiver training for home PT self-monitoring needs to be provided under physician supervision. The training must at a minimum consist of demonstrating 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. Patient compliance and good cooperation is a primary factor in patient selection.

### Not Medically Necessary:

Home prothrombin time monitoring is considered **not medically necessary** for individuals who do not meet the criteria set forth above.

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## Rationale

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The studies reviewed evaluated patient populations with a variety of indications for anticoagulation therapy. However, the majority of patients were receiving anticoagulation therapy for prosthetic heart valve replacements. Studies have also included patients with deep venous thrombosis, atrial fibrillation, total hip arthroplasty, and history of pulmonary emboli. Controlled studies have shown that prothrombin time self-monitoring systems were effective in maintaining the INR values within a therapeutic range. None of the studies indicated a decrease in anticoagulation control, and many indicated improved anticoagulation control with home monitoring devices. Such improvement is thought to be due to several factors. PT testing in the self-monitoring patient is generally performed weekly, compared with every two weeks to monthly testing intervals performed by physicians. The complications associated with self-monitoring appear to be equivalent to or less than those associated with anticoagulation therapy monitored by a physician or a specialized clinic. The cumulative evidence from these clinical trials suggest that PT self-monitoring with a portable home PT testing device is accurate, feasible, effective and possibly more effective than standard laboratory PT testing in maintaining anticoagulation control within target therapeutic ranges in patients given proper training and support. The results obtained with PT self-monitoring do not appear to vary with patient diagnosis in the studies evaluated. All patients in the cited studies had conditions that were in need of long-term anticoagulation.

The FDA approval for all home prothrombin time monitoring devices was based on the demonstration that home prothrombin monitors would produce results similar to laboratory based measurements. The FDA approval did not require clinical data demonstrating that the increased frequency of monitoring enabled by the home monitors would improve health outcomes. However, several randomized studies have reported improved health outcomes (primarily increased time in the therapeutic range) associated with home self-monitoring and management, compared to monitoring either in a physician's office or in a specialty anticoagulation clinic. In 2001, the Centers for Medicare and Medicaid (CMS, formerly HCFA) conducted a literature review that offered the following conclusions:

- Published studies are consistent in the demonstration that the use of home monitoring results in a significant increase in the time within the therapeutic range (TTR).
- Two studies, which enrolled a large number of patients, reported a decrease in the incidence of hemorrhage or events requiring hospitalization.
- The majority of these studies included patients requiring chronic warfarin therapy. In these studies, the most common indication for chronic warfarin therapy was patients with mechanical heart valves.

The CMS analysis concluded that patients with mechanical heart valves would be most likely to benefit from home prothrombin monitoring for the following reasons:

- Patients with mechanical heart valves need to be anticoagulated for life, whereas other indications do not necessarily require lifelong anticoagulation.
- Patients with mechanical heart valves need to be anticoagulated at a higher range, with a greater potential risk for complications. Thus, the magnitude of benefit is greatest for this indication.

The CMS analysis also noted that, in order to achieve increased time within the therapeutic range of >90%, a patient would likely need to undergo self-testing once a week.

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## **Background/Overview**

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Prothrombin time self-monitoring systems are battery-operated devices used to monitor blood-clotting rates by patients in the home. Each of these systems includes a monitor, a disposable plastic reagent cartridge and a finger stick blood collection kit. The device stores from 30 to 40 of the most recent test results which are dated and time-stamped. This enables the physician and/or the patient to review the results and monitor trends in the patient's oral anticoagulant therapy control. After testing, patients either notify their physicians of the results or use an individualized algorithm, developed with physician supervision; to adjust

their anticoagulation dosage (warfarin/Coumadin®) to maintain PT levels within a target zone. The goal of self-monitoring and self-management of PT levels is to improve anticoagulation control and reduce the frequency of adverse events. Several FDA approved devices are available for use in the home. All home PT self-monitoring system devices require a prescription for use, and the prescribing physician is responsible for the training and ongoing management of patients selected for self-monitoring.

Oral anticoagulant drugs have been used in the prophylaxis and treatment of venous thrombosis, pulmonary embolus, thromboembolic complications of atrial fibrillation, prosthetic heart valve replacement, and to prevent recurrent myocardial infarctions and transient ischemic attacks. In the United States, Coumarin derivatives are the most commonly used oral anticoagulants and include warfarin (Coumadin®) and dicumarol.) All oral anticoagulants have a narrow therapeutic index. Changes in diet, drug interactions, illness, individual differences, and spontaneous fluctuations in the sensitivity to oral anticoagulant influence the dose-response relationships for these drugs. As a result, oral anticoagulant therapy requires individualized treatment for each patient and frequent blood coagulation monitoring to prevent serious bleeding from too much anticoagulation or thromboembolic complications from inadequate coagulation.

