

MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

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SUBJECT: Home PT / INR Monitoring
INDEX TITLE: Medical Management
ORIGINAL DATE: January 2013

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

COMMERCIAL	<input type="checkbox"/> HMO	<input type="checkbox"/> PPO	<input type="checkbox"/> Fully Insured	<input type="checkbox"/> Individual Product	<input type="checkbox"/> Marketplace (Exchange)	<input checked="" type="checkbox"/> All
GOVERNMENT PROGRAMS	<input type="checkbox"/> MA HMO	<input type="checkbox"/> MA PPO	<input type="checkbox"/> MA C-SNP	<input type="checkbox"/> MA D-SNP	<input checked="" type="checkbox"/> MA All	
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO					

I. POLICY

It is the policy of MedStar Health, Inc. 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 (DVT): a blood clot forming in a vein deep within the body. DVTs most commonly occur in the lower leg or thigh.

Home PT/ INR Monitoring device: an FDA approved portable testing device used to monitor the time it takes for a person's blood to clot by measuring PT/INR using a finger stick blood sample.

International Normalized Ratio (INR): the ratio of the patient's PT compared to the mean PT for a group of normal individuals and adjusted for the sensitivity of the laboratory's thromboplastin as determined by the International Sensitivity Index (ISI) standardizing the results [INR = (patient PT/ mean normal PT)^{ISI}].

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.



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Thromboembolism: Formation of a clot (thrombus) in a blood vessel that breaks loose and is carried by the blood stream to block another vessel. These clots may plug a vessel in the lungs, brain, gastrointestinal tract, kidneys, or legs.

Warfarin (Coumadin): a self-administered oral anticoagulant medication used for the treatment and prevention of venous and arterial thrombosis. Warfarin, sometimes referred to under its most common trade name Coumadin, affects the vitamin K-dependent clotting factors II, VII, IX, and X.

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 MedStar Health, Inc. departments as indicated by the Benefit and Reimbursement Committee.

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. This agent suppresses the action of vitamin K responsible for the activation of specific proteins that form and maintain a clot. It is a potentially hazardous drug because when taking it there is a major bleeding risk. The incidence of bleeding is related to the degree of anticoagulation. For this reason, patients are periodically monitored with a PT measurement. The results are measured in seconds (normal is 11-15 seconds) and converted to an INR. 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 conditions like stroke or pulmonary embolism (PE). 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



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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. Specific Indications

Home PT/INR monitoring is indicated for members on warfarin needing long-term (> 6 months) or life-long coagulation for any of the following conditions:

- Mechanical heart valves
- Chronic atrial fibrillation
- Venous thromboembolism inclusive of DVT and PE

And

All of the following requirements have to be met for Home PT/INR monitoring of a member:

- The device must be FDA approved
- 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 documented face-to-face educational program on anticoagulation management demonstrating the correct use of the device prior to its use in the home
- The patient continues to correctly use the device for anticoagulation therapy following the initiation of home monitoring which is supported with documentation
- Self-testing with the device should not occur more frequently than once a week
- 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 (G0250)

C. Limitations include members with any of the following:

- Porcine valves
- Poor eyesight with no caregiver
- Memory impairment
- Difficulty with motor coordination or manual dexterity
- History of noncompliance



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D. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS Codes:

Description:

G0248	Demonstration, prior to initiation 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's ability to perform testing and report results
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; testing not occurring more frequently than once a week; testing materials, billing units of service include 4 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; testing not occurring more frequently than once a week; billing units of service include 4 tests

ICD-9 Codes:

Description:

289.81	Primary hypercoagulable state
415.11 – 415.19	Pulmonary embolism and infarction
416.2	Chronic pulmonary embolism
427.31	Chronic atrial fibrillation
451.0 – 451.9	Phlebitis and thrombophlebitis
451.19	Deep vein thrombosis
453.0 – 453.3	Other venous embolism and thrombosis
453.40 – 453.42	Venous embolism and thrombosis of deep vessels of the lower extremity
453.50 – 453.6	Chronic venous embolism and thrombosis of deep vessels of lower extremity
453.71 – 453.89	Chronic venous embolism and thrombosis
V43.3	Heart valve replaced by other means (mechanical)
V58.61	Long-term (current) use of anticoagulants (warfarin)



