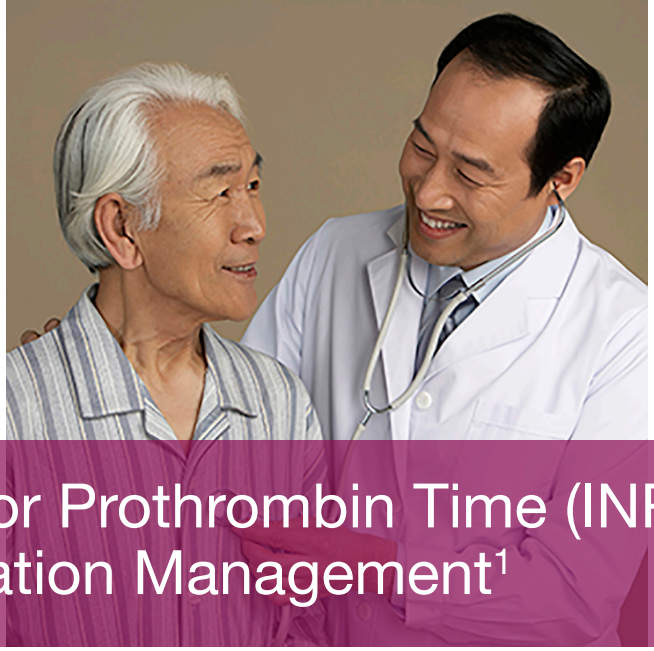

National Coverage Decision for Prothrombin Time (INR) Monitor for Home Anticoagulation Management[1]

For further information on the CMS Coverage Decision, please visit:
https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=209&fromdb=true.

Medicare Expanded Coverage Based on Clinical Evidence

The Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Decision (NCD) on March 19, 2008 expanding coverage of Home PT/INR Monitoring to specifically include eligible Medicare beneficiaries with Atrial Fibrillation (Afib) and Deep Vein Thrombosis (DVT). This is in addition to the existing coverage for patients with Mechanical Heart Valves (MHV). The NCD was based on recent clinical evidence and public comments that support the benefits of Home PT/INR Monitoring compared with clinical laboratory based INR monitoring for patients with Afib or DVT being treated with oral anticoagulants. In addition, CMS now requires "that beneficiaries receive face-to-face education before they start home testing and as needed subsequently if they continue home testing."[1]

Risk Reductions Implications

Patients with Afib and DVT may now take advantage of the proven benefit of Home PT/INR Monitoring to manage oral anticoagulation therapy under physician supervision. The need for improved INR monitoring was confirmed by a national analysis of Emergency Department admittances which identified errors in warfarin management as a high percentage of medication errors.[2] In 2009, the Food and Drug Administration (FDA) required the addition of a Black Box Warning on the warfarin label to stress the need for "regular monitoring of INR on all treated patients." At the same time, the FDA indicated that "time in therapeutic range is significantly greater (56%-93%) in patients managed by anticoagulation clinics, among self-testing and self-monitoring patients, and in patients managed with the help of computer programs. Self-testing had fewer bleeding events than usual care."[3]

Medicare's expanded coverage of home INR testing may also help healthcare organizations meet the need to "reduce the likelihood of patient harm associated with the use of anticoagulation therapy" as required by 3E in the 2008 Patient Safety Goals set forth by the Joint Commission.[4] Enabling patients to test more frequently in between their regularly scheduled office visits, combined with robust care management, should improve patient safety, reduce the risk of a dangerously out of range INR value, and improve efficiency of office operations.

Frequently Asked Questions

Q: What conditions are covered?

A. Patients with the qualifying diagnosis codes are covered for service[5]:

- Presence of Prosthetic Heart Valve
- Atrial fibrillation
- Pulmonary embolism and infarction
- Other venous embolism and thrombosis
- Phlebitis and thrombophlebitis

Please see *Allowable Covered Diagnosis for Home INR Monitoring* for a full list of currently covered ICD-10-CM Codes.

Q: What other criteria must be met?

A. Patients must:

- Have been on warfarin for at least 90 days.
- Have undergone an appropriate educational program on anticoagulation management and demonstrated the correct use of the device prior to its use in the home.
- Continue to correctly use the device following initiation of home monitoring.

Q: What home INR services, equipment and supplies are covered by Alere?

A. Submission of completed Alere Home Monitoring Physician Form or a completed prescription using eRX (both available at AlereCoag.com) are required to begin the enrollment process in this service program. Patient demographic information must also be received either by a completed Patient Information Form or Demographic Sheet and insurance card copies. Face-2-Face® training and ongoing support is provided as a package by an Independent Diagnostic Testing Facility (IDTF) equipped to finance, warrant and repair equipment, ship testing supplies, ensure ongoing compliance and report the test results to the patient's treating physician.

Q: Which HCPCS Codes apply?

A. There are three HCPCS codes currently in use.[6] The first two codes (G0248 and G0249) are typically provided by IDTFs who have been approved by Medicare to provide these specialty services. The third code (G0250) can only be provided by the patient's treating physician.

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 use.

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; not occurring more frequently than once a week.

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; includes face-to-face verification by the physician that the patient uses the device in the context of the management of the anticoagulation therapy following initiation of the Home INR Monitoring; not occurring more frequently than once a week.

References:
1. CMS National Decision Memo for Prothrombin Time (INR) Monitor for Home Anticoagulation Management (CAG-00087R), 03/19/2008.
2. Budnitz DS, Pollock, et al. "National Surveillance of Emergency Department Visits for Outpatient Adverse Drug Events." JAMA. 2006; 296:1858-1866.
3. Coumadin® package insert. Princeton, NJ. Bristol-Meyers Squibb Company, 2007.
4. The Joint Commission 2008 Patient Safety Goals.
5. CMS Manual System PUB 100-20 Medicare Claims Processing. Centers for Medicare & Medicaid Services (CMS) Transmittal 1580 Date: December 3, 2015
6. CMS Manual Change Pub 100-04 Transmittal 1562 July 25, 2008

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