

MEDICAL POLICY

SUBJECT: HOME PROTHROMBIN TIME MONITORING DEVICE	EFFECTIVE DATE: 12/18/03 REVISED DATE: 04/15/04, 04/21/05, 03/16/06, 04/26/07, 06/26/08, 07/02/09, 06/24/10 ARCHIVED DATE: 06/24/11 EDITED DATE: 06/28/12, 06/27/13, 06/26/14 PAGE: 1 OF: 5
POLICY NUMBER: 1.01.44 CATEGORY: Equipment/Supplies	
<ul style="list-style-type: none">• <i>If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.</i>• <i>Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.</i>• <i>Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, the home prothrombin time monitoring device has proven to be effective and is, therefore, **medically appropriate** for anticoagulation monitoring and management for patients who require long-term oral anticoagulation with warfarin because of:
 - A. mechanical heart valves; or
 - B. hypercoagulable states (e.g. Protein C and S deficiencies, Factor V-Leiden); or
 - C. a history of recurrent thromboembolic events (e.g., deep vein thrombosis or pulmonary embolism); or
 - D. atrial fibrillation and a high risk for stroke.
- II. Based upon our criteria and assessment of peer-reviewed literature, the home prothrombin time monitoring device has not been medically proven to be effective and is considered **not medically necessary** for managing other types of acute oral anticoagulant therapy including acute deep vein thrombosis.
- III. Replacement of home prothrombin time monitors are **eligible for coverage** unless a manufacturer's warranty or a purchase agreement covers the cost of replacement.
- IV. Replacement when the device has been damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.
- V. Coverage for more than one home prothrombin time monitor is considered a matter of convenience for the member and his/her family and is **ineligible for coverage**.

POLICY GUIDELINES:

- I. Medical documentation of all of the following is required for consideration of the home prothrombin time monitoring device:
 - A. A prescription from the physician for the device; and
 - B. Have been anticoagulated for at least 3 months prior to institution of the home INR device; and
 - C. Anticoagulation therapy is anticipated for greater than 2 years; and
 - D. Ability to be trained to use the device and conduct self-monitoring or a caregiver is available to perform this service.
- II. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (2014) recommend anticoagulation therapy for patients with atrial fibrillation and assessment of stroke risk using the CHA₂DS₂-VASc score.. High risk of stroke as defined in the guidelines. Components of the CHA₂DS₂-VASc score include the following risk factors:
 - A. Congestive Heart Failure; and/or
 - B. Hypertension; and/or
 - C. Age greater than 75 years; and/or
 - D. Diabetes Mellitus; and/or
 - E. Stroke/TIA/TE; and/or
 - F. Vascular Disease (prior MI, PAD, or aortic plaque; and/or
 - G. Age 65-74 years; and/or
 - H. Sex category (e.g., female sex).

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- III. Durable Medical Equipment rider/coverage is required.
- IV. The physician who prescribes the device is responsible for a patient education program on anticoagulation management and the use of the device.
- V. Supplies (e.g., lancets and test strips) are provided for testing a maximum of once per week or less often.

DESCRIPTION:

Chronic oral anticoagulation therapy with warfarin is recommended for all patients who have undergone mechanical heart valve replacement. Patients with mechanical heart valves require higher levels of anticoagulation than other patients on chronic oral anticoagulation therapy and, thus, are at increased risk of complications from warfarin therapy. Appropriate levels of warfarin therapy are monitored with periodic prothrombin time measurements, as measured by the International Normalized Ratio (INR). Self-monitoring and self-management of medication dosage when combined with patient education programs have been shown to increase patient compliance, medical outcomes, and quality of life.

Deep venous thrombosis (DVT) and pulmonary embolism (PE) represent different manifestations of the same clinical entity referred to as a venous thromboembolism (VTE). Venous thrombosis occurs when red blood cells, fibrin and, to a lesser extent, platelets and leukocytes, form a mass within an intact vein. A pulmonary embolism results when a piece of thrombus detaches from a vein wall, travels to the lungs, and lodges within the pulmonary arteries. The goals of VTE treatment are the prevention of clot propagation, prevention of embolism, and prevention of recurrent thrombosis. Therefore, the mainstay of therapy is anticoagulation.