The anticoagulant effect of warfarin should be kept at an international normalized ratio (INR) of about 2.5 (desirable range, 2.0-3.0), although a higher level may be better in certain clinical conditions, such as in patients with prosthetic heart valves. The risk of bleeding increases exponentially with INR and becomes clinically unacceptable once the INR exceeds 5.0. Major bleeding has been reported in 1.1%-8.1% of patients during each year of long-term warfarin therapy. Risk factors include old age, serious illness (cerebral, cardiac, kidney or liver disease), cerebrovascular or peripheral vascular disease, and an unstable anticoagulant effect.

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## Definitions

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**International Normalized Ratio (INR):** Until a few years ago, the warfarin dose was altered based on the ratio of the patient's prothrombin time (PT) relative to the (normal) PT of a control preparation. However, the PTs tended to vary depending on the source of the reagents used in the lab. It is now widely accepted that the anticoagulation level and the appropriate warfarin regimen are best determined on the basis of the international normalized ratio (INR). The INR value depends on the sensitivity ratio of the thromboplastin reagent used in the laboratory relative to the International Reference Preparation (IRP). This standardization system was introduced by the World Health Organization (WHO) to provide a common basis for the interpretation of the PT results, independent of sensitivity of the laboratory thromboplastin reagent, which tends to vary from one manufacturer to another.

**Prothrombin Time (PT):** The prothrombin time test belongs to a group of blood tests that assess the clotting ability of blood. The test is also known as the pro-time or PT test.

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## Coding

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*The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

### When services may be Medically Necessary when criteria are met:

#### HCPCS

G0248	Demonstration, at initial use, of home INR monitoring for a patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstrating use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for
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	reporting home INR test results, and documentation of patient ability to perform testing.
G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes: provision of materials for use in the home and reporting of test results to physician, per 8 tests.
G0250	Physician review, interpretation and patient management of home INR monitoring for a patient with mechanical heart valve(s) who meets other coverage criteria; per 8 tests (does not require face-to-face service)

ICD-9 Diagnosis

All diagnoses

**When services are Not Medically Necessary:**

For the procedure codes listed above, when criteria are not met.

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**Government Agency, Medical Society, and Other Authoritative Publications:**

1. Centers for Medicare and Medicaid Services. National Coverage Determination for Home Prothrombin Time INR Monitoring for Anticoagulation Management. NCD #190.11. Effective July 1, 2002. Available at: <http://www.cms.hhs.gov>. Or [http://www.cms.hhs.gov/mcd/index\\_list.asp?list\\_type=ncd#PP](http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd#PP). Accessed on March 08, 2006.
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Avocet  
 Biotrack 512 System  
 CoaguChek PST System  
 Harmony™ INR Monitoring System  
 Home Prothrombin Time Monitoring  
 Prothrombin Time Monitoring  
 Prothrombin Time Self-Monitoring  
 Protime Microcoagulation System  
 Rubicon Prothrombin Time Monitoring System  
 Thrombolytic Assessment System (TAS)

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**Policy History**

Status	Date	Action
Reviewed	06/08/2006	Medical Policy & Technology Assessment Committee (MPTAC) annual review. References updated, no change to the policy stance. Published on web 03/09/2007.
	11/21/2005	Added reference for Centers for Medicare and Medicaid Services (CMS) – National Coverage Determination (NCD).
Revised	07/14/2005	MPTAC review. Revision based on Policy Harmonization: Pre-merger Anthem and Pre-merger WellPoint.

Pre-Merger Organizations	Last Review Date	Policy Number	Title
Anthem, Inc.	09/19/2003	DME.00001	Prothrombin Time Self-Monitoring Devices
WellPoint Health Networks, Inc.	06/24/2004	9.04.01	Home Prothrombin Time Monitoring

*Note: this form is provided only as a guide for the collection of information.*

**Attachment A**

**Prothrombin Time Self-Monitoring Devices**  
Medical Review Sheet

Patient Name: \_\_\_\_\_ Requesting Physician: \_\_\_\_\_

Subscriber Name: \_\_\_\_\_ Office Telephone No.: \_\_\_\_\_

1. Confirm that the patient requires long-term (>1 year) anticoagulation, and needs at least weekly determinations of INR values.

YES

NO

2. Confirm that the patient has completed a self-management training program and fully understands how to monitor his/her coagulation control with a portable device.

YES

NO

3. Indicate which of the following devices the patient has been given a prescription:

Protime Microcoagulation System by International Technidyne Corp®

CoaguChek PST System by Roche Diagnostic Corp®

Avocet by Avocet Medical Incorporated®

Rubicon Prothrombin Time Monitoring System by Lifescan®

Thrombolytic Assessment System (TAS)®

Biotrack 512 System®

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