MEDICAL ASSOCIATES HEALTH PLANS
HEALTH CARE SERVICES POLICY AND PROCEDURE MANUAL
POLICY NUMBER: PP 15

POLICY TITLE: HOME PROTHROMBIN DEVICES (INR)

POLICY STATEMENT: Provide consistent criteria when determining coverage for Home Prothrombin Device (INR) for Health Plans' members on an anticoagulant.

NOTE: For Commercial HMO Members and Health Choice Groups – First, review contract to determine coverage and secondly, do they meet medically necessity.

PROCEDURE:
Home Prothrombin Devices (INR) may be necessary when the following criteria are met:

1. Member has one of the following diagnoses
    - Mechanical heart valve
    - Chronic Atrial Fibrillation
    - Venous Thromboembolism (deep vein or pulmonary)

2. The monitor and the home testing must be prescribed by a treating physician and ALL of the following requirements must be met:
    a. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device; and,
    b. The patient must undergo a face-to-face educational program on anticoagulation management and demonstrate the correct use of the device prior to use in the home,
    c. 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.

3. Additional clinical indications for self-testing of prothrombin results using a home monitor may include high risk patients who have one or more of the following:

    a. poor venous access,
    b. are physically unable to visit a clinical laboratory,
    c. have a fluctuating response to warfarin,
    d. are at risk for hemorrhagic complications,
    e. may be adversely affected by frequent venous sampling or laboratory visits.

References: CMS NDC Number 190.11
Anticoagulation Forum, Vol. 12, Number 2, Spring 2008

Tammi Hollenback, R.N. Date
Manager of Health Care Services

. Date
Director of Health Care Services

Original: 05/12 Reviewed: 02/13
Reviewed: 01/14
Revised: 12/14

National Coverage Determination (NCD) for Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (190.11)

Benefit Category
Diagnostic Tests (other)
Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description
A. General
Use of the International Normalized Ratio (INR) or prothrombin time (PT) - standard measurement for reporting the blood's clotting time - allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's PT (extrinsic or tissue-factor coagulation pathway) compared to the mean PT for a group of normal individuals. Maintaining patients within his/her prescribed therapeutic range minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events. Patient self-testing and self-management through the use of a home INR monitor may be used to improve the time in therapeutic rate (TTR) for select groups of patients. Increased TTR leads to improved clinical outcomes and reductions in thromboembolic and hemorrhagic events.
Warfarin (also prescribed under other trade names, e.g., Coumadin®) is a self-administered, oral anticoagulant (blood thinner) medication that affects the vitamin K-dependent clotting factors II, VII, IX and X. It is widely used for various medical conditions, and has a narrow therapeutic index, meaning it is a drug with less than a 2-fold difference between median lethal dose and median effective dose. For this reason, since October 4, 2006, it falls under the category of a Food and Drug Administration (FDA) “black-box” drug whose dosage must be closely monitored to avoid serious complications. 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.

Indications and Limitations of Coverage
B. Nationally Covered Indications
For services furnished on or after March 19, 2008, Medicare will cover for the use of home PT/INR monitoring for chronic, 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:

1. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device; and,

2. 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,

3. 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,

4. Self-testing with the device should not occur more frequently than once a week.

C. Nationally Non-Covered Indications
N/A

D. Other
1. All other indications for home PT/INR monitoring not indicated as nationally covered above remain at local Medicare contractor discretion.
2. This national coverage determination (NCD) is distinct from, and makes no changes to, the PT clinical laboratory NCD at section 190.17 of Publication 100-03 of the NCD Manual.
(This NCD last reviewed March 2008)