Medical Policy

Home Prothrombin Time Monitoring Devices

Policy Number:  OCA 3.27  
Version Number:  12  
Version Effective Date:  05/01/16

Product Applicability  

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<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tr>
<td>☑ New Hampshire Medicaid</td>
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Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy 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 medical criteria. Plan prior authorization is required.

It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested indication. See the Plan’s policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment.
**Description of Item or Service**

Home prothrombin time (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.

**Medical Policy Statement**

Home prothrombin time (PT) monitoring devices are considered medically necessary as a durable medical equipment item for a member when ALL of the following criteria are met and documented in the member’s medical record, as specified below in item 1, item 2, and item 3:

1. The member is receiving long-term oral anticoagulation therapy (OAT) and has been anticoagulated for a minimum of three (3) months and is on a stable regimen of anticoagulation medications; AND

2. The member is receiving OAT for ONE (1) of the following diagnoses (specified as items a through f below):
   a. Chronic atrial fibrillation; OR
   b. Congestive cardiomyopathy; OR
   c. Mechanical heart valve replacement; OR
   d. Post myocardial infarction with impaired left ventricular function; OR
   e. Thrombophilia with a history of deep vein thrombosis; OR
   f. Venous thromboembolism (a disease that includes both deep vein thrombosis and pulmonary embolism); AND

3. The member is a suitable candidate for self-management and ALL of the following criteria are met, as specified below in items a through e:
   a. The self-monitoring device must be prescribed by a physician who manages the member’s OAT dosage; AND
   b. The member has participated in a formal, face-to-face educational program on anticoagulation management and has demonstrates the correct use of the device prior to its use in the home setting; AND
c. The member has sufficient capacity to understand how to correctly interpret the international normalized ratio (INR) results and has a history of compliance for self management; AND

d. The member continues to correctly use the device in the context of management of the anticoagulation therapy following initiation of home monitoring; AND

e. Self-testing with the device is not required and does not occur more frequently than once a week.

Limitations

Limitations include ANY of the following, as specified below in items 1 through 4:

1. A home prothrombin time (PT) monitoring device for a member who requires self-testing less than an average of once per week is considered NOT medically necessary; OR

2. A home PT monitoring device is considered NOT medically necessary for a member who is unable to competently use the home monitoring device or interpret and record results of testing; OR

3. Replacement or repair of a home PT monitoring device is considered NOT medically necessary in ANY of the following instances, as specified below in items a through c:

   a. The device is still under manufacturer warranty; OR

   b. The device is lost, stolen, or damaged due to improper care, misuse, or neglect (and documentation such as a police report and corroborating statements may be requested by the Plan); OR

   c. The member has a functioning model (even if it is not the most current model); the Plan will not authorize an upgrade of the home PT monitoring device when the current device is functioning properly.

4. Some home 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.
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 0.8 to 1.1. 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 11-13.5 seconds.

**Venous thromboembolism (VTE):** A disease that includes both deep vein thrombosis (DVT) and pulmonary embolism (PE). VTE contributes to significant morbidity and mortality both in the community and in hospital. The mainstay of therapy for DVT is anticoagulation, provided there is no contraindication. Following initial anticoagulation, patients with DVT are anticoagulated further to prevent future recurrences, embolism, and thrombosis-related death.

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.
<table>
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<tr>
<th>HCPCS Codes</th>
<th>Description: Codes Covered When Medically Necessary</th>
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<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>
<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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**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 for use 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 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 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


<table>
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<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tr>
<td>Regulatory Approval: N/A Internal Approval: 11/13/07: MPCTAC 11/27/07: UMC 12/06/07: QIC</td>
<td>04/01/08 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>MPCTAC, Utilization Management Committee (UMC), and QIC</td>
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*Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
*Effective Date for the Well Sense Heath Plan New Hampshire Medicaid Product(s): 01/01/13

(Policy number was formerly OCA 3.78.)
<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
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<tr>
<td>10/14/08</td>
<td>No changes</td>
<td>Version 2</td>
<td>10/14/08: MPCTAC 10/28/08: UMC 11/18/08: QIC</td>
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<tr>
<td>10/27/09</td>
<td>No changes to criteria, updated coding to include the following HCPCS codes: G0248 and G0249.</td>
<td>Version 3</td>
<td>10/27/09: MPCTAC 11/19/09: QIC</td>
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<tr>
<td>10/01/10</td>
<td>No changes to criteria, updated references and coding.</td>
<td>Version 4</td>
<td>11/23/10: MPCTAC 12/22/10: QIC</td>
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<tr>
<td>11/01/11</td>
<td>No criteria changes, updated references and coding.</td>
<td>Version 5</td>
<td>11/16/11: MPCTAC 12/20/11: QIC</td>
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<tr>
<td>07/01/12</td>
<td>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.</td>
<td>Version 6</td>
<td>07/18/12: MPCTAC 08/22/12: QIC</td>
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<td>07/30/12</td>
<td>Off cycle review for Well Sense Health Plan, reformatted Medical Policy Statement section.</td>
<td>Version 7</td>
<td>08/03/12: MPCTAC 09/05/12: QIC</td>
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<tr>
<td>07/01/13</td>
<td>Review for effective date 09/01/13. Reformatted Medical Policy Statement section without revising criteria. Updated references.</td>
<td>09/01/13 Version 8</td>
<td>07/17/13: MPCTAC 08/15/13: QIC</td>
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<tr>
<td>11/01/13</td>
<td>Review for effective date 01/01/14. No revisions.</td>
<td>01/01/14 Version 9</td>
<td>11/20/13: MPCTAC 12/19/13: QIC</td>
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<tr>
<td>11/01/14</td>
<td>Review for effective date 03/01/15. Updated criterion in the Medical Policy Statement section and added references. Change in review calendar.</td>
<td>03/01/15 Version 10</td>
<td>11/19/14: MPCTAC 12/10/14: QIC</td>
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* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Policy Revisions History

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<tr>
<th>Date</th>
<th>Details</th>
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<tr>
<td>01/01/16</td>
<td>Review for effective date 05/01/16. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Definitions and References section.</td>
<td>05/01/16</td>
<td>01/20/16: MPCTAC 02/10/16: QIC</td>
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Last Review Date

01/01/16

Next Review Date

01/01/17

Authorizing Entity

QIC

Other Applicable Policies

Medical Policy - *Medically Necessary*, policy number OCA 3.14

Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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