Clinical Coverage Guidelines: **Home Prothrombin Time Monitoring Devices**

**Current Effective Date:** 11/01/12  
**Original Effective Date:** 04/01/08*  
**Policy Number:** OCA: 3.78  
**Product Applicability:**  
- MassHealth  
- Commonwealth Care  
- Commercial

**Summary:** Home prothrombin time (PT) monitoring devices are considered medically necessary for members who are receiving long-term oral anticoagulation therapy (OAT) and are suitable candidates for self-management based on the Plan’s clinical criteria. Plan prior authorization is required.

**Description of Item or Service:** Home PT monitors are portable, battery-operated, hand-held devices that measure PT using capillary whole blood from a fingerstick. These devices can store 30-40 of the most recent test results that the physician can review to monitor trends in oral anticoagulant therapy. Numerous monitors have been FDA approved through the 510K process.

**Clinical Guideline Statement:**  
Home prothrombin time (PT) monitoring devices require prior authorization and are considered medically necessary as a durable medical equipment item for members who are receiving long-term oral anticoagulation therapy who have been anticoagulated for a minimum of three (3) months and who are suitable candidates for self-management according to the following criteria:

- The member is receiving OAT for one of the following diagnoses:
  1. Artificial heart valve replacement
  2. Chronic atrial fibrillation
  3. Thrombophilia after recurrent deep vein thrombosis in the legs
  4. Pulmonary embolism
  5. Post myocardial infarction with impaired left ventricular function
  6. Congestive cardiomyopathy

*This guideline provides information on BMC HealthNet Plan claims adjudication processing guidelines. The use of this guideline is not a guarantee of payment and will not determine how a specific claim(s) will be paid. Reimbursement is based on member benefits and eligibility, medical necessity review, where applicable, coordination of benefits, adherence to Plan policies, clinical coding criteria, and the BMC HealthNet Plan agreement with the rendering or dispensing provider. Reimbursement policies may be amended at BMC HealthNet Plan’s discretion. BMC HealthNet Plan will always use the most recent CPT and HCPCS coding guidelines. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements, including NCQA.*
The member must participate in a formal educational program on anticoagulation management and the use of the device in the home setting; AND
The member must have an understanding to correctly interpret the INR result and a history of compliance for self management; AND
The self monitoring device must be prescribed by a physician who manages the patient’s dosage of OAT.

Definitions:
International Normalized Ratio (INR): The ratio of the patient’s prothrombin time compared to the mean prothrombin time for a group of individuals formulated by the World Health Organization (WHO) and the International Committee on Thrombosis and Hemostasis. Normal INR is 1.0. Full anticoagulant therapy is considered reached when the value is 2.0-3.0 depending upon the level necessary for each individual patient circumstance.

Prothrombin Time: The minimum amount of time needed for a small amount of blood to clot. Normal range is 10.0-12.5 seconds.

Applicable Coding:
Applicable coding is listed below, subject to codes being active on the date of service. Because the American Medical Association (AMA), Centers for Medicare & Medicaid Services (CMS), and the U.S. Department of Health and Human Services may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes may not be all inclusive. These codes are not intended to be used for coverage determinations.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<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>
</tr>
<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>
</tr>
</tbody>
</table>

This guideline provides information on BMC HealthNet Plan claims adjudication processing guidelines. The use of this guideline is not a guarantee of payment and will not determine how a specific claim(s) will be paid. Reimbursement is based on member benefits and eligibility, medical necessity review, where applicable, coordination of benefits, adherence to Plan policies, clinical coding criteria, and the BMC HealthNet Plan agreement with the rendering or dispensing provider. Reimbursement policies may be amended at BMC HealthNet Plan’s discretion. BMC HealthNet Plan will always use the most recent CPT and HCPCS coding guidelines. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements, including NCQA.

BMC HealthNet Plan –Home PT Monitors

2 of 7
G0250  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

**Limitations:**
Some home prothrombin time (PT) monitoring devices have additional software and/or hardware to track and download test results to the treating provider. Since the home PT monitoring devices already store test results, the Plan considers the use of additional software and/or hardware a convenience item, and therefore is not considered medically necessary and would not be authorized by the Plan.

**Clinical Background Information:**
Indications for oral anticoagulant therapy (OAT) with warfarin (Coumadin) to prevent thromboembolic disease without increasing the risk of hemorrhagic complications have increased in recent years to include a variety of cardiac and vascular diseases. The most common indications for OAT include patients who are at risk for the formation of blood clots because of atrial fibrillation, prosthetic heart valve replacements, inherited or acquired disorders, and to prevent the reoccurrence of heart attacks and transient ischemic attacks (TIAs). Prothrombin times must be monitored frequently in patients who are taking oral anticoagulants to determine the safest dose and minimize the risk for complications by maintaining the INR within the appropriate therapeutic range. Over treatment with Coumadin can result in central nervous system and/or gastrointestinal bleeding and under treatment or failure to treat can result in thrombotic strokes and other thromboembolic complications.