ICD-10 Coding:

D68.51-D68.62
I26.01-I26.99
I27.82
I48.0-I48.2
I80.00-I80.9
I82.0-I82.1
I82.211
I82.221
I82.291
I82.3
I82.401

I82.402
I82.403
I82.409
I82.501-I82.5Z9
I82.701-I82.729
I82.A21-I82.A29
I82.B21-I82.B29
I82.C21-I82.C29
I82.811-I82.819
I82.891
Z95.2
Z79.01

Description:

Primary hypercoagulable state
Pulmonary embolism (acute)
Chronic pulmonary embolism
Chronic atrial fibrillation (persistent and paroxysmal)
Phlebitis and thrombophlebitis (including deep vein thrombosis)
Budd-Chiari syndrome / Thrombophlebitis migrans
Chronic embolism and thrombosis of superior vena cava
Chronic embolism and thrombosis of inferior vena cava
Chronic embolism and thrombosis of other thoracic veins
Embolism and thrombosis of renal vein
Acute embolism and thrombosis of unspecified deep veins right lower extremity
Left lower extremity
Bilateral lower extremity
Unspecified lower extremity
Chronic embolism and thrombosis of lower extremity (deep) veins
Chronic embolism and thrombosis of upper extremity veins
Chronic embolism and thrombosis of axillary vein
Chronic embolism and thrombosis of subclavian vein
Chronic embolism and thrombosis of internal jugular vein
Embolism and thrombosis of other specified veins
Chronic embolism and thrombosis of other specified veins
Presence of prosthetic heart valve
Long-term (current) use of anticoagulants

E. Variations

N/A

F. Quality Audit

Quality Audit monitors policy compliance and/or billing accuracy at the request of the MedStar Health, Inc.'s Technology Assessment Committee or the Benefits Reimbursement Committee.

G. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc. Policy and Procedure for Records Retention.

H. References

Medical Literature/Clinical Information:

1. Dignan R, Keech AC, GebSKI VJ et al. & Warfarin SMART Investigators. Is home warfin self-management effective? Results of the randomized

- Self-Management of Anticoagulation Research Trail. Int J Cardiol. 2013 Oct; 168(6): 5378-5384.
<http://www.sciencedirect.com/science/article/pii/S0167527313016161>
2. Guyatt GH, Akl EA, Crowther M, et al. Executive summary: Antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines, Chest. 2012 Feb; 141(2_Suppl), 7S-47S.
<http://journal.publications.chestnet.org/article.aspx?articleid=1159399>

Regulatory/Government Source:

1. Department of Health and Human Services. Agency for Healthcare Research and Quality. (AHRQ). National Guideline Clearinghouse: Guideline Summary (NGC 8926) Evidence-based Management of Anticoagulant Therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th Ed. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines, Issued February 2012. Last Updated: May 2, 2012. National Heart, Lung, and Blood Institute: What is Deep Vein Thrombosis? Posted October 28, 2011.
<http://www.nhlbi.nih.gov/health/health-topics/topics/dvt/>
2. Centers for Medicare and Medicaid Services (CMS): CMS Manual System-Pub 100-4 Medicare Claims Processing Transmittal 1562. Issued July 25, 2008. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1562CP.pdf>
3. Centers for Medicare and Medicaid Services (CMS): National Coverage Determination (NCD) No. (190.11) for Home Prothrombin Time /International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management. Effective March 19, 2008. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=269&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&>
4. Centers for Medicare and Medicaid Services (CMS): Decision Memo (CAG-00087R) for Prothrombin Time (INR) Monitor for Home Anticoagulation Management. Issued: March 19, 2008.
<http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=209&fromdb=true>



Disclaimer:

MedStar Health, Inc. medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health, Inc. and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

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