RMHP Prothrombin Time (INR) Home Monitoring Device

MCG Health
Ambulatory Care
27th Edition

AUTH: RMHP-A-065027 (AC)

Link to Codes

Clinical Indications

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For members with **RMHP PRIME (Medicaid) or CHP+** coverage, home prothrombin (INR) monitoring device, associated training and supply allowances are Not a Benefit in accordance with Colorado Department of Health Care Policy and Financing (HCPF) guidance. The case will be denied.

For members with **RMHP Medicare (CareAdvantage and DSNP Dual Special Needs Plan) coverage**, the case will be pended for the reviewer to apply the CMS NCD 190.11. See Reviewer Guidance.

- For members with **RMHP Individual and Family Plan (IFP) Commercial** coverage, 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.(7)(8)
  - Anticoagulation with oral vitamin K antagonist (eg, warfarin) needed for 6 more months or longer(7)(9)
  - Appropriate and motivated patient or caregiver for INR home monitoring (including adequate visual acuity, manual dexterity, and mental ability)(10)
  - Home monitoring program is characterized by **1 or more** of the following(11)(12)(13):
    - Self-management, involving self-testing as well as dose adjustment based on algorithm provided by prescribing physician or specialty clinic(8)
    - Self-testing, involving home testing of INR but reporting values to centralized service that prescribes recommended dose adjustment, if any(14)(15)(7)
  - Required training of patient or caregiver has been scheduled, with assessment of competence in performing home monitoring.(7)(8)(16)(17)

Alternatives

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- Alternatives include:
    - Anticoagulation with oral vitamin K antagonist (eg, warfarin) monitoring via physician office or specialty clinic(18)(11)(13)(19)
    - Newer anticoagulation agents for which intensive monitoring is not required, if appropriate for clinical condition(20)(21)(22)(23)(24)

Evidence Summary

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Background

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Oral anticoagulation therapy with vitamin K antagonists has been shown to reduce subsequent thromboembolic events in a variety of clinical settings.(25)(26) **(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.(25)(10)(27) **(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).(20)(28)(29) **(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.(30) **(EG 2)**

Criteria

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For anticoagulation with an oral vitamin K antagonist that has already been used for 3 months or longer, 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.(26)(29)(31)(32)(33) **(EG 1)** Safety and effectiveness of home monitoring have been demonstrated in both children and elderly patients.(7)(8)(34)(35) **(EG 1)** However, studies do not address the question of whether home monitoring is safe during the high-risk initiation phase.(36)(10)(32) **(EG 1)** A prospective cohort study of 1140 adult patients who self-managed use of vitamin K antagonists concluded, after a network meta-analysis that included 6 major studies, that self-management was comparable to standard care and to new oral anticoagulants in terms of death, thromboembolic events, and major bleeding, demonstrating that self-management of properly trained patients (including those with atrial fibrillation, mechanical heart valves, venous thrombosis, and the elderly) can be effective and safe in a long-term real-life setting.(37) **(EG 1)** A prospective, randomized, controlled, open-label trial that included 114 patients found that a self-management program led by pharmacists, as compared with usual care at a specialty anticoagulation clinic, resulted in significant improvement in 4 of 5 quality-of-life measures, reduction in the time spent performing INR monitoring, and maintenance of a level of anticoagulation similar to that of the usual-care group.(38) **(EG 1)** A randomized controlled blinded study of 310 patients on long-term warfarin found that self-management via a validated home individualized algorithm performed at least as well as usual care in maintaining the INR within a target range; there were significantly fewer extreme readings and less INR variability in the self-management group.(18) **(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.(39) **(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.(40) **(EG 2)** However, a randomized trial that included 2922 patients who were taking warfarin due to mechanical heart valves or atrial fibrillation compared weekly INR monitoring at home with monthly testing in a clinic and found no significant difference between the groups over a period of 2 to 4.75 years in time to a first major event (stroke, major bleeding episode, or death), which was the primary study outcome. The self-testing group demonstrated small but statistically significant improvements in percentage of time that INR was in target range, as well as in patient satisfaction with anticoagulation therapy.(41) **(EG 1)** 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.(20) **(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.(42) **(EG 2)**

Reviewer Guidance

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For **RMHP PRIME (Medicaid) and CHP+** plans - send to medical director with recommendation to deny as not a benefit. The prothrombin (INR) monitoring device, associated training and supply allowances are Not a Benefit in accordance with Colorado Department of Health Care Policy and Financing (HCPF) guidance. Listed as not a benefit on the current fee schedule. The most current CHP + fee schedule shows term date of 6/30/2022. See References.

For **Individual and Family Plan (IFP) Commercial** coverage, use MCG 27th edition A-0650 above.

For **Medicare** plans, follow the National Coverage Determination (NCD) for Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (190.11). Publication Number 100-3. Effective Date 3/19/2008. Reviewed 10/27/2023. Summarized below:

For services furnished on or after March 19, 2008, Medicare will cover for the use of home PT/INR monitoring forchronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a), and all of the following requirements must be met: The patient must have been anticoagulated for at least 3 months prior to use of the home INR device;and,The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home; and,The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and,Self-testing with the device should not occur more frequently than once a week.

Policy History

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History Summary: 7/2/2013 Policy created. Ongoing annual reviews, updates with each MCG edition through 27th in 2023. RMHP uses MCG for Commercial, CMS NCD for Medicare, HCPF for Medicaid and CHP+ (NAB). See archive copies for detailed history. 10/27/2023 annual review.

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CMS Manual System. Pub. 100-04 Medicare Claims Processing. Transmittal 1562. July 25, 2008, reviewed 10/27/2023. http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1562CP.pdf

Decision Memo for Prothrombin Time (INR) Monitor for Home Anticoagulation Management (CAG-00087R), https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=209, dated 3/19/2008, reviewed 10/27/2023.

The 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). Publication Number 100-3. Effective Date 3/19/2008, reviewed 10/27/2023.

The current version of the Colorado Department of Health Care Policy and Financing (HCPF) Health First Colorado Fee Schedule effective 7/1/2023, on which the associated HCPCS codes are called out as Not A Benefit, reviewed 10/27/2023.

The last version of the Child Health Plan Plus (CHP+) Professional Fee Schedule (2021), on which the associated HCPCS codes were priced, but show term date 6/30/2022, therefore defer to HCPF guidance on Health First Colorado Fee Schedule in reference above showing not a benefit. Reviewed 10/27/2023.

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Codes

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CPT® : 85610, 93792, 93793

HCPCS: G0248, G0249, G0250

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