

The Department of Vermont Health Access Medical Guidelines

Subject: PT/INR HOME MONITOR (a.k.a. “Pro-Time Microcoagulation System”)

Last Review: 07/16/10

Revision 3:

Revision 2:

Revision 1: 07/16/10

Original Effective: 10/10/08

Description of Service or Procedure

Beneficiaries receiving long-term oral anticoagulation therapy can monitor their own coagulation control with portable devices that measure capillary whole-blood prothrombin time (PT) using the International Normalized Ratio (INR). After testing, the beneficiaries either notify their physicians of the results or use an individualized algorithm to adjust their warfarin dosage to maintain PT within a target zone. These monitors perform self-testing and have built-in controls which cancel any test for reasons such as an inadequate amount of blood/sample. The provider’s office or the clinic contacts the beneficiary when a result is not reported as scheduled. Beneficiaries can avoid travel and the costs of lab-drawn samples with home use of this monitor.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule that pertains to the beneficiary’s aid category. Prior authorization is only valid if the beneficiary is eligible for the applicable item or service on the date of service.

Medicaid Rule

7102.2 Prior Authorization Determination

7103 Medical Necessity

7505 Definition of DME: “...primarily and customarily used to serve a medical purpose; ...generally not useful to a person in the absence of illness, injury or disability...”

Coverage Position

A PT/INR home monitor may be covered for those individuals:

- Who are VT Medicaid beneficiaries on the date of service, AND
- When this device is prescribed by a licensed medical provider enrolled in the VT Medicaid program who is knowledgeable in the use of PT/INR home monitor and who provides medical care to the beneficiary AND
- Who meet the clinical guidelines below.

Coverage guidelines

PT/INR home monitoring is considered medically necessary if **all** of the following criteria are met:

- Beneficiaries has a mechanical heart valve (non-porcine) or chronic atrial fibrillation or venous thromboembolism (inclusive of deep vein thrombosis and pulmonary embolism), AND
- is on long-term warfarin (or other oral anticoagulants such as Coumadin) therapy for chronic anticoagulation management, AND
- the anticoagulation therapy and the home monitor are prescribed by a treating physician, AND
- the beneficiary has been anticoagulated for at least 3 months prior to use of the home INR device, AND
- the beneficiaries has completed a face-to-face educational program on anticoagulation management, AND
- the beneficiaries has demonstrated the ability, reliability, and compliance to utilize the device effectively and correctly prior to its use in the home, AND
- the beneficiaries continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring, AND
- self-testing with the device does not occur more frequently than once per week.

Clinical guidelines for repeat service or procedure

The same criteria apply as for the initial use.

Type of service or procedure covered

PT/INR home monitor and related supplies and services.

Type of service or procedure not covered (this list may not be all inclusive)

When the DVHA criteria are not met, when authorization (when required) is not obtained in advance of ordering or supplying the item/service, when the item/service is not the least expensive appropriate alternative (7102), or when the item/service is investigational.

Coverage of this monitor and related supplies is not available when the beneficiary's heart valve is porcine.

Hardware or software, to electronically submit data to provider, is not covered.

References

Centers for Medicare & Medicaid Services (2006). Medicare National Coverage Determination Manual Chapter 1, Part 3 (Sections 170 – 190.34) Coverage Determination. Home *Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (190.11)*. Retrieved April 21, 2010, from: http://www3.cms.gov/manuals/downloads/ncd103c1_Part3.pdf

Centers for Medicare & Medicaid Services (2009). *2009 MLN Matters Articles*. (HHS Publication). Retrieved April 21, 2010, from: <http://www.cms.hhs.gov/MLNMattersArticles/2009MMAN/itemdetail.asp?filterType=dual,%20keyword&filterValue=PT/INR&filterByDID=0&sortByDID=8&sortOrder=ascending&itemID=CMS1219240&intNumPerPage=10>

Centers for Medicare & Medicaid Services (2008). *2008 MLN Matters Articles*. (HHS Publication). Retrieved April 21, 2010, from: <http://www.cms.hhs.gov/MLNMattersArticles/2008MMAN/list.asp?filtertype=dual&datefiltertype=&datefilterinterval=&filtertype=keyword&keyword=pt%2Finr&intNumPerPage=10&cmdFilterList=Show+Items>

Hayes, Inc. Hayes Medical Technology Directory and Executive Summary. *Self-Monitoring and Self-Management of Oral Anticoagulant Therapy*. Landsdale, PA: Hayes, Inc.; October 2006.

Medscape. Management of oral anticoagulation therapy. A review of principles and practice. Retrieved September 24, 2008, from: <http://www.medscape.com/infosite/pointofcaretesting/article-5>

Meurer, L.N., Jamieson, B. (2008). What is the interval for monitoring warfarin therapy once therapeutic levels are achieved? *The Journal of Family Practice*, Retrieved September 24, 2008, from: <http://www.jfponline.com/Pages.asp?AID=1870>

This document has been classified as public information.