Anthem

Clinical UM Guideline

Subject: Prothrombin Time Self-Monitoring Devices
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Description

This document addresses the clinical indications for use of battery-operated prothrombin time self-monitoring devices, also referred to as International Normalized Ratio (INR) devices, used by individuals in the home to monitor blood-clotting rates.

Clinical Indications

Medically Necessary:

Home prothrombin time self-monitoring using an INR device is considered **medically necessary** for an individual who meets **all** of the following criteria:

A. Requires long term (greater than one year) anticoagulation with warfarin; **and**
B. Requires at least weekly determinations of INR values; **and**
C. The treating physician prescribes the self-monitoring device and home testing.

Not Medically Necessary:

Home prothrombin time self-monitoring is considered **not medically necessary** for an individual who does not meet the above criteria.

Coding

The following codes for treatments and procedures applicable to this document 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:

CPT

93792	Patient/caregiver training for initiation of home international normalized ratio (INR) monitoring under the direction of a physician or other qualified health care professional, face-to-face, including use and care of the INR monitor, obtaining blood sample, instructions for reporting home INR test results, and documentation of patient's/caregiver's ability to perform testing and report results

HCPCS

E1399	Durable medical equipment, miscellaneous [when specified as a home INR monitor]
G0248	Demonstration, prior to initiation 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's ability to perform testing and report results
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; testing not occurring more frequently than once a week; testing materials, billing units of service include 4 tests
G0250	Physician review, interpretation and patient management of home INR testing for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; testing not occurring more frequently than once a week; billing units of service include 4 tests

ICD-10 Diagnosis

	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

Discussion/General Information

Home prothrombin time self-monitoring permits frequent measurement and self-management of anticoagulant therapy (for example, warfarin). The ultimate goal is to increase the time that anticoagulation is within a therapeutic INR range and decrease the risk of thromboembolic or hemorrhagic events. The most common indications for chronic oral anticoagulation therapy include individuals with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism).

An individual or caregiver who undertakes 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.

Compliance and cooperation are primary factors in the selection of appropriate candidates for home prothrombin time self-monitoring.

Individual or caregiver training for home prothrombin time self-monitoring is provided under physician supervision. The training must, at a minimum, consist of:

a. Demonstrating use and care of the INR monitor;**and**
b. Obtaining at least one blood sample;**and**
c. Providing instructions for reporting home INR test results;**and**
d. Documentation of the ability to perform testing.

Prothrombin time self-monitoring systems are battery-operated devices used to monitor blood-clotting rates by an individual in the home setting. Each of these systems includes a monitor, a disposable plastic reagent cartridge and a finger stick blood collection kit. The devices store between 30 and 40 of the most recent test results, which are date and time-stamped. This enables the physician, individual, or caregiver to review the results and monitor trends in the individual's oral anticoagulant therapy control. After testing, the individual either notifies the physician of the results or uses an individualized algorithm, developed with physician supervision, to adjust the anticoagulation dosage to maintain prothrombin time levels within a target zone. The goal of self-monitoring and self-management of prothrombin time levels is to improve anticoagulation control and reduce the risk of adverse events.

Several U.S. Food and Drug Administration (FDA) cleared prothrombin time self-monitoring devices are available for use in the home including, but not limited to: CoaguSense™ Self-Test PT/INR Monitoring System (CoaguSense, Inc., Fremont, CA), ProTime® Microcoagulation System (International Technidyne Corporation [Accriva Diagnostics], South Piscataway, NJ), CoaguChek® XS System for Patient Self-Testing (PST) (Roche Diagnostics-North America, Indianapolis, IN), and CoagCare® (ZyCare® Inc, Chapel Hill, NC). Home prothrombin time self-monitoring devices require a prescription for use. The prescribing physician is responsible for the training and ongoing management of individuals selected for self-monitoring. FDA clearance of home prothrombin time self-monitoring devices was based on the demonstration that home prothrombin monitors produce results similar to laboratory-based measurements. The FDA did not require clinical data demonstrating that the increased frequency of home self-monitoring would improve health outcomes.

