

01-99000-06

Original Effective Date: 06/15/02

Reviewed: 09/28/23

Revised: 10/15/23

Subject: Home Prothrombin Time Monitoring

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Home prothrombin time self-monitoring permits frequent measurement and self-management of anticoagulant therapy (for example, warfarin). Use of the International Normalized Ratio (INR) or prothrombin time (PT) allows physicians to determine the level of anticoagulation in an individual independent of the laboratory reagents used. The goal is to increase the time that anticoagulation is within a therapeutic INR range and decrease the risk of thromboembolic or hemorrhagic events.

POSITION STATEMENT:

Home prothrombin time INR monitoring for anticoagulation management **meets the definition of medical necessity** when **ALL** of the following criteria are met:

- Has a mechanical heart valve, ventricular assist device, chronic atrial fibrillation, pulmonary embolism, or venous thromboembolism and has undergone anticoagulation management for at least 3 months, **OR**
- Requires anticoagulation to similar levels as a mechanical heart valve (i.e., an INR greater than 3), **AND**
- Requires long term (> 1 year) anticoagulation, **AND**
- The monitor and home testing has been prescribed by a physician, **AND**
- Has undergone an educational program on anticoagulation management and the use of the device prior to its use in the home, **AND**
- Self-testing with the device is performed on a weekly basis

Home prothrombin time monitoring for all other indications **does not meet the definition of medical necessity**.

BILLING/CODING INFORMATION:

HCPCS Coding:

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
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 a 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 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; testing materials, billing units of service include 4 tests
G0250	Physician review; interpretation, and patient management of home INR testing for a 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 Codes That Support Medical Necessity:

D68.51 – D68.59	Primary thrombophilia
D68.61 – D68.69	Other thrombophilia
I26.01 – I26.09	Pulmonary embolism with acute cor pulmonale
I26.90 – I26.99	Pulmonary embolism without acute cor pulmonale
I48.0	Paroxysmal atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I48.2	Chronic atrial fibrillation
I48.20	Chronic atrial fibrillation, unspecified
I48.21	Permanent atrial fibrillation
I48.91	Unspecified atrial fibrillation
I80.00 – I80.9	Phlebitis and Thrombophlebitis
I82.211	Chronic embolism and thrombosis of superior vena cava
I82.221	Chronic embolism and thrombosis of inferior vena cava
I82.291	Chronic embolism and thrombosis of other thoracic veins

I82.401 – I82.529	Embolism and thrombosis of deep veins of lower extremity
I82.701 – I82.729	Chronic embolism and thrombosis of veins of upper extremity
I82.811 – I82.891	Embolism and thrombosis of other specified veins
I82.A21 – I82.A29	Chronic embolism and thrombosis of axillary vein
I82.B21 – I82.B29	Chronic embolism and thrombosis of unspecified vein
I82.C21 – I82.C29	Chronic embolism and thrombosis of internal jugular vein
I84.401 – I82.599	Venous embolism and thrombosis of deep veins of lower extremity
Z95.2	Presence of prosthetic heart valve

REIMBURSEMENT INFORMATION:

None applicable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (190.11), located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#)

DEFINITIONS:

None applicable.

RELATED GUIDELINES:

None applicable.

OTHER:

Index terms:

Note: 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.

Coag-Sense PT/INR Monitoring System

CoaguChek XS System

INRatio® 2 PT/INR Monitoring System

Prottime Microcoagulation System

REFERENCES:

1. AHRQ Agency for Healthcare Research and Quality. NGC:007743. Guideline Summary: Outpatient management of uncomplicated deep venous thrombosis. Michigan Quality Improvement Consortium. 2010 Mar. 1 p.
2. American College of Chest Physicians (ACCP), The Seventh ACCP Conference on Antithrombotic and Thrombotic Therapy Evidence Based Guidelines. *Chest* 2004; 126; 172-173, (09/04).
3. Ansell J, Hirsh J, Hylek E 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(6 Suppl):160S-198S.
4. Barcellona D, Mastino D, Marongiu F. Portable coagulometer for vitamin K-antagonist monitoring: the patients' point of view. *Patient Prefer Adherence*. 2018 Aug 22;12:1521-1526. doi: 10.2147/PPA.S164680. eCollection 2018.
5. Blue Cross Blue Shield Association Evidence Positioning System®. 1.01.14 – Home Prothrombin Time Monitoring (Archived 03/15).
6. Canadian Agency for Drugs and Technologies in Health (CADTH). Devices for Point-of-Care Monitoring of Long-Term Oral Anticoagulation Therapy: Clinical and Cost Effectiveness. (02/07).
7. Centers for Medicare and Medicare Services (CMS). National Coverage Determination (NCD). Home Prothrombin Time INR Monitoring for Anticoagulation Management (190.11) (03/19/08).
8. ClinicalTrials.gov. NCT00032591. The Home INR Study (THINRS), Department of Veterans Affairs. Last Updated on 01/25/12.
9. ClinicalTrials.gov. NCT00978445. Remote Home Prothrombin Time (PT)/International Normalized Ratio (INR) Monitoring and Patient Management System (vMetrics-AMS). The Cleveland Clinic and ZIN Technologies, Inc. Last Updated on 05/31/12.
10. Connock M, Stevens C, Fry-Smith A, Jowett S, Fitzmaurice D, Moore D, Song F. Clinical effectiveness and cost-effectiveness of different models of managing long-term oral anticoagulation therapy: a systematic review and economic modelling. *Health Technol Assess*. 2007 Oct;11(38):iii-iv, ix-66.
11. ECRI Target Report: #753, "Portable devices for home monitoring of oral anticoagulation therapy", (04/03/07).
12. ECRI Institute Health Technology Trends: Remote patient monitoring industry grows as hospitalization costs rise. 04/01/12.
13. ECRI Institute Health Technology Trends: CMS supports in-home tests for sleep apnea and anticoagulation therapy; proposes covering CPAP treatment trial. 03/01/08.
14. Gardiner C, Longair I, Pescott MA et al. Self-monitoring of oral anticoagulation: does it work outside trial conditions? *J Clin Pathol* 2009; 62(2):168-71.
15. Hayes, Inc. Medical Technology Directory. Self-Monitoring of Oral Anticoagulant Therapy. (04/02, updated 11/09/07).
16. Hiratzka LF, Bakris GL, et al. Practice Guideline: ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM Guidelines for the Diagnosis and Management of Patients With Thoracic Aortic Disease. *J Am Coll Cardiol*, 2010; 55:27-129, doi: 10.1016. j.jacc.2010.02.015.
17. Hirsh J, Fuster V, Ansell J, Halperin J. American Heart Association/American College of Cardiology Foundation Guide to Warfarin Therapy. *Circulation*. 2003; 107:1692-711.
18. Holbrook A, Schulman S, Witt DM, Vandvik PO, Fish J, Kovacs MJ, Svensson PJ, Veenstra DL, Crowther M, Guyatt GH. Evidence-based management of anticoagulant therapy: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest* 2012 Feb;141.

