

UPMC Health Plan POLICY AND PROCEDURE MANUAL

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SUBJECT: Home PT / INR Monitoring
INDEX TITLE: Medical Management
ORIGINAL DATE: January 2009

This policy applies to the following lines of business: (Check those that apply.)

Commercial:					
HMO ()	POS ()	PPO ()	OOA/DOC ()		
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)		
Medicare Select ()	Medicare Supplement ()				
DPW-MA:					
Health Choices ()	Voluntary ()	All ()			
CMS-MA:					
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS (X)	All ()
PID-CHIP:					
Free ()	Sub ()	All (X)			

I. POLICY

It is the policy of UPMC Health Plan to recognize the use of Home Prothrombin Time/ International Normalized Ratio Monitoring for Anticoagulation Management as appropriate and consistent with good medical practice when performed for the indications listed in this policy. Coverage for this service is based upon medical necessity as detailed in this policy and according to the member's specific benefit plan.

II. DEFINITIONS

Anticoagulant: an agent used to prevent the formation of blood clots

Deep Vein Thrombosis: a blood clot that occurs in the veins of the inner thigh or leg

Home PT/ INR Monitoring device: a portable testing device that includes a finger-stick and an FDA approved monitor that measures the time it takes for a person's blood to clot

International Normalized Ratio (INR): is the international normalized ratio of the patient's prothrombin time compared to the mean prothrombin for a group of normal individuals in order to standardize the results. (INR = patient PT divided by mean normal PT).

Prothrombin time (PT): a test that evaluates the blood's ability to clot properly. PT/INR is the standard measurement for therapeutic effectiveness of warfarin therapy.

Therapeutic index: the dose of a drug required to produce a desired effect

Thromboembolism: blocking of a blood vessel by a blood clot

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Warfarin (Coumadin): is an anticoagulant drug (blood thinner) used for the treatment and prevention of venous and arterial thrombosis

III. PURPOSE

The purpose of this policy is to define the appropriate indications for coverage of Home PT/ INR Monitoring.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to: Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Medical Description / Background

Anticoagulation therapy is recommended in the prevention and/or treatment of venous thromboembolism, chronic atrial fibrillation and for patients with artificial heart valves. Warfarin (Coumadin) is the most commonly used oral anticoagulation agent and suppresses the action of vitamin K which is responsible for the activation of specific proteins that form and maintain a clot. Three million people in the United States are treated with Coumadin. It is a potentially hazardous drug because it can produce major bleeding. The incidence of bleeding is related to the degree of anticoagulation. For this reason, patients are periodically monitored with a prothrombin time measurement. The results are measured in seconds (normal is 11-15 seconds) and then compared with the value known as the INR. To determine the INR, the ratio of the patient's PT is compared to the average of a group of normal individuals. The dose of Warfarin is adjusted to achieve a therapeutic effect with an INR range of 2.0 to 3.0 for most clinical indications although the therapeutic dose range varies for each patient and specific indication. Levels lower than 2.0 may result in strokes and levels greater than 4.0 nearly double the risk of hemorrhage.

There are three sites for obtaining and monitoring a patient's anticoagulation therapy: a physician's office, a clinical laboratory or home PT/INR monitors. These monitors are portable devices used to monitor blood-clotting rates by patients at home with a goal of increasing the time that anticoagulation is within a therapeutic INR range and to decrease the incidence of a thromboembolic or hemorrhagic event. Home prothrombin monitors produce results similar to laboratory-based measurements with results available in minutes. The patient may call his physician with each result for instructions (known as patient self-testing) or may be given an algorithm to guide dosing adjustment with instructions to call if the result falls outside of the predetermined limits (known as patient self-management).

B. Indications include patients on warfarin needing long-term (> 6 months) or life-long coagulation for any of the following:

- Mechanical heart valves
- Chronic atrial fibrillation
- Venous thromboembolism inclusive of deep vein thrombosis (DVT) and pulmonary embolism (PE) **AND**

With all of the following additional requirements:

- The patient must have been anticoagulated for at least 3 months prior to the use of the home PT/INR device
- 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
- The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring
- Self-testing with the device should not occur more frequently than **once a week**

C. Limitations include all of the following:

- Patients with poor eyesight with no caregiver
- Patients with memory impairment
- Patients with difficulty with motor coordination or manual dexterity
- Patients with a history of noncompliance
- Patients with porcine valves
- Only one provider may bill the review, interpretation and management of this service per period of **4** billable tests and this should be the ordering physician.

Note: The device must be FDA approved

D. Variations

N/A

E. References

1. Centers for Medicare and Medicaid Services, NCD 190.11, *Home Prothrombin Time INR monitoring for Anticoagulation Management*, 08/25/2008
2. Cigna HealthCare, Coverage Position 0109, *Prothrombin Time Home Testing Systems*, 07/15/2008
3. DeGregorio, N, *Portable Devices for Home INR Testing to Monitor Anticoagulation Therapy*, 07/09/2007
4. ECRI Institute, Target Evidence Report, *Portable devices for home monitoring of*

- oral anticoagulation therapy, 04/03/2007*
5. Humana, Medical Coverage Policy, *Home Prothrombin Time (PT) Monitoring*, 02/22/2007
 6. Highmark Medicare Advantage, Medical Policy Bulletin M-61, *Home Prothrombin Time INR Monitoring for Anticoagulation Management*, 02/12/2007
 7. Aetna, Clinical Policy Bulletin Number 0173, *Prothrombin Time (INR) Home Devices*, 04/04/2008
 8. Anthem, Clinical UM Guideline #CG-DME-30, *Prothrombin Time Self-Monitoring Devices*, Effective Date 04/16/2008
 9. BlueCross BlueShield of Tennessee, Medical Policy, *Home Prothrombin Time Monitor for Anticoagulation Management*, 05/01/2008
 10. Centers for Medicare and Medicaid Service, *Decision Memo for Prothrombin Time (INR) Monitor for Home Anticoagulation Management (CAG-00087R)*, 03/19/2008

Disclaimer:

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