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 reduce the risk of recurrent myocardial infarctions and transient ischemic attacks. In the United States, coumarin derivatives are the most commonly used oral anticoagulants and include warfarin sodium (Coumadin®, Bristol-Myers Squibb, Princeton, NJ) and dicumarol. 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 person and frequent blood coagulation monitoring to prevent serious bleeding from too much anticoagulation or thromboembolic complications from inadequate coagulation.

In general, the anticoagulant effect of warfarin is optimized at an 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 individuals with prosthetic heart valves. The risk of bleeding increases with an increasing INR and becomes clinically unacceptable when the INR exceeds 5.0. Major bleeding has been reported in 1.1%-8.1% of individuals during each year of long-term warfarin therapy. Risk factors include advanced age, serious illness (for example, cerebral, cardiac, kidney or liver disease), cerebrovascular or peripheral vascular disease, and an unstable anticoagulant effect.

Published studies have evaluated individuals with a variety of indications for anticoagulation therapy. The majority of individuals received anticoagulation therapy for prosthetic heart valve replacement. Studies also included individuals with deep venous thrombosis, atrial fibrillation, total hip arthroplasty, and history of pulmonary emboli. Controlled studies have shown that prothrombin time self-monitoring devices are effective in maintaining the INR values within a therapeutic range. None of the studies indicate a decrease in anticoagulation control. Improvement is thought to be due to several factors. Prothrombin time testing intervals in the self-monitored individual are performed weekly as compared to every 2 weeks to monthly intervals when performed by a physician. 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. When individuals are given proper training and support, the cumulative evidence from clinical trials suggests that prothrombin time self-monitoring with a home testing device is accurate, feasible, and possibly more effective than standard laboratory prothrombin time testing in maintaining anticoagulation control within target therapeutic ranges. In the studies evaluated, the results obtained with prothrombin time self-monitoring do not appear to vary with the individual's diagnosis.

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. A Cochrane meta-analysis (Garcia-Alamino, 2010) reported on a pooled estimate of 18 randomized controlled trials (RCTs) (4723 participants), which found statistically significant reductions in both thromboembolic events (risk ratio [RR], 0.50; 95% confidence interval [CI], 0.36 to 0.69) and all-cause mortality (RR, 0.64; 95% CI, 0.46 to 0.89). Trials of self-management alone showed significant reductions in thromboembolic events (RR, 0.47; 95% CI, 0.31 to 0.70) and all-cause mortality (RR, 0.55; 95% CI, 0.36 to 0.84); self-monitoring did not (thrombotic events RR, 0.57; 95% CI, 0.32 to 1.00; mortality RR, 0.84; 95% CI, 0.50 to 1.41). Self-monitoring significantly reduced major hemorrhages (RR, 0.56; 95% CI, 0.35 to 0.91) while self-management did not (RR, 1.12; 95% CI, 0.78 to 1.61). A total of 12 trials reported improvements in the percentage of mean INR measurements in the therapeutic range. No heterogeneity was identified in any of these comparisons. The authors concluded that compared to standard monitoring, individuals who self-monitor or self-manage improve the quality of their oral anticoagulation therapy. The number of thromboembolic events and mortality were decreased without increases in harms. However, self-monitoring or self-management were not feasible for up to half of the individuals requiring anticoagulant therapy due to refusal to participate, exclusion by their general practitioner, and inability to complete training.

Several other meta-analyses of the studies on home prothrombin monitoring have also been published. Bloomfield and colleagues (2011) published a meta-analysis and systematic review that included RCTs with adult subjects comparing home monitoring to monitoring in a physician's office or anticoagulation clinic; studies included adults receiving long-term (> 3 months) therapy. The systematic reviews identified 22 trials; 5 on self-monitoring only and 14 that included self-management. In a pooled analysis, there were significantly fewer major thromboembolic events in the self-monitoring and self-management group (99 of 4004 subjects, 2.5%) compared to the standard treatment group (149 of 3755 subjects, 4.0%; odds ratio [OR], 0.58; 95% CI, 0.45 to 0.75). Rates of major bleeding events did not differ significantly in the 2 groups. Similar to the Cochrane meta-analysis (Garcia-Alamino, 2010), the authors noted the low rate of study participation in subjects who met preliminary eligibility criteria. The authors did not conduct separate analysis of studies that did and did not enroll inception cohorts.

