

HOME PROTHROMBIN TIME OR INR MONITORING

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5/21, 5/22, 5/23, 8/23, 8/24, 8/25

Date of Origin: May 11, 2005 Status: Current

Summary of Changes

Deletions:

• I.C – Removed Medicaid coverage language. Please consult plan documents or the MDHHS Provider manual for benefits.

Additions:

• New sections: Government Regulations, and Guidelines/Position Statements.

I. POLICY/CRITERIA

- A. At-home prothrombin time (PT) monitoring or International Normalized Ratio (INR) of chronic warfarin therapy is covered when all of the following criteria are met:
 - 1. The home monitor is FDA approved.
 - 2. The patient has undergone anticoagulation management for at least 3 months prior to the use of the home INR device.
 - 3. The patient must undergo a formal educational program on anticoagulation management and the use of the device prior to its use in the home.
 - 4. Self-testing with the device is limited to a frequency of once per week. Testing more frequently than once per week is generally considered not medically necessary.
- B. PT monitoring or INR is not medically necessary for any agents that do not affect prothrombin time such as direct oral anticoagulants or low molecular weight heparin as the effectiveness has not been demonstrated.

II. GOVERNMENT REGULATIONS

| CMS Coverage Determinations | Title and Number |
|--------------------------------------|--|
| National Coverage Determinations | Home Prothrombin Time/International |
| (NCDs) | Normalized Ratio (PT/INR) Monitoring |
| | for Anticoagulation Management, 190.11 |
| Local Coverage Determinations | N/A |

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III. MEDICAL NECESSITY REVIEW

Prior authorization for certain drug, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the <u>Priority Health Provider Manual</u>.

IV. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **❖** HMO/EPO: This policy applies to insured HMO/EPO plans.
- ❖ POS: This policy applies to insured POS plans.
- * PPO: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- ASO: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- * INDIVIDUAL: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- ❖ MEDICARE: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.
- * MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945 42542 42543 42546 42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945 5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

V. DESCRIPTION

Warfarin anticoagulation requires monitoring to determine the degree of anticoagulation and to guide dose adjustments to optimize the time in the therapeutic range. Members receiving long-term oral anticoagulation therapy can monitor their own coagulation control with portable devices that measure capillary whole-blood prothrombin time (PT) or the amount of time needed for a small amount of blood to clot.

The International Normalized Ratio (INR) is the ratio of the patient's prothrombin time compared to the mean prothrombin time for a group of normal individuals. It



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was developed by the WHO to allow patients receiving warfarin at steady state to compare values obtained at different times and from different laboratories. After testing, patients either notify their physicians of the results or use an individualized algorithm to adjust their warfarin dosage to maintain PT levels within a target zone. The goal of self-monitoring and self-management of PT levels is to improve anticoagulation control and reduce the frequency of adverse events such as serious bleeding or thromboembolic events. Patient self-testing and self-management using a home INR monitor may improve the time in therapeutic rate (TTR) for select groups of patients. Increased TTR leads to improved clinical outcomes and reductions in thromboembolic and hemorrhagic events.

Direct oral anticoagulants (DOACs) are approved for use without PT monitoring. It is not necessary to check the PT in an individual receiving a DOAC or heparin and make changes to dosing or monitoring of these agents based on the result of the PT.

VI. CODING INFORMATION

| CODING INFORMATION | |
|------------------------------|---|
| ICD-10 Codes that may apply: | |
| D68.52 | Prothrombin gene mutation |
| D68.59 | Other primary thrombophilia |
| D68.61 | Antiphospholipid syndrome |
| D68.62 | Lupus anticoagulant syndrome |
| I23.6 | Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction |
| I26.01 | Septic pulmonary embolism with acute cor pulmonale |
| I26.09 | Other pulmonary embolism with acute cor pulmonale |
| I26.90 | Septic pulmonary embolism without acute cor pulmonale |
| I26.99 | Other pulmonary embolism without acute cor pulmonale |
| I27.82 | Chronic pulmonary embolism |
| I48.0 | Paroxysmal atrial fibrillation |
| I48.1x | Persistent atrial fibrillation |
| I48.2x | Chronic atrial fibrillation |
| I48.91 | Unspecified atrial fibrillation |
| I67.6 | Nonpyogenic thrombosis of intracranial venous system |
| I80.00 - I80.9 | Phlebitis and thrombophlebitis |
| O22.50 – O22.53 | Cerebral venous thrombosis in pregnancy |
| O87.1 | Deep phlebothrombosis in the puerperium |
| O87.3 | Cerebral venous thrombosis in the puerperium |
| Z79.01 | Long term (current) use of anticoagulants |
| Z86.718 | Personal history of other venous thrombosis and embolism |
| Z95.2 | Presence of prosthetic heart valve |



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Z95.4

Presence of other heart-valve replacement

CPT/HCPCS Codes:

- *These services not covered for Priority Medicaid
- 93792 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
- Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed
- *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 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; 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 a 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.

VII. REFERENCES

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