BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

WELL SENSE HEALTH PLAN

wellsense.org | 877-957-1300

Medical Policy

Home Prothrombin Time Monitoring Devices

Policy Number: OCA 3.27
Version Number: 20
Version Effective Date: 01/01/22

Product Applicability	☒ **All Plan+ Products**
WellSense Health Plan	**Boston Medical Center HealthNet Plan**
☒ NH Medicaid	☒ MassHealth
☒ NH Medicare Advantage	☒ Qualified Health Plans/Connector Care/Employer Choice Direct
	☒ Senior Care Options

+ Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

Home prothrombin time (PT) monitors are portable, battery operated, hand held devices that measure PT using capillary whole blood from a finger stick. Home PT monitoring devices are considered medically necessary for members who are suitable candidates for self-management. Plan prior authorization is required.

Clinical Criteria

Home prothrombin time (PT) monitoring devices are considered medically necessary when ALL following criteria are met in items 1 through 4:

1. The member is receiving long-term warfarin and there is an expected need for home INR testing for six (6) or more consecutive months; AND

2. The member has been on a stable regimen of warfarin for a minimum of three (3) months; AND

3. The member is receiving warfarin for ONE (1) of the conditions in items a through h:

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. History of deep vein thrombosis; OR

f. Venous thromboembolism (a disease that includes both deep vein thrombosis and pulmonary embolism); OR

g. Ventricular assist device; AND

h. Hypercoagulable state (e.g. antithrombin II deficiency, Factor V Leiden, protein C deficiency, protein S deficiency).

4. The member is a suitable candidate for self-management and ALL of the following criteria are met, as specified below in items a through d:

   a. The self-monitoring device must be prescribed by a physician who manages the member's warfarin; AND

   b. The member has participated in a formal, face-to-face educational program on warfarin and has demonstrated the correct use of the device prior to its use in the home setting; AND

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

   d. Self-testing is required once a week to maintain therapeutic range (i.e., self-testing more frequently or less frequency than once a week with the device does NOT occur and is NOT required).

Limitations and Exclusions

Home prothrombin time (PT) monitoring devices are NOT medically necessary for ANY of the following:

1. Replacement of repair when the device is under warranty, is lost or stolen or damaged, or still functioning properly.

2. Use of additional software or hardware to transmit results.

Variations

The Plan uses guidance from the Centers for Medicare & Medicaid Services (CMS) for medical necessity and coverage determinations for Senior Care Options (SCO) members and WellSense Medicare Advantage HMO members, including but not limited to national coverage determinations (NCDs), local coverage determinations (LCDs), local coverage articles (LCAs), and documentation included in Medicare manuals. At the time of the Plan's most recent policy review, NCD 190.11 includes guidelines for the use of home prothrombin time/international normalized ratio (PT/INR) monitoring. Verify CMS guidelines in effect on the date of the prior authorization request. When there is no guidance from CMS for the requested service, Plan-adopted clinical review criteria will be used to determine the medical necessity of the service.

In response to the COVID-19 pandemic, CMS will NOT be enforcing clinical indications for coverage for a LIMITED number of NCDs and LCDs (and corresponding services, treatments, and devices included in those documents) for care provided to the Plan's SCO and WellSense Medicare Advantage HMO members. The suspension of clinical indications for coverage for limited number of services, treatments, and devices will be in effect on an interim basis for maximum flexibility and will allow SCO and WellSense Medicare Advantage HMO members to receive care in an unexpected setting such as the home. The list of NCDs and LCDs with waived clinical review criteria may be revised periodically by CMS and does NOT apply to other aspects of CMS guidelines such as benefit category determinations. It is expected that CMS will return to the enforcement of all clinical review criteria included in NCDs and LCDs used to make medical necessity determinations at the conclusion of this public health emergency. **As of March 31, 2020, CMS will NOT enforce clinical indications for coverage included in NCD 190.11 for home PT/INR monitoring until the conclusion of the COVID-19 pandemic. Prior authorization is required for these services even when clinical indications for coverage are not enforced for SCO and WellSense Medicare Advantage HMO members.** The Plan recommends that providers verify benefit coverage and CMS guidelines for the requested service, device, and treatment on the date of service using the CMS website.

