



HOME PROTHROMBIN TIME (PT) TESTING

Policy number: 200308-0003
Effective date: 08/05/2003
Revision date: 01/26/2009

Overview:

Warfarin (Coumadin®) is a prescription medication that is used to prevent the formation of blood clots. Warfarin is in a class of medications called anticoagulants. Many people refer to these medications as “blood-thinners,” although they do not actually cause the blood to become less thick, only less likely to clot. Warfarin is often prescribed in the treatment of cardiovascular conditions, including deep venous thrombosis (DVT), pulmonary embolism, atrial fibrillation, myocardial infarction, and cardiac valve replacement.

The goal of warfarin therapy is to decrease the clotting tendency of blood, but not to prevent clotting completely. (A major complication associated with warfarin is excessive bleeding, or hemorrhage.) Therefore, the effect of warfarin on the blood’s ability to clot must be carefully monitored. The most frequently used method of monitoring anticoagulant therapy is the prothrombin time (PT). PT is a blood test that measures the amount of time it takes for a person’s blood to clot. Because the risk of bleeding increases as the PT rises, the PT is closely monitored during warfarin therapy and adjustments in the dose of warfarin are made as needed to maintain the PT at an acceptable level.

A system of standardizing the PT in oral anticoagulant therapy was introduced by the World Health Organization in 1983. It is based upon the determination of an International Normalized Ratio (INR) which provides a common basis for communication of PT results and interpretation of therapeutic ranges. Most laboratories report PT results that have been adjusted to the International Normalized Ratio (INR). For example, a normal clotting time of 10-20 seconds equals an INR of 1.0. The physician will determine the dose of warfarin that is necessary to maintain the level of anticoagulant therapy that is right for each patient. For some patients, an INR of 2.0 to 3.0 may be appropriate. For other patients who have a higher risk of clot formation, the INR may need to be 2.5 to 3.5. An INR of greater than 4.0 appears to provide no additional therapeutic benefit in most patients, and is associated with a higher risk of hemorrhage.



Effective July 1, 2002, Medicare began paying for home PT testing for beneficiaries with mechanical heart valves.¹ Patients with mechanical heart valves require long-term anticoagulation therapy and are at increased risk for the serious adverse events associated with under and over-anticoagulation (i.e., thromboembolytic events and hemorrhagic events, respectively).

In an unprecedented move, the Centers for Medicare and Medicaid (CMS) decided that they would cover home PT testing as a physician-directed diagnostic service rather than as durable medical equipment. This means that the patient does not purchase the home PT monitor or supplies. Consistent with Medicare guidelines, FCHP covers home PT testing provided under the direction of a physician, with the equipment and supplies dispensed by the physician, rather than purchased by the patient. The benefit for home PT testing involves three components:

1. Training in the use of the home PT monitor
2. Provision of equipment and supplies for home PT monitoring (the physician purchases the equipment and supplies, and dispenses them to the patient as needed)
3. Review and interpretation of PT testing results

Covered Services:

[Home PT testing requires preauthorization by FCHP. The physician ordering home PT testing must submit the request for preauthorization to FCHP.](#)

FCHP covers home PT monitoring for plan members with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism, and for plan members requiring oral anticoagulation to similar levels as are required for individuals with mechanical heart valves (see *ACC/AHA Recommendations for Antithrombotic Therapy for Patients with Mechanical Heart Valves* below).² In addition, all of the following criteria must be met:

- 1. The patient must have been anticoagulated for at least three months prior to the use of a home PT monitoring device, and**

¹ Effective for dates of service on or after 03/19/2008, Medicare expanded coverage for home PT/INR monitoring to include chronic atrial fibrillation and venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism).

² In 2006, the FDA added a boxed warning to the label for warfarin which reminds physicians that patients may experience major or fatal bleeding from this drug. The warning emphasizes that bleeding is more likely to occur when warfarin therapy is being initiated, with higher doses, and with long periods of treatment. The warning states that INR should be monitored regularly during treatment with warfarin, and that patients judged to be at higher risk for bleeding may benefit from more frequent monitoring, careful dose adjustment, and a shorter duration of therapy.



2. The patient must require once weekly determinations of PT/INR values to ensure that the patient's PT/INR is in the therapeutic range³, and
3. The patient must complete a face-to-face training program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home, and
4. The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring.

Coverage for home PT testing is premised upon the use of FDA-approved PT monitoring equipment and supplies.

