Clinical Policy: Home Prothrombin Time Monitoring

Reference Number: WA.CP.MP.207
Last Review Date: 04/21
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Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

International Normalized Ratio (INR) or prothrombin time (PT) is the standard measurement for reporting the blood's clotting time and allows physicians to determine the level of anticoagulation in a patient. A PT/INR monitoring system is a portable testing device that includes a finger-stick and an FDA-cleared meter that measures the time it takes for a person's blood plasma to clot.[1] This policy outlines the medical necessity criteria for home prothrombin time monitoring.

Policy/Criteria

I. It is the policy of Coordinated Care of Washington, Inc., that when home prothrombin time monitoring is covered, it may be **medically necessary** when all of the following criteria are met:
   A. Diagnosis of a condition requiring long-term anticoagulant use for mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism on warfarin;
   B. Anticoagulant use greater than 3 months;
   C. Physician approval for use of a home monitoring device for self-testing;
   D. Testing not required more than once per week;
   E. Anticipated home monitoring device use ≥ 6 months;
   F. Member/enrollee or caregiver competent in device use and ongoing management;
   G. Member/enrollee or caregiver willing to perform testing

Background

Treatment with vitamin K antagonists (warfarin or Coumadin derivatives) requires repeated monitoring of the intensity of anticoagulation and regular dose-adjustment in order to maintain a prescribed therapeutic range and minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events.[1,2]

PT testing is performed by recalcifying citrated patient plasma in the presence of tissue factor and phospholipid and determining the time it takes to form a fibrin clot. The result is measured in seconds and reported along with a control value and/or an INR. In most laboratories, the normal range is approximately 11 to 13 seconds.[3] Despite the importance of maintaining a therapeutic range, many patients are not in the therapeutic target range for a considerable proportion (30-50%) of the time.[2]

Recently, reliable portable coagulometers have become available for home use. These devices allow the measurement of the International Normalized Ratio (INR) from a small drop of capillary blood, enabling patients to self-manage their anticoagulation at home.[2]

Benefits of at home testing include:[2]

- Clinical studies show that self-testing of the INR and self-adjusting of the warfarin dose results in a better control of anticoagulation in comparison with regular care by general practitioners or specialists and is at least as good as management by a specialized anticoagulation clinic.
- Treatment-related patient satisfaction and quality of life improves in patients performing self-management of anticoagulation.
- Avoidance of time consuming repeated laboratory checks and visits to the anticoagulation clinic or office.
- Home PT monitoring by patients can increase testing frequency and may thus decrease complications associated with oral anticoagulant therapy.

Coding Implications

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HCPCS ®* Codes	Description
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 its 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

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	04/21	05/21

References

1. National coverage determination: home prothrombin time international normalized ratio (INR) monitoring for anticoagulation management (190.11). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. March 19, 2008. Accessed December 17, 2020.
2. Levi M. Role of self-management of anticoagulation in patients with atrial fibrillation. International Self-Monitoring Association website https://www.ismaap.org/self-monitoring/. Published July 2018. Accessed December 21, 2020.
3. Zehnder JL. Clinical use of coagulation tests. UpToDate website www.uptodate.com. Published September 9, 2020. Accessed December 17, 2020.
4. Yang DT, Robetorye RS, Rodgers GM. Home prothrombin time monitoring: a literature analysis. *Am J Hematol.* 2004 Oct; 77(2):177-86.
5. Koertke H. INR self-management: a promising tool to achieve low complication rates after mechanical heart valve replacement. International Self-Monitoring Association Web site. https://www.ismaap.org/self-monitoring/. Published 2006. Accessed December 21, 2020.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.