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). Since 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 Clinical Criteria section and Limitations and Exclusions 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 this Applicable Coding section. Review the Plan's reimbursement policies for Plan billing guidelines. Coverage for services is subject to benefit eligibility under the member's benefit plan in effect at the time of the service. Member benefit documents are available at the following websites: www.bmchp.org for BMC HealthNet Plan members, www.SeniorsGetMore.org for Senior Care Options members, www.wellsense.org for WellSense New Hampshire Medicaid members, and www.WellSense.org/Medicare for WellSense Medicare Advantage HMO members.

HCPCS Codes	Description: Codes Covered When Medically Necessary
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 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

References

American College of Cardiology (ACC). Anticoagulation Management.

American College of Chest Physicians (ACCP). Ansell J, Hirsh J, Hylek E, Jacobson A, Crowther M, Palareti G. Pharmacology and management of the vitamin K antagonists: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). Chest. 2008 Jun;133(6 Suppl):160S-98S. doi: 10.1378/chest.08-0670. PMID: 18574265.

American College of Chest Physicians (ACCP). Holbrook A, Schulman S, Witt DM, Vandvik PO, Fish J, Kovacs MJ, Svensson PJ, Veenstra DL, Crowther M, Guyatt GH. Evidence-based management of anticoagulant therapy: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest 2012;141(2 Suppl):e152S-84S. doi: 10.1378/chest.11-2295. PMID: 22315259.

American Heart Association (AHA), American College of Cardiology (ACC). Hirsh J, Fuster V, Ansell J, Halperin L. AHA/ACC Foundation Guide to Warfarin Therapy. Circulation 2003 Apr 1;107(12):1692:711. doi:10.1161/01.CIR.0000063575.17904.4E. PMID: 12668507.

Ansell J, Hollowell J, Pengo V, Martinez-Brotons F, Caro J, Drouet L. Descriptive analysis of the process and quality of oral anticoagulation management in real-life practice in patients with chronic non-valvular atrial fibrillation: the international study of anticoagulation management (ISAM). J Thromb Thrombolysis. 2007 Apr;23(2):83-91. doi: 10.1007/s11239-006-9022-7. PMID: 17221328.

Bloomfield HE, Krause A, Greer N, Taylor BC, MacDonald R, Rutks I, Reddy P, Wilt TJ. Meta-analysis: effect of patient self-testing and self-management of long-term anticoagulation on major clinical outcomes. Ann Intern Med. 2011 Apr 5;154(7):472-82. doi: 10.7326/0003-4819-154-7-201104050-00005. PMID: 21464349.

Bradbury MJ, Taylor G, Short P, Williams MD. A comparative study of anticoagulant control in patients on long-term warfarin using home and hospital monitoring of the international normalized ratio. Arch Dis Child. 2008 Apr;93(4):303-6. Epub 2007 Aug 3. doi: 10.1136/adc.2006.113886. PMID: 17675359.

Brasen CL, Madsen JS, Parkner T, Brandslund I. Home Management of Warfarin Treatment Through a Real-Time Supervised Telemedicine Solution: A Randomized Controlled Trial. Telemed J E Health. 2019 Feb;25(2):109-115. doi: 10.1089/tmj.2017.0260. Epub 2018 Jun 7. PMID: 29877778.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-02. Medicare Benefit Policy Manual.

Centers for Medicare & Medicaid Services (CMS). Manuals. Publication # 100-03. Medicare National Coverage Determinations (NCD) Manual.

Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (MCD).

Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management 190.11. Version 2. 2008 Mar 19.

Centers for Medicare & Medicaid Services (CMS). Transmittals.

