

Geisinger Health Plan Policies and Procedure Manual

Policy: MP157

Section: Medical Benefit Policy

Subject: Prothrombin Time Home Testing

Applicable Lines of Business

Commercial	Х	CHIP	Χ
Medicare	Х	ACA	X
Medicaid	Х		

I. Policy: Prothrombin Time Home Testing

II. Purpose/Objective:

To provide a policy of coverage regarding Prothrombin Time Home Testing

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking
into account both the functional capacity of the Member and those functional capacities that are appropriate for
Members of the same age

DESCRIPTION:

Home prothrombin time testing systems are portable, hand-held, battery operated devices designed to analyze fresh capillary blood samples obtained by finger-stick using a lancet device. Both prothrombin time (PT) and international normalized ratio (INR) are displayed to aid in the management of high-risk members who are taking oral anticoagulation medications.

INDICATIONS:

Home prothrombin time testing systems will be evaluated for clinical appropriateness for selected members who are considered to be high risk of thromboembolism because of illness severity, instability of anticoagulation levels, or other complicating factors, and who meet all of the following criteria:

- Member requires anticoagulation therapy due to a mechanical heart valve, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) or hypercoagulable states (eg, Factor V Leiden, antithrombin III deficiency, Protein C or Protein S deficiency, etc); and
- Member requires long term (defined as greater than 6 months) oral anticoagulation therapy; and
- Member has been anticoagulated for a minimum of three months prior to the request for the home prothrombin time monitor; and
- Documentation has been submitted to show that the member has completed a face-to-face physician directed
 educational program on anticoagulation management and the use of the device and has demonstrated the ability
 to use the device correctly.
- The member continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring.

LIMITATIONS:

Based on the supporting published clinical trials data, self-testing more frequently than once per week is not medically necessary.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Home Prothrombin Time monitor

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- G0248 Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets
 Medicare coverage criteria, under the direction of a physician; includes: demonstration 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 a patient ability to perform testing
- G0249 Provision of test material and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests (does not require face-to-face service).
- G0250 Physician review, interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face- service).
- Patient/caregiver training for initiation of home international normalized ratio (INR) monitoring under the direction of a physician or other qualified health care professional, face-to-face, including use and care of the INR monitor, obtaining blood sample, instructions for reporting home INR test results, and documentation of patient's/caregiver's ability to perform testing and report results

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Winifred S. Hayes. Hayes Inc. Online. Self-monitoring of oral anticoagulant therapy. April 12, 2002. (35 Refs)

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Centers for Medicare and Medicaid Services, Coverage Issues Manual. Section 50-56 Home prothrombin time International Normalized Ratio (INR) monitoring for anticoagulation management.

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Menendez-Jandula B, Souto JC, Oliver A, et. al. Comparing self-management of oral anticoagulant therapy with clinic management. Annals of Internal Medicine. Jan 4, 2005;142(1):1-10.

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Heneghan C, Ward A, Perera R; et al. Self-monitoring of oral anticoagulation: systematic review and meta-analysis of individual patient data. Lancet. 2012 Jan 28;379(9813):322-34.

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 10/20/05

Revised: 10/06, 11/10 (criteria); 6/15 (revised criteria), 10/17 (Removed Homebound List); 10/23 (add indication)

Reviewed: 11/07, 11/11, 11/12, 11/13, 11/14, 12/16, 10/18, 10/19, 10/20, 10/21, 10/22

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.