Medica Central Medical Policy

Policy Name:	**Blood Coagulation Home Testing Devices MP9788**
Effective Date:	**09/01/2024**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Note: This policy is no longer scheduled for routine review of the scientific literature.

Blood coagulation home testing devices are COVERED for patients requiring long-term (i.e., greater than six months) or lifelong oral anticoagulant therapy, including but not limited to post-heart valve replacement, recurrent deep vein thrombosis, or chronic atrial fibrillation.

Description

Warfarin (Coumadin®, dicumarol) anticoagulation therapy interferes with the formation of vitamin K-dependent clotting factors and has a narrow therapeutic range that is easily influenced by such things as changes in diet, drug interactions, and illness. This necessitates frequent blood coagulation monitoring. The most frequently performed test for warfarin monitoring is the prothrombin time (PT). In the office or clinic, PT is measured by adding thromboplastin and calcium ions to the patient's plasma following a venous blood collection. Home testing monitors PT using capillary blood most often collected from a fingerstick. In both cases, PT is reported as an International Normalized Ratio (INR), which standardizes clotting time by relating it to an International Sensitivity Index (ISI) that quantifies differences in thromboplastin sensitivities. This allows PT to be reported as a ratio that is reproducible irrespective of testing location or instrumentation.

Prior to self-monitoring, therapeutic range is established by coagulation testing in a clinical setting. Following self-testing, therapeutic range results are called to the health care provider for regulation of anticoagulant dosage. In some cases, dosage adjustment may be self-managed. The goal of therapy is consistent maintenance of the patient's therapeutic range in order to diminish the risk of internal bleeding or internal clotting.

Anticoagulation home testing is proposed as an alternate to testing at the physician's office or a coagulation clinic. Home systems are only available as a prescription issued under a physician's supervision. Assuming patient compliance and understanding, blood coagulation home testing is purported to alleviate some of the problems associated with standard long-term anticoagulation therapy, such as use for patients with poor venous access, with a life-long anticoagulation need, at an increased risk for hemorrhage or thromboembolism, or who are unable to access testing facilities. In addition to instruction in the accurate use of the instrument and supplies, a key component of self-management is a structured patient anticoagulation therapy education program.

FDA Approval

Multiple coagulation systems have received FDA approval for home self-monitoring of prothrombin time/International Normalized Ratio (PT/INR) by patients receiving warfarin therapy. Examples include, but are not limited to:

1. CoaguChek® System and CoaguChek® S System
2. ProTime® Microcoagulation System
3. AvoSure™ PT-Pro, AvoSure™ PT-Pro+, AvoSure™ PT
4. Avoset PT-Pro™
5. INRatio® Monitor

Prior Authorization

Prior authorization is not required.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

- **G0248** - Demonstration, prior to initial use, 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 ability to perform testing prior to its use
- **G0249** - Provision of test materials and equipment for home INR monitoring to 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; not occurring more frequently than once a week
- **G0250** - Physician review, interpretation and patient management of home INR testing for a patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes face-to-face verification by the physician that the patient uses the device in the context of the management of the anticoagulation therapy following initiation of the home INR monitoring; not occurring more frequently than once a week.
- **A9999** – miscellaneous DME supply or accessory, not otherwise specified
- **E1399** - miscellaneous medical device

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Original Effective Date:	09/01/2024
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