Commonwealth of Massachusetts. Division of Insurance (DOI) Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Bulletins.

Commonwealth of Massachusetts. MassHealth Provider Manuals.

Commonwealth of Massachusetts. MassHealth Transmittal Letters.

Gardiner C, Longair I, Pescott MA, Erwin H, Hills J, Machin SJ, Cohen H. Self-monitoring of oral anticoagulation: does it work outside trial conditions? J Clin Pathol. 2009 Feb;62(2):168–71. doi: 10.1136/jcp.2008.059634. PMID: 19181634.

Garcia-Alamino JM, Ward AM, Alonso-Coello P, Perera R, Bankhead C, Fitzmaurice D, Heneghan CJ. Self-monitoring and self-management of oral anticoagulation. Cochrane Database Syst Rev. 2010 Apr 14;(4):CD003839. doi: 10.1002/14651858.CD003839.pub2. PMID: 20393937.

Greenway A, Ignjatovic V, Summerhayes R, Newall F, Burgess J, DeRosa L, Monagle P. Point-of-care monitoring of oral anticoagulation therapy in children. Comparison of the CoaguChek XS system with venous INR and venous INR using an International Reference Thromboplastin preparation (rTF/95). Thromb Haemost. 2009 Jul;102(1):159-65. doi: 10.1160/TH09-01-0056. PMID: 19572081.

Heneghan C, Ward A, Perera R; Self-Monitoring Trialist Collaboration, Bankhead C, Fuller A, Stevens R, Bradford K, Tyndel S, Alonso-Coello P, Ansell J, Beyth R, Bernardo A, Christensen TD, Cromheecke ME, Edson RG, Fitzmaurice D, Gadisseur AP, Garcia-Alamino JM, Gardiner C, Hasenkam JM, Jacobson A, Kaatz S, Kamali F, Khan TI, Knight E, Körtke H, Levi M, Matchar D, Menéndez-Jándula B, Rakovac I, Schaefer C, Siebenhofer A, Souto JC, Sunderji R, Gin K, Shalansky K, Völler H, Wagner O, Zittermann A. Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data. Lancet 2012 Jan 28;379(9813):322-34. doi: 10.1016/S0140-6736(11)61294-4. Epub 2011 Nov 30. doi: 10.1016/S0140-6736(11)61294-4. PMID: 22137798.

Hill J, Perreault S, Dorval M. Validity of CoaguChek S for home monitoring of anticoagulant therapy in pediatrics. Can J Cardiol. 2007 Jan; 23(1):47–50. PMID: 17245482.

International Self-Monitoring Association for Oral Anticoagulation. Ansell J, Jacobson A, Levy J, Völler H, Hasenkam JM; International Self-Monitoring Association for Oral Anticoagulation. Guidelines for implementation of patient self-testing and patient self-management of oral anticoagulation. International consensus guidelines prepared by International Self-Monitoring Association for Oral Anticoagulation. Int J Cardiol. 2005 Mar 10;99(1):37-45. doi: 10.1016/j.ijcard.2003.11.008. PMID: 15721497.

Jenner KM, Simmons BJ, Delate T, Clark NP, Kurz D, Witt DM. An Education Program for Patient Self-Management of Warfarin. Perm J. 2015 Fall;19(4):33–8. doi: 10.7812/TPP/14-246. PMID: 26517434.

Matchar DB, Love SR, Jacobson AK, Edson R, Uyeda L, Phibbs CS, Dolor RJ. The impact of frequency of patient self-testing of prothrombin time on time in target range within VA Cooperative Study #481: The Home INR Study (THINRS), a randomized, controlled trial. J Thromb Thrombolysis. 2015 Jul;40(1):17-25. doi: 10.1007/s11239-014-1128-8. PMID: 25209313.

Money AG, Barnett J, Kuljis J, Duffin D. Patient perceptions and expectations of an anticoagulation service: a quantitative comparison study of clinic-based testers and patient self-testers. Scand J Caring Sci. 2015 Dec;29(4):662–78. doi: 10.1111/scs.12195. PMID:: 25684404

New Hampshire Department of Health and Human Services. Billing Manuals.