Most patients receiving OAT are managed by their own physician requiring frequent trips to the laboratory for prothrombin testing and more recently by point of care (POC) patient self testing with PT/INR devices. These devices should only be considered in patients who are expected to be on long-term oral anticoagulation who have artificial heart valves, chronic atrial fibrillation, thrombophilia after recurrent deep vein thrombosis in the leg, pulmonary embolism, post myocardial infarction with impaired left ventricular function, and/or congestive cardiomyopathy.

There are many PT/INR devices that have been FDA approved and all are portable and easy to use. One drop of capillary whole blood from a fingerstick is placed on a test strip and inserted into the meter for a quick determination of the patient’s prothrombin time. The patient must be responsible for using the device appropriately, recording and interpreting the results accurately and compliant with clinic or physician appointments for follow-up OAT management. The patient’s physician is responsible for the selection, training, and continuing management of any patient selected for home testing. The goal of home PT monitoring is to ensure that the patient is receiving the appropriate anticoagulation therapy to prevent thromboembolic events while minimizing the risk of hemorrhagic complications.

This guideline provides information on BMC HealthNet Plan claims adjudication processing guidelines. The use of this guideline is not a guarantee of payment and will not determine how a specific claim(s) will be paid. Reimbursement is based on member benefits and eligibility, medical necessity review, where applicable, coordination of benefits, adherence to Plan policies, clinical coding criteria, and the BMC HealthNet Plan agreement with the rendering or dispensing provider. Reimbursement policies may be amended at BMC HealthNet Plan’s discretion. BMC HealthNet Plan will always use the most recent CPT and HCPCS coding guidelines. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements, including NCQA.
of POC patient self testing with a PT/INR device is to achieve optimum therapeutic anticoagulation control with reduction of the risk of complications that are associated with OAT.

References:


Policy History:
Original Effective Date: 04/01/08
*Effective date for Commercial is 01/01/12

Date of Review/Revision:
10/14/08: Annual review, no changes.
10/27/09: Annual review, no changes to criteria, updated coding to include the following HCPCS codes: G0248 and G0249.
10/01/10: Annual review, no changes to criteria, updated references and coding.
11/01/11: Annual review, no criteria changes, updated references and coding.
07/01/12: Revised language in Applicable code section, updated code definitions and references, added language in Limitations section which states the Plan does not consider additional software and/or hardware used with home PT monitoring devices to track and download test results to the treating provider to be medically necessary since it is a convenience item only.

Last Review Date:
07/01/12

Next Review Date:
07/01/13

Approval Dates:
Regulatory Approval: N/A
Internal Approval:
11/13/07: MPCTAC
11/27/07: UMC
12/06/07: QIC
10/14/08: MPCTAC
10/28/08: UMC
11/18/08: QIC
10/27/09: MPCTAC
11/19/09: QIC
11/23/10: MPCTAC
12/22/10: QIC
11/16/11: MPCTAC
12/20/11: QIC
07/18/12: MPCTAC
08/22/12: QIC

This guideline provides information on BMC HealthNet Plan claims adjudication processing guidelines. The use of this guideline is not a guarantee of payment and will not determine how a specific claim(s) will be paid. Reimbursement is based on member benefits and eligibility, medical necessity review, where applicable, coordination of benefits, adherence to Plan policies, clinical coding criteria, and the BMC HealthNet Plan agreement with the rendering or dispensing provider. Reimbursement policies may be amended at BMC HealthNet Plan’s discretion. BMC HealthNet Plan will always use the most recent CPT and HCPCS coding guidelines. All Plan policies are developed in accordance with state, federal and accrediting organization guidelines and requirements, including NCQA.
Authorizing Entity:
QIC

IMPORTANT NOTE: Not all services are covered for all products or employer groups. This medical policy expresses the Plan's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. The Plan has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered or not covered, this conclusion is not based upon the terms of a member’s particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all services that are determined to be medically necessary will necessarily be covered services under the terms of a member’s benefit plan. Members and their providers need to consult the applicable benefit plan document (e.g., Evidence of Coverage) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this medical policy and the benefit plan document, the provisions of the benefit plan document will govern. In addition, this policy and the benefit plan document are subject to applicable state and federal laws that may mandate coverage for certain services and supplies.