Medical Coverage Policy | Home Prothrombin Time Monitoring

EFFECTIVE DATE: 10|01|2015
POLICY LAST REVIEWED: 04/03/2024

OVERVIEW
Patients who are prescribed chronic warfarin anticoagulation need ongoing monitoring that has generally taken place in a physician's office or anticoagulation clinic. Home prothrombin monitoring with a U.S. Food and Drug Administration (FDA)-approved device is proposed as an alternative to office or laboratory-based testing.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans and Commercial Products
At-home monitoring of chronic warfarin therapy may be considered medically necessary in patients who require continuous anticoagulation for chronic medical conditions. These conditions include, but are not limited to, patients with mechanical heart valves and chronic atrial fibrillation.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable coverage/benefits:

G0248 and 93792 covered under applicable office visit coverage
G0249 covered under applicable lab coverage
G0250 and 93793 covered under applicable physician services with no co-payment

BACKGROUND
Warfarin is an effective anticoagulant for the treatment and prevention of venous and arterial thrombosis. Chronic warfarin therapy is recommended in all patients with mechanical heart valves and in some patients with chronic atrial fibrillation (i.e., patients with risk factors that indicate a higher likelihood of stroke). Patients with mechanical heart valves are frequently prescribed anticoagulants at higher levels than patients given anticoagulants for other indications, which puts them at higher risk of complications from warfarin therapy. Appropriate levels of warfarin anticoagulation are monitored with periodic prothrombin time measurements, as measured by the International Normalized Ratio (INR). The target INR range is 2.0 to 3.0 for most patients. An INR result greater than 3 indicates an increased risk of serious hemorrhage, while an INR less than 2 is associates with an increased risk of stroke. An INR of 6 indicates an increased risk of developing a serious bleed nearly 7 times that of someone with an INR less than 3. Therefore, monitoring of the prothrombin time is recommended to ensure that the prescribed dosing regimens result in INRs within the therapeutic range. Anticoagulation can be monitored: in the physician's office (usually once a month), at an anticoagulation clinic (usually once every 2 to 3 weeks), or at home.

For home prothrombin time monitoring to be effective, patients need to be appropriately trained and able to generate INR test results comparable to laboratory measures. Moreover, the clinical impact of home prothrombin time monitoring is related to improved warfarin management. Specifically, home prothrombin time monitoring permits more frequent monitoring and self-management of warfarin therapy with the ultimate goal of 1) increasing the time that the anticoagulation is within a therapeutic INR range (intermediate

health outcome); and 2) decreasing the incidence of thromboembolic or hemorrhagic events (final health outcome). Home self-monitoring is typically associated with some form of self-management of warfarin therapy. In some cases, the patient may be supplied with treatment algorithms and instructed to alter the dose based on the results of self-monitoring. In other cases, the patient may be instructed to provide the results of the self-monitoring (e.g., on the telephone or internet) and receive instructions on warfarin dosage.

In January 2007, the CoaguChek® XS System (patient self-testing) (Roche Diagnostics Corporation) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices, including the CoaguChek SX System (professional, cleared in 2006). Other than a labeling change, the device is identical to the professional version of the CoaguChek XS System. The patient self-testing system is intended for self -monitoring of prothrombin time in patients who are on a stable regimen of anticoagulation medications. Other devices cleared by the FDA for home prothrombin time monitoring include the ProTime® Microcoagulation System (International Technidyne Corporation) and the Alere™ (formerly Hemosense) INRatio®2 PT/INR Monitoring System.

CODING

Medicare Advantage Plans and Commercial Products

The following codes are separately reimbursed services:

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

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

The following codes are separately reimbursed services and should only be reported by physicians:

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; testing materials, billing units of service include 4 tests

93793 Anticoagulation 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

ICD-10 Diagnosis Codes that may support medical necessity:

2024 ICD 10 Home Prothrombin List

RELATED POLICIES

None

PUBLISHED

Provider Update, June 2024
Provider Update, August 2023
Provider Update, September 2022
Provider Update, October 2021
Provider Update, January 2020, December 2020

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Home PROTHROMBIN Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (190.11)
2. Garcia-Alamino JM, Ward AM, Alonso-Coello P et al. Self-monitoring and self-management of oral anticoagulation. Cochrane Database Syst Rev 2010; (4):CD003839.
3. Bloomfield HE, Krause A, Greer N et al. Meta-analysis: Effect of patient self-testing and self-management of long-term anticoagulation on major clinical outcomes. Ann Intern Med 2011; 154(7):472-82.
4. Heneghan C, Ward A, Perera R et al. Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data. Lancet 2012; 379(813):322-34.
5. Matchar DB, Jacobson A, Dolor R et al. Effect of home testing of international normalized ratio on clinical events. N Engl J Med 2010; 363(17):1608-20.
6. Matchar DB, Jacobson AK, Edson RG et al. The impact of patient self-testing of prothrombin time for managing anticoagulation: rationale and design of VA cooperative study #481- the Home INR study (THINRS). J Thromb Thrombolysis 2005; 19(3):163-72.
7. Fitzmaurice DA, Murray ET, McCahon D et al. Self management of oral anticoagulation: randomised trial. BMJ 2005; 331 (7524):1057.
8. Menendez-Jandula B, Souto JC, Oliver A et al. Comparing self-management of oral anticoagulant therapy with clinic management: a randomized trial. Ann Intern Med 2005; 142(1):1-10.
9. Kortke H, Korfer R. International normalized ratio self-management after mechanical heart valve replacement: is an early start advantageous? Ann Thorac Surg 2001; 72(1):44-8. PMID 11465228
10. Hamad MA, van EE, van AT, et al. Self-management program improves anticoagulation control and quality of life: a prospective randomized study. Eur J Cardiothorac Surg. 2009;35(2):265-269. PMID
11. Thompson JL, Burkhart HM, Daly RC, et al. Anticoagulation early after mechanical valve replacement: improve management with patient self-testing. J Thorac Cardiovasc Surg. Sep 2013;146(3):599-604. PMID 22921821
12. Holbrook A, Schulman S, Witt DM, et al. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based ClinicalPractice Guidelines. Chest. Feb 2012;141(2 Suppl):e152S-184S. PMID 22315259