Home prothrombin time monitoring devices are portable, battery-operated instruments for the quantitative determination of prothrombin time from fingerstick whole blood that allow the patient to measure one dimension of the clotting mechanism at home. These devices are designed to aid in the management of high-risk patients taking oral anticoagulants. Considerable patient training and compliance is needed for these devices to be beneficial.

RATIONALE:

Patients with mechanical heart valves represented the majority of patients studied. The available studies published in peer-reviewed literature have demonstrated that patients who require long-term anticoagulation are most likely to benefit from self-monitoring and management. Studies have also shown that in patients using the home prothrombin time monitoring device, prothrombin levels were more frequently within therapeutic range. Thus, adverse events such as, stroke and bleeding may be decreased.

The 2014 AHA/ACC/HRS Atrial Fibrillation Guidelines recommends that in patients with AF, antithrombotic therapy should be individualized based on shared decision making after discussion of the absolute and relative risks of stroke and bleeding, and the patient's values and preferences. (*Level of Evidence: C*). Selection of antithrombotic therapy should be based on the risk of thromboembolism irrespective of whether the AF pattern is paroxysmal, persistent, or permanent. (*Level of Evidence: B*). In patients with nonvalvular AF, the CHA₂DS₂-VASc score is recommended for assessment of stroke risk. (*Level of Evidence: B*). For patients with AF who have mechanical heart valves, warfarin is recommended and the target international normalized ratio (INR) intensity (2.0 to 3.0 or 2.5 to 3.5) should be based on the type and location of the prosthesis. (*Level of Evidence: B*). For patients with nonvalvular AF with prior stroke, transient ischemic attack (TIA), or a CHA₂DS₂-VASc score of 2 or greater, oral anticoagulants are recommended.

A number of devices, including ProTime® Microcoagulation System, the CoaguCheck® System, INRatio®2 PT Monitoring System, have received FDA 501(k) market approval for FDA for home self-monitoring of PT/INR for patients receiving warfarin therapy. Peer-reviewed literature is limited regarding the safety of home prothrombin time monitoring in patients who are not capable of performing self-testing reliably or who have other specific contraindications to self-testing.

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CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

<u>CPT:</u>	99363	Anticoagulant management for an outpatient taking warfarin, physician review and interpretation of International Normalized Ratio (INR) testing, patient instructions, dosage adjustment (as needed), and ordering of additional tests; initial 90 days of therapy (must include a minimum of 8 INR measurements)
	99364	each subsequent 90 days of therapy (must include a minimum of 3 INR measurements)

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<u>HCPCS:</u>	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.
	G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical 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.
	G0250	Physician review; interpretation and patient management of home INR testing for a patient with mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets other coverage criteria; includes face-to-face verification by the physician at least once a year (e.g., during an evaluation and management service) that the patients uses the device in the context of management of the anticoagulation therapy following initiation of the home INR monitoring; not occurring more frequently than once a week.

<u>ICD9:</u>	289.81	Primary hypercoagulable state
	394.9	Mitral valve disease
	V43.3	Organ or tissue replaced by other means, artificial device (Aortic/mitral valve replacement, bioprosthetic heart valves, mechanical prosthetic heart valves)
	416.2	Chronic Pulmonary embolism
	427.31	Atrial fibrillation
	453.0-453.9	Other venous embolism and thrombosis (code range)

<u>ICD10:</u>	D68.51-D68.62	Primary thrombophilia or other thrombophilia (code range)
	I05.8-I05.9	Other or unspecified rheumatic mitral valve diseases (code range)
	I27.82	Chronic pulmonary embolism

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I48.0-I48.91	Atrial fibrillation and flutter (code range)
I82.0	Budd-Chiari syndrome
I82.1	Thrombophlebitis migrans
I82.1-I82.91	Other venous embolism and thrombosis (code range)
Z86.711	Personal history of pulmonary embolism
Z95.2	Presence of prosthetic heart valve

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KEY WORDS:

AcuSure™, Anticoagulant therapy, CoaguChek®, INR, International Normalized Ratio, Prothrombin time, Prottime, PT, Rubicon®.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Home Prothrombin Time INR Monitoring for Anticoagulation Management. Please refer to the following NCD website for Medicare Members:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=269&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&>