Heneghan and colleagues (2012) published a meta-analysis using a design similar to the other published meta-analyses. The investigators searched for RCTs comparing self-monitoring or self-management of oral anticoagulation by adults compared to management by a physician or anticoagulation clinic. This review did not discuss the issue of whether or not home monitoring occurred in the initial 3 months of anticoagulation therapy. The meta-analysis included data on 6417 participants from 11 of the eligible 21 trials. In a pooled analysis, there was a statistically significant reduction in thromboembolic events in the home prothrombin

time when the protime monitoring group was compared to the standard therapy group (hazard ratio [HR], 0.51; 95% CI, 0.31 to 0.85). There was not a significant difference between groups in the rate of major hemorrhagic events (HR, 0.88; 95% CI, 0.74 to 1.06) or death (HR, 0.82; 95% CI, 0.62 to 1.09).

Effective March 19, 2008, the Centers for Medicare and Medicaid Services (CMS) implemented a National Coverage Determination (NCD) for *Home Prothrombin Time Monitoring for Anticoagulation Management.* Coverage indications include “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” (CMS, 2008). The coverage determination includes specific participant selection criteria and monitoring by the prescribing physician.

Definitions

International Normalized Ratio (INR): A standardized system established by the World Health Organization (WHO) and the International Committee on Thrombosis and Hemostasis (ICTH) for reporting the results of blood coagulation (clotting) tests using the international sensitivity index for the particular thromboplastin reagent and instrument combination utilized to perform the test.

Prothrombin time (PT): A test belonging to a group of blood tests that assess the clotting ability of blood; also known as the protime or PT test.

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CoagCare Anticoagulation Management System
CoaguChek XS System
Coagu-Sense Self-Test PT/INR Monitoring System
ProTime Microcoagulation System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References and History sections.
Reviewed	11/10/2022	MPTAC review. Updated References and History sections.
Reviewed	11/11/2021	MPTAC review. Updated References and History sections.
Revised	11/05/2020	MPTAC review. Moved text of note from Clinical Indications section to Discussion section. Updated Discussion/General Information and References sections. Reformatted Coding section; added E1399 (NOC).
Reviewed	11/07/2019	MPTAC review. Updated Discussion/General Information and References sections.
	02/04/2019	Updated Coding section to add CPT code 93792.
Reviewed	11/08/2018	MPTAC review. Updated References section.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Discussion, References, and Index sections.
Reviewed	02/02/2017	MPTAC review. Updated formatting in Clinical Indications section. Updated Discussion, References, and Index sections.
Reviewed	02/04/2016	MPTAC review. Updated Discussion and References sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Minor format change to Note in the Clinical Indications section. Updated Description, Discussion, and References sections.
Reviewed	02/13/2014	MPTAC review. Updated Discussion. Minor format changes throughout sections.
Reviewed	02/14/2013	MPTAC review. Updated Discussion, References, and Index.
Reviewed	02/16/2012	MPTAC review. Removed cross-reference to Attachment A including the Medical Review Sheet/form. Updated Description, Discussion, References, Coding and Index.
Reviewed	02/17/2011	MPTAC review. Updated Discussion/General Information, References, Index and Attachment A.
Reviewed	02/25/2010	MPTAC review. Clarified Clinical Indications. Updated References.
	10/01/2009	Updated Coding section with 10/01/2009 ICD-9 changes.
Reviewed	02/26/2009	MPTAC review. Updated Description, Discussion, References and Index.
Reviewed	02/21/2008	MPTAC review. Updated Description, Definitions, References and Index.
Reviewed	07/02/2007	Updated FDA-approved devices in Description, Index, and Attachment A. Clarified medical review guidance statement in Attachment A.
New	03/08/2007	MPTAC review. Initial document development. Transferred content from DME.00001 Prothrombin Time Self-Monitoring Devices. References updated.