American College of Cardiology/American Heart Association (ACC/AHA) 2006 Recommendations for Antithrombotic Therapy for Patients with Mechanical Heart Valves ≥ 3 months after valve replacement	
<i>Indication</i>	<i>PT/INR Range</i>
Aortic valve replacement with no risk factors* <ul style="list-style-type: none"> • Bileaflet valve or Medtronic Hall valve • Other disk valves or Starr-Edwards valve 	INR 2.0 to 3.0 INR 2.5 to 3.5
Aortic valve replacement with risk factors*	INR 2.5 to 3.5
Mitral valve replacement	INR 2.5 to 3.5

** Risk factors: Atrial fibrillation, LV dysfunction, previous thromboembolytic event, or hypercoagulable condition.*

Source: ACC/AHA 2006 Guidelines For The Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Exclusions

Home PT testing if a home health care nurse is routinely at the patient's home for other reasons and has the ability to draw blood for laboratory testing.

³ The safety and efficacy of warfarin therapy is greatly improved by ensuring that a patient's PT/INR is in the therapeutic range. Time in the therapeutic range is significantly greater in patients who are closely managed. Studies show that patients who self-monitor their PT are in the therapeutic range a significantly greater percentage of the time, and have fewer adverse events, as compared with patients who have their PT drawn at a physician's office or laboratory.



Home PT testing more frequently than once per week. PT/INR testing more frequently than once per week is not medically necessary, given that the half-life of warfarin is approximately 1.5 days and it typically requires 3-4 half-lives to achieve a steady state. In order to achieve time in therapeutic range > 90%, a patient likely needs to be tested once a week. (CMS Decision Memo CAG-00087N).

Codes

Codes	Number	Description
HCPCS	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
	G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; per four tests
	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 anticoagulation therapy following initiation of the home INR monitoring; not occurring more frequently than once a week

Copyright © 2009 American Medical Association, Chicago, IL

References

1. Heneghan C, Alonso-Coello P, Garcia-Alamino JM, Rerera R, Meats E, Glasziou. Self-Monitoring of Oral Anticoagulation: A Systematic Review and Meta-Analysis. *Lancet* 2006;367:404-411.
2. American College of Cardiology; American Heart Association Task Force on Practice Guidelines (Writing Committee to revise the 1998 guidelines for the management of patients with valvular heart disease); Society of Cardiovascular Anesthesiologists; Bonow RO, Carabello BA, Chatterjee K, de Leon AC Jr, Faxon DP, Freed MD, Gaasch WH, Lytle BW, Nishimura RA, O'Gara PT, O'Rourke RA, Otto CM, Shah PM, Shanewise JS, Smith SC Jr, Jacobs AK, Adams CD, Anderson JL, Antman EM, Fuster V, Halperin JL, Hiratzka LF, Hunt SA, Lytle BW, Nishimura R,



Page RL, Riegel B. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2006 Aug 1;48(3):e1-148.

3. Centers for Medicare & Medicaid Services, Medicare Coverage Database. NCD for Home Prothrombin Time INR Monitoring for Anticoagulation Management. http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd.
4. Centers for Medicare & Medicaid Services. Decision Memo for Prothrombin Time (INR) Monitor for Home Anticoagulation Management (CAG-00087N). <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=72>.
5. Regier DA, Sunderji R, Lynd LD, Gin K, Marra CA. Cost-effectiveness of self-managed versus physician-managed oral anticoagulation therapy. *CMAJ*. 2006 Jun 20;174(13):1847-52.
6. Menendez-Jandula B, Souto JC, Oliver A, Montserrat I, Quintana M, Gich I, Bonfill X, Fontcuberta J. comparing Self-Management of Oral Anticoagulant Therapy with Clinic Management. *Ann Intern Med*. 2005 Jan; 142(1):1-10.
7. King DE, Dickerson LM, Sack JL. Acute Management of Atrial Fibrillation: Part II: Prevention of Thromboembolic Complications. *Am Fam Phys*. 2002 Jul;66(2):261-264.
8. Brown A, Wells P, Jaffey J, McGahan L, Poon M C, Cimon K, Campbell K., Canadian Agency for Drugs and Technologies in Health (CADTH). Point-of-Care Monitoring Devices for Long-Term Oral Anticoagulation Therapy: Clinical and Cost Effectiveness. February 2007. <http://www.cadth.ca/index.php/en/hta/reports-publications/search/publication/679>.
9. Centers for Medicare & Medicaid Services. CMS Manual System. Pub 100-04 Medicare Claims Processing. Transmittal 1663. Change Request 6313. January 8, 2009.
10. Hayes Directory. Self-Monitoring and Self-Management of Oral Anticoagulant Therapy. October 4, 2004. © 2006 Winifred S. Hayes, Inc.

Products to Which This Policy Applies

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Fallon Senior Plan™
- ⊕ Commonwealth Care

Committee review dates:

Technology Assessment Subcommittee: 08/19/2003, 07/24/2007, 01/26/2009

Technology Assessment Committee: 06/10/2009



IMPORTANT NOTE: Not all services are covered for all products or employer groups. This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless