Prothrombin Time (INR) Home Monitoring Device

MCG Health
Ambulatory Care
30th Edition

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Link to Codes

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Clinical Indications

- Prothrombin time (INR) home monitoring device may be indicated when **ALL** of the following are present(1)(2)(3)(4)(5)(6):
  - Anticoagulation with oral vitamin K antagonist (eg, warfarin) has already been used for 3 months or longer.(17)(18)
  - Anticoagulation with oral vitamin K antagonist (eg, warfarin) needed for 6 more months or longer(17)(28)
  - Appropriate and motivated patient or caregiver for INR home monitoring (including adequate visual acuity, manual dexterity, and mental ability)(9)(29)
  - Home monitoring program is characterized by **1 or more** of the following(30)(31)(32):
    - Self-management, involving self-testing as well as dose adjustment based on algorithm provided by prescribing physician or specialty clinic(18)
    - Self-testing, involving home testing of INR but reporting values to centralized service that prescribes recommended dose adjustment, if any(14)(15)(17)
  - Required training of patient or caregiver has been scheduled, with assessment of competence in performing home monitoring. (17)(18)(33)(34)

Alternatives

- Alternatives include:
  - Anticoagulation with oral vitamin K antagonist (eg, warfarin) monitoring via physician office or specialty clinic(30)(32)(35)(36)
  - Newer anticoagulation agents for which intensive monitoring is not required, if appropriate for clinical condition(11)(37)(38)(39)(40)

Evidence Summary

Background

Oral anticoagulation therapy with vitamin K antagonists has been shown to reduce subsequent thromboembolic events in a variety of clinical settings.(7)(8) **(EG 1)** The narrow therapeutic range of vitamin K antagonists and the wide variation in individual dose-response require patients on extended therapy to undergo regular testing and possible dose readjustment to ensure that anticoagulation is sufficient to prevent thrombosis but not at such a high level as to cause bleeding.(7)(9)(10) **(EG 1)** The advent of portable devices to accurately measure anticoagulation from capillary whole blood via the INR has led to the ability of patients or their caregivers, if

motivated and trained, to monitor anticoagulation at home (patient self-testing), and even to make necessary dose adjustments based on algorithms from the patient's provider (patient self-management).(11)(12)(13) **(EG 1)** Interactive patient support via the internet is also available.(14)(15) **(EG 2)** These devices usually store multiple measurements with a date and time stamp, and can also transmit such information electronically.(16) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 29 published peer reviewed articles, 3 specialty society or other evidence-based guidelines, and 1 Cochrane systematic review.

For anticoagulation with an oral vitamin K antagonist that has already been used for 3 months or longer, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Systematic reviews and meta-analyses have concluded that patient self-testing and self-management using approved INR home monitoring devices is at least equivalent to management by usual care. It is a safe option for suitable patients of all ages who have used oral vitamin K antagonists for at least 3 months and is associated with decreased mortality, decreased major complications, and increased amount of time spent by the patient in a therapeutic range of anticoagulation without increased risk for a serious bleeding event.(8)(13)(19)(20)(21) **(EG 1)** Safety and effectiveness of home monitoring have been demonstrated in both children and elderly patients.(17)(18)(22)(23) **(EG 1)** However, studies do not address the question of whether home monitoring is safe during the high-risk initiation phase.(1)(9)(20) **(EG 1)** A systematic review and network meta-analysis of 28 studies (8100 patients) comparing the efficacy of 4 management strategies for patients on warfarin (patient self-management (self-testing plus self-dose adjustment), patient self-testing (with dose adjustments made by the provider), anticoagulation management services (ie, anticoagulation clinic), or usual care (dose adjustments made by the primary care provider)) found moderate-certainty evidence that self-management was associated with a lower risk of thromboembolic events compared with anticoagulation management services or usual care, and low-certainty evidence that self-management and self-testing were associated with improved time in the therapeutic range compared with usual care; no differences were seen between groups in all-cause mortality or major bleeding events.(24) **(EG 1)** Regarding patients with mechanical heart valves, a meta-analysis that included 5 randomized controlled trials and 2219 patients found that self-testing and self-management, as compared with conventional care, was associated with improvement in the quality of oral anticoagulant therapy by increasing time spent in the therapeutic range and decreasing rates of thromboembolic events and mortality, with no increase in hemorrhage.(25) **(EG 1)** A matched cohort study of 615 patients with mechanical heart valves found that, after 5 years of follow-up, patient self-management (which included INR self-testing) of oral anticoagulant therapy with vitamin K antagonists was associated with a lower risk of all-cause mortality compared with conventional management.(26) **(EG 2)** A retrospective analysis of commercial and Medicare databases (37,387 patients) comparing outcomes in patients on warfarin treated with either home INR monitoring (1592 patients) or office-based therapy (36,245 patients) found higher rates of thromboembolism, major bleeding, and stroke in patients treated with office-based therapy compared with patients treated with home INR monitoring.(27) **(EG 2)** A national guideline recommends that patients on long-term warfarin who are motivated and demonstrate competency in related procedures be considered for patient self-testing or patient self-management.(11) **(EG 2)** A specialty society guideline recommends patient INR self-management for patients treated with vitamin K antagonists who are motivated and can demonstrate competency in self-management strategies, including use of the self-testing equipment.(4) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(41); 42 CFR 422.101(42)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(43); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(44); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(45)

Medicare Coverage Determinations: Medicare Coverage Database(46)

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Codes

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