

PT or INP Monitoring at Home

Origination: 06/06/11	Revised:	Annual Review: 12/15/11
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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to *PT or INP Monitoring at Home* in order to determine inclusion in the benefit plan.

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

Additional Information

- Prothrombin (PT) or INR time home testing systems are portable, battery-operated instruments for the quantitative determination of PT or INR from finger-stick whole blood. They are designed to aid in the management of high-risk Members taking oral anticoagulants. They provide the potential for improved outcomes as well as greater convenience. Self-testing may provide a convenient opportunity for increased frequency of testing when deemed necessary.

Coverage Guidelines

- A Home PT or INR testing set from a participating vendor is covered for Members who are being treated with warfarin for the following:
 - A. Mechanical heart valve;
 - B. Chronic atrial fibrillation;
 - C. Deep venous thrombosis, pulmonary embolism; or
 - D. Venous embolism and thrombosis of deep vessels of lower extremity;
 - E. AND both of the following criteria are met:
 1. Home PT or INR testing is needed for at least six (6) months; *and*
 2. Member has been anticoagulated for at least three (3) months prior to use of the home PT or INR device.

Exclusions

All other indications are not covered as they are considered experimental and investigational.

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References:

1. Center for Medicare and Medicaid Services (CMS). Prothrombin time (INR) monitor for home anticoagulation management (#CAG-00087N). National Coverage Analysis (NCA). Baltimore, MD: CMS; September 18, 2001. Horstkotte D, Piper C. Improvement of oral anticoagulation therapy by INR self-management. *J Heart Valve Dis.* 2004;13(3):335-338.
2. Brown A, Wells P, Jaffey J, et al. Point-of-care monitoring devices for long-term oral anticoagulation therapy: Clinical and cost effectiveness. Technology Report No. 72. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); February 2007. Center for Medicare and Medicaid Services (CMS). Decision memo for prothrombin time (INR) monitor for home anticoagulation management (CAG-00087R). Baltimore, MD: CMS; March 19, 2008.
3. Bradbury MJ, Taylor G, Short P, Williams MD. A comparative study of anticoagulant control in patients on long-term warfarin using home and hospital monitoring of the international normalised ratio. *Arch Dis Child.* 2008;93(4):303-306.
4. Plesch W, van den Besselaar AM. Validation of the international normalized ratio (INR) in a new point-of-care system designed for home monitoring of oral anticoagulation therapy. *Int J Lab Hematol.* 2009;31(1):20-25.
5. testing. A comparison of CoaguChek S and XS INR measurements with hospital laboratory monitoring. *Int J Lab Hematol.* 2010;32(1 Pt 1):e26-e33.
6. Dolor RJ, Ruybalid RL, Uyeda L, et al; THINRS Site Investigators. An evaluation of patient self-testing competency of prothrombin time for managing anticoagulation: pre-randomization results of VA Cooperative Study #481 -- The Home INR Study (THINRS). *J Thromb Thrombolysis.* 2010;30(3):263-275.
7. Matchar DB, Jacobson A, Dolor R, et al; THINRS Executive Committee and Site Investigators. Effect of home testing of international normalized ratio on clinical events. *N Engl J Med.* 2010;363(17):1608-1620.

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Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plans service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.