GUIDELINES

This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION

Prothrombin time (PT) home monitoring systems are portable, battery-operated instruments for the quantitative determination of PT from fingerstick whole blood. These products are generally designed to aid in the management of patients requiring long-term oral anticoagulation therapy for indications such as mechanical heart valves, atrial fibrillation, and venous thromboembolism. There are several types of point of care (POC) PT monitors on the market, including office, anticoagulation clinic, or home settings. For home testing, the instrument selected should be extremely easy to use with a limited number of steps.

The FDA has approved portable testing devices that are available by prescription for home use as Class II devices through the 510(k) process. They include, but are not limited to:

- ProTIME® microcoagulation analyzer (International Technidyne Corporation [ITC], Edison, NJ)
- CoaguChek® XS System (Roche Diagnostics Corporation, Indianapolis, IN)
- Alere INRatio®2 PT/INR Home Monitoring System (HemoSense, Milpitas, CA)
- AvoSure™ PT (Avocet Medical Inc., San Jose, CA)

The studies evaluating the use of POC PT monitors indicate that the monitors are accurate and can be used appropriately by selected patients with adequate training who are motivated to perform self-testing. PT monitor limitations include the necessity for proper finger stick blood sample technique for accurate results. Definitive patient selection criteria have not been established for self-monitoring of anticoagulation therapy. PT self-monitoring by patients receiving long-term warfarin therapy had been shown to be accurate and effective in maintaining anticoagulant control within target therapeutic ranges. Published studies have demonstrated that there are advantages to patient self-testing and that this testing is effective as anti-coagulation clinics in maintaining the quality of anticoagulation therapy. Guidelines from professional organizations include the use of POC monitors for selected patients who have received training.

Data management systems including the software associated with home PT monitors is generally considered a convenience and not medically necessary. There is insufficient peer-reviewed literature to support the use of data management systems in improving health outcomes in this population.

POLICY

**Home prothrombin monitoring (G0248-G0250) does not require prior authorization for all product lines.**

HMO, PPO, Individual Marketplace, Advantage, Elite

Home prothrombin monitoring may be medically necessary 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 when ALL of the following requirements are met:

1. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device and require long term (greater than one year) anticoagulation.
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.
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.
4. Self-testing with the device should not occur more frequently than once a week.

Paramount does not cover any type of remote monitoring and/or software/hardware required for downloading data from home prothrombin time testing systems to computers for the management of anticoagulation because each is considered a convenience item and not medically necessary.
CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>Description</th>
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<tbody>
<tr>
<td>G0248</td>
<td>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</td>
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<tr>
<td>G0249</td>
<td>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</td>
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<tr>
<td>G0250</td>
<td>Physician review, interpretation, and patient management of home INR testing for 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</td>
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REVISION HISTORY EXPLANATION
05/15/09: No changes
02/01/10: No changes
04/01/11: No changes
02/12/13: No changes
10/11/16: Home prothrombin monitoring (G0248-G0250) will now be covered without prior authorization for HMO, PPO, Individual Marketplace, & Advantage product lines also. Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.

REFERENCES/RESOURCES
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.