MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Home Prothrombin Time Monitoring Device**
Policy Number	**1.01.44**
Category	**Contract Clarification**
Original Effective Date	**12/18/03**
Committee Approval Date	**04/15/04, 04/21/05, 03/16/06, 04/26/07, 06/26/08, 07/02/09, 06/24/10**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of peer-reviewed literature, the home prothrombin time (PT) monitoring device has proven to be effective and, therefore, is considered **medically appropriate** for anticoagulation monitoring and management for patients who require long-term oral anticoagulation with warfarin because of:
   A. mechanical heart valves or ventricular assist devices;
   B. hypercoagulable states (e.g., Protein C and S deficiencies, Factor V-Leiden);
   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, therefore, is considered **not medically necessary** for managing other types of acute oral anticoagulant therapy including acute deep vein thrombosis.

III. Replacement of a home prothrombin time monitor is **eligible for coverage** unless a manufacturer's warranty or a purchase agreement covers the cost of replacement.

IV. Replacement of a home prothrombin time monitor is **ineligible for coverage** 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, or liability insurance, etc.).

V. More than one home prothrombin time monitor is considered a matter of convenience for the member and the member's 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 physician has prescribed the device for the patient;
   B. The patient has been anticoagulated for at least three months prior to institution of the home INR device;
   C. Anticoagulation therapy is anticipated for greater than two years; and
   D. The patient has the 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) recommends anticoagulation therapy for patients with atrial fibrillation and assessment of stroke risk using the CHA_2DS_2-VASc score. High risk of stroke as defined in the guidelines. Components of the CHA_2DS_2-VASc score include the following risk factors:
   A. Congestive Heart Failure;
   B. Hypertension;
   C. Age greater than 75 years;
   D. Diabetes Mellitus;
   E. Stroke/TIA/TE;
   F. Vascular Disease (prior MI, PAD, or aortic plaque;
   G. Age 65 to 74 years; and/or
   H. Sex category (e.g., female sex).

III. Coverage is contract-dependent; durable medical equipment contract benefit or 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, which allows 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 2019 updated AHA/ACC/HRS Atrial Fibrillation Guidelines recommends that in patients with AF, anticoagulant therapy should be individualized based on the patient's and physician's 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 anticoagulant 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 CHA_2DS_2-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 CHA_2DS_2-VASc score of 2 or greater, oral anticoagulants are recommended.

A number of devices, including the ProTime Microcoagulation System and the CoaguCheck System have received Section FDA 501(k) market approval from the U.S. Food and Drug Administration 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.

CODES

- *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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
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
93793	Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed

HCPCS Codes

Code	Description
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

Code	Description
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 four 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 four tests

ICD10 Codes

Code	Description
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
I48.0-I48.92	Atrial fibrillation and flutter (code range)
I82.0	Budd-Chiari syndrome
I82.1	Thrombophlebitis migrans
I82.2-I82.91	Other venous embolism and thrombosis (code range)
Z86.711	Personal history of pulmonary embolism
Z95.2	Presence of prosthetic heart valve

REFERENCES

*Anderson JL, et al. Management of patients with atrial fibrillation (compilation of 2006 ACCF/AHA/ESC and 2011 ACCF/AHA/HRS Recommendations). A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. JACC 2013;61(18):1935-44.

*Ansell J, et al. Pharmacology and management of the Vitamin K antagonists *: American College of Chest Physicians evidence-based clinical practice guidelines (8th Edition). Chest 2008;133;160S-98S.

*Baruch L, et al. Can patients at elevated risk of stroke treated with anticoagulants be further risk stratified? Stroke 2007;38;2459-63.

*Canadian Agency for Drugs and Technologies in Health (CADTH). Point-of-care monitoring devices for long-term oral anticoagulation therapy: clinical and cost effectiveness. Health Technology Assessment 2007 Feb.

*Christensen TD, et al. Self-versus conventional management of oral anticoagulant therapy. Am J Cardiovasc Drugs 2007;7:191-7.

*Eitz, T, et al. International normalized ratio self-management lowers the risk of thromboembolic events after prosthetic heart valve replacement. Ann Thorac Surg 2008;85:949-55.

*Eldor A, et al. Self-management of oral anticoagulants with a whole blood prothrombin-time monitor in elderly patients with atrial fibrillation. Pathophysiol Haemost Thromb 2002 May-Jun;32(3):99-106.

*Engh CA Jr., et al. Patient self-testing of prothrombin time after hip arthroplasty. J South Orthop Assoc 2001 Fall;10(3):140-6.

*Fitzmaurice DA, et al. A randomised control trial of patient self-management of oral anticoagulation treatment compared with primary care management. J Clin Pathol 2002 Nov;55(11):845-9.

*Fuster V, et al. ACC/AHA/ESC 2006 Guidelines for the management of patients with atrial fibrillation - executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation) developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. J Am Coll Cardiol 2006;48:854-906.

*Garcia-Alamino JM, et al. Self-monitoring and self-management of oral anticoagulation. Cochrane Database of Systematic Reviews 2010, Issue 4. CD003839.

*Heneghan C, et al. Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data. Lancet 2012; 379(813):322-34.

*Hughes M et al. Stroke and thromboembolism in atrial fibrillation: A systematic review of stroke and risk factors, risk stratification schema and cost effectiveness data. Thromb Haemost 2008;99:295-304.

*January CT, et al. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. Circ 2014 Dec 2;130(23):2071-104.

*Kortke H, et al. International normalized ratio self-management after mechanical heart valve replacement: is an early start advantageous? Ann Thorac Surg 2001 Jul;72(1):44-8.

*Mant J, et al. Warfarin versus aspirin for stroke prevention in an elderly community population with atrial fibrillation (the Birmingham Atrial Fibrillation Treatment of the Aged Study, BAFTA): a randomized controlled trial. Lancet 2007;370:493-503.

*Marzinotto et al. Capillary whole blood monitoring of oral anticoagulants in children in outpatient clinics and the home setting. Pediatr Cardiol 2000;21(4):347-52.

*Newall F et al. Home INR monitoring of oral anticoagulant therapy in children using CoaguChek S point-of-care monitor and a robust education program. Thromb Res 2006;118(6):587-93.

*NHS R&D HTA Programme. Clinical effectiveness and cost-effectiveness of different models of managing long-term oral anticoagulation therapy: a systematic review and economic modeling. Health Technology Assessment 2007 Oct;11(38).

*Piso B, et al. The quality of oral anticoagulation before, during and after a period of patient self-management. Thromb Res 2002 Apr;106(2):101-4.

*Ryan F, et al. The reliability of point-of-care prothrombin time testing. A comparison of CoaguChek S® and XS® INR measurements with hospital laboratory monitoring. Int J Lab Hematol 2010 Feb;32(1Pt 1):e26-33.

*Key Article

KEY WORDS

AcuSure, Anticoagulant therapy, CoaguChek, INR, International Normalized Ratio, Prothrombin time, Protime, 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&