19. Holmes Jr DR, Becker JA, Granger CB, Limacher MC, Page II RL, Sila C. American College of Cardiology Foundation/American Heart Association 2011 Health Policy Statement on Therapeutic Interchange and Substitution: A Report of the American College of Cardiology Foundation Clinical Quality Committee. J Am Coll Cardiol, 2011; 58:1287-1307, doi:10.1016/j.jacc.2011.06.001.
20. Schwandt A. MetroHealth Medical Center/University Hospitals of Cleveland, Case Western University School of Medicine. Case Study: Personalizing Anticoagulation: Determination of Warfarin Dosing. Copyright ©2011 American Society of Hematology.
21. Shikdar S, Bhattacharya PT. International Normalized Ratio (INR). StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2019 Jan-2019 Mar 25.
22. UpToDate. Clinical use of coagulation tests. 2023. Accessed at uptodate.com.
23. UpToDate. Warfarin and other VKAs: Dosing and adverse effects. 2023. Accessed at uptodate.com.
24. Warnes CA, Williams RD, et al. Practice Guideline: ACC/AHA 2008 Guidelines for the Management of Adults with Congenital Heart Disease. J Am Coll Cardiol, 2008; 52:143-263, doi:10.1016/j.jacc.2008.10.001.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/28/23.

GUIDELINE UPDATE INFORMATION:

05/15/01	New Medical Coverage Guideline.
08/15/02	Coverage criteria and HCPCS codes added for Medicare & More.
11/15/02	Revised description section to include information for patients with mechanical heart valves. Added coverage statement for at home monitoring for anticoagulation management of patients with mechanical heart valves on warfarin.
07/15/04	Scheduled review; no changes.
03/15/05	Revision consisting of change in policy number; typographical corrections.
05/15/06	Revision consisting of the addition of clarification regarding provider type.
10/15/06	Scheduled review; no change in coverage statement; added Medicare as the source for the coding information regarding the G codes.
10/15/07	Reviewed; expanded coverage criteria; added coding notation regarding monitoring devices provided by DME suppliers; reformatted guideline; updated references.
10/15/08	Scheduled review; revise position statement to include requirement for long term anticoagulation (>1 year), and self testing must be performed on a weekly basis. Add Medicare exception. Revise HCPCS code descriptors. Update ICD 9 codes. Update references.
02/15/09	Remove notes referring to code E1399.
04/06/09	HCPCS codes descriptors updated.
10/15/09	Scheduled review; no change in position statement. Update description section. Update reimbursement statement to include CPT codes 99363 and 99364.
10/15/10	Revision; related ICD-10 codes added.
10/15/11	Revision; reimbursement information updated.

11/15/11	Scheduled review. Position statement maintained; updated description section and references.
04/01/12	Revision; updated ICD10 coding with new and revised codes.
11/15/12	Scheduled review. Position statement maintained; revised description, CPT coding, ICD9/ICD10 coding and index terms; updated references and reformatted guideline.
05/11/14	Revision: Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
01/01/18	Annual CPT/HCPCS coding update: added 93792; deleted 99363. Revised Reimbursement Information (deleted 99364) and Program Exceptions sections. Reformatted guideline.
08/15/19	Scheduled review. Revised description and index terms; maintained position statement and updated references.
10/01/19	ICD10 coding update: added I48.11, I48.19, I48.20, I48.21.
10/15/21	Scheduled review. Maintained position statement and updated references.
05/22/23	Update to Program Exceptions section.
10/15/23	Scheduled review. Revised description and position statement. Updated references.