Medical Coverage Policy | Home Prothrombin Time Monitoring

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 09|01|2016

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
BlueCHiP for Medicare 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 covered under applicable office visit coverage
G0249 covered under applicable lab coverage
G0250 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). For example, an INR result greater than 3 indicates a higher risk of serious hemorrhage, while 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. In contrast, an INR less than 2 is associated with an increased risk of stroke. 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.

In order 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

BlueCHiP for Medicare and Commercial Products

The following codes are separately reimbursed services:

G0248
G0249

The following code is a separately reimbursed service and should only be reported by physicians:

G0250

ICD-10 and ICD-9 Diagnosis Codes that may support medical necessity:

Home Prothrombin ICD 10 Codes that Su

Home Prothrombin ICD 9 Codes that Sup

The following codes are intended to be used for laboratory services and physician interpretation of laboratory services only and are not for use with the G codes above. Is it not appropriate to use the codes below with home prothrombin time monitoring as the G codes are more specific. Anticoagulant services are intended to describe the outpatient management of warfarin therapy, including ordering, review and interpretation of INR testing, communication with patient and dosage adjustments as appropriate.

85610
99363
99364

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, June 2016
Provider Update, April 2015
Provider Update, June 2014
Provider Update, April 2013
Provider Update, April 2012
Provider Update, September 2011

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)

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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.

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7. Fitzmaurice DA, Murray ET, McCahon D et al. Self management of oral anticoagulation: randomised trial. BMJ 2005; 331 (7524):1057.

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9. Beyth RJ, Quinn L, Landefeld CS. A multicomponent intervention to prevent major bleeding complications in older patients receiving warfarin. Ann Intern Med; 2000; 133(9):687-95.

10. 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.