New Hampshire Department of Health and Human Services. Provider Notices.
Ontario Ministry of Health and Long-term Care, Medical Advisory Secretariat (MAS). Point-of-care international normalized ratio (INR) monitoring devices for patients on long-term oral anticoagulation therapy: An evidence-based analysis. Ont Health Technol Assess Ser. 2009;9(12):1–114.
PMID: 23074516.

Plesch W, van den Besselaar AM. Validation of the international normalized ratio (INR) in a new point-of-care system designed for home monitoring of oral anticoagulation therapy. Int J Lab Hematol. 2009 Feb;31(1):20-5. doi: 10.1111/j.1751-553X.2007.00998.x. PMID: 19143869.

Ryan F, O'Shea S, Byrne S. The reliability of point-of-care prothrombin time testing. A comparison of CoaguChek S and XS INR measurements with hospital laboratory monitoring. Int J Lab Hematol. 2010 Feb;32(1 Pt 1):e26-33. doi: 10.1111/j.1751-553X.2008.01120.x. Epub 2008 Nov 18. doi: 10.1111/j.1751-553X.2008.01120.x. PMID: 19032373.

Sobieraj-Teague M, Daniel D, Farrelly B,, Coghlan D, Gallus A. Accuracy and clinical usefulness of the CoaguChek S and XS Point of Care devices when starting warfarin in a hospital outreach setting. Thromb Res. 2009 Apr;123(6):909-13. doi: 10.1016/j.thromres.2008.10.006. Epub 2008 Nov 29. PMID: 19042011.

Tamayo Aguirre E, Galo-Anza A, Dorronsoro-Barandiaran O, Del Burgo EU, Ostiza Irigoyen A, Garcia-Carro A, Lopez-Fernandez I, Colera N, Saez-Garbayo P, Tamayo-Uria I. Oral anticoagulation with vitamin K inhibitors and determinants of successful self-management in primary care. BMC Cardiovasc Disord. 2016 Sep 13;16(1):180. doi: 10.1186/s12872-016-0326-z. PMID: 27624485.

Tamayo Aguirre E, Vergara-Mitxeltorena I, Uranga Saez Del Burgo E, Ostiza-Irigoyen A, Garcia-Carro A, Lopez-Fernandez I, Galo-Anza A. Oral anticoagulation and self-management: analysis of the factors that determine the feasibility of using self-testing and self-management in primary care. BMC Cardiovasc Disord. 2013 Aug 22;13:59. doi: 10.1186/1471-2261-13-59. PMID: 23968316.

U.S. Food & Drug Administration (FDA). Medical Devices.

Wittkowsky AK, Sekreta CM, Nutescu EA, Ansell J. Barriers to Patient Self Testing of Prothrombin Time: National Survey of Anticoagulation Practitioners. Pharmacotherapy. 2005 Feb; 25(2):265-9.
doi: 10.1592/phco.25.2.265.56949. PMID: 15767240.

Policy History

Original Approval Date	Original Effective Date* and Version Number	Policy Owner	Original Policy Approved by

Regulatory Approval: N/A Internal Approval: 11/13/07: Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) 11/27/07: Utilization Management Committee (UMC) 12/06/07: Quality Improvement Committee (QIC)	04/01/08 Version 1	Medical Policy Manager as Chair of MPCTAC	MPCTAC, UMC, and QIC

*Effective Date for the BMC HealthNet Plan Commercial Product: 01/01/12
*Effective Date for the WellSense New Hampshire Medicaid Product: 01/01/13
*Effective Date for the Senior Care Options Product: 01/01/16
*Effective Date for the WellSense Medicare Advantage HMO Product: 01/01/22

(Policy number was formerly OCA 3.78.)

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date and Version Number	Approved by
10/14/08	No changes.	Version 2	10/14/08: MPCTAC 10/28/08: UMC 11/18/08: QIC
10/27/09	No changes to criteria, updated coding to include the following HCPCS codes: G0248 and G0249.	Version 3	10/27/09: MPCTAC 11/19/09: QIC
10/01/10	No changes to criteria, updated references and coding.	Version 4	11/23/10: MPCTAC 12/22/10: QIC
11/01/11	No criteria changes, updated references and coding.	Version 5	11/16/11: MPCTAC 12/20/11: QIC
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.	Version 6	07/18/12: MPCTAC 08/22/12: QIC
07/30/12	Off cycle review for Well Sense Health Plan, reformatted Medical Policy	Version 7	08/03/12: MPCTAC 09/05/12: QIC

Policy Revisions History			
	Statement section.		
07/01/13	Review for effective date 09/01/13. Reformatted Medical Policy Statement section without revising criteria. Updated references.	09/01/13 Version 8	07/17/13: MPCTAC 08/15/13: QIC
11/01/13	Review for effective date 01/01/14. No revisions.	01/01/14 Version 9	11/20/13: MPCTAC 12/19/13: QIC
11/01/14	Review for effective date 03/01/15. Updated criterion in the Medical Policy Statement section and added references. Change in review calendar.	03/01/15 Version 10	11/19/14: MPCTAC 12/10/14: QIC
11/25/15	Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section. Updated references.	01/01/16 Version 11	11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC
01/01/16	Review for effective date 05/01/16. Revised criteria in the Medical Policy Statement and Limitations sections. Updated Definitions and References section.	05/01/16 Version 12	01/20/16: MPCTAC 02/10/16: QIC
01/01/17	Review for effective date 03/01/17. Updated Clinical Background Information, References, and References to Applicable Laws and Regulations sections.	03/01/17 Version 13	01/18/17: MPCTAC 02/08/17: QIC
01/01/18	Review for effective date 02/01/18. Updated Summary, Clinical Background Information, and References sections. Administrative change made to the Medical Policy Statement section.	02/01/18 Version 14	01/17/18: MPCTAC
01/01/19	Review for effective date 02/01/19. Administrative changes made to the References, Other Applicable Policies, and Reference to Applicable Laws and Regulations sections.	02/01/19 Version 15	01/16/19: MPCTAC
12/01/19	Review for effective date 03/01/20. Administrative changes made to the References and Reference to Applicable Laws and Regulations sections. Clarified Plan guidelines in the Limitations section. Revised criteria in the Medical Policy Statement section.	03/01/20 Version 16	12/18/19: MPCTAC
09/25/20	Review for effective date 10/01/20.	10/01/20	09/25/20: MPCTAC

Policy Revisions History			
	Administrative changes made to the Medical Policy Statement, Limitations, Applicable Coding, Clinical Background Information, and Reference to Applicable Laws and Regulations sections to reference CMS guidelines for clinical indications for coverage for SCO members with Medicare coverage during the COVID-19 pandemic.	Version 17	(electronic vote)
12/01/20	Review for effective date 01/01/21. Administrative change made to the Description of Item or Service section.	01/01/21 Version 18	12/16/20: MPCTAC
11/01/21	Review for effective date 12/01/21. Adopted new medical policy template; removed administrative sections, the Medical Policy Statement section renamed the Clinical Criteria section, and the Limitations section renamed the Limitations and Exclusions section. Added WellSense Medicare Advantage HMO as an applicable product effective 01/01/22. Administrative changes made to the Policy Summary, Applicable Coding, and References sections. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, Applicable Coding, and References sections.	12/01/21 Version 19	11/17/21: MPCTAC
12/01/21	Review for effective date 01/01/22. Administrative changes made to the Policy Summary, Clinical Criteria, Limitations and Exclusions, and References sections.	01/01/22 Version 20	12/15/21: MPCTAC

Next Review Date

01/01/22

Authorizing Entity

MPCTAC

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.