HOME PROTHROMBIN TIME/INTERNATIONAL NORMALIZED RATIO (PT/INR) MONITORING FOR ANTICOAGULATION TREATMENT (NCD 190.11)

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- Laboratory Tests and Services

INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier. This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview
Use of the International Normalized Ratio (INR) or prothrombin time (PT) - standard measurement for reporting the blood's clotting time - allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's PT (extrinsic or tissue-factor coagulation pathway) compared to the mean PT for a group of normal individuals. Maintaining patients within his/her prescribed therapeutic range minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events. Patient self-testing and self-management through the use of a home INR monitor may be used to 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.

Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Treatment (NCD 190.11)

UnitedHealthcare Medicare Advantage Policy Guideline
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Warfarin (also prescribed under other trade names, e.g., Coumadin®) is a self-administered, oral anticoagulant (blood thinner) medication that affects the vitamin K-dependent clotting factors II, VII, IX and X. It is widely used for various medical conditions, and has a narrow therapeutic index, meaning it is a drug with less than a 2-fold difference between median lethal dose and median effective dose. For this reason, since October 4, 2006, it falls under the category of a Food and Drug Administration (FDA) “black-box” drug whose dosage must be closely monitored to avoid serious complications. A PT/INR monitoring system is a portable testing device that includes a finger-stick and an FDA-cleared meter that measures the time it takes for a person’s blood plasma to clot.

Guidelines
For services furnished on or after March 19, 2008, UnitedHealth Care will cover the use of home PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a), and all of the following requirements must be met:

- The patient must have been anticoagulated for at least 3 months prior to use of the home INR device; and,
- The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home; and,
- The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and,
- Self-testing with the device should not occur more frequently than once a week.

Other
All other indications for home PT/INR monitoring not indicated as nationally covered above remain at local Medicare contractor discretion.

This national coverage determination (NCD) is distinct from, and makes no changes to, the PT clinical laboratory NCD at section 190.17 of Publication 100-03 of the NCD Manual.

APPlicable Codes
The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
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<tr>
<th>HCPCS Code</th>
<th>Description</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>
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<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>
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<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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ICD-10 Diagnosis Codes
Coding Clarification: There are numerous reasonable and necessary conditions that might warrant the use of these procedures but which are too many to list. However, an appropriate ICD-10-CM diagnosis must be submitted with each claim and failure to do so may result in denial or delay in claim processing. The highest level of specificity should be used to report the patient’s condition. The most current ICD-10-CM codebook should be used to ensure proper payment.
REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 190.11 Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management
Reference NCD: NCD 190.17 Prothrombin Time (PT)

CMS Claims Processing Manual
Chapter 32; § 60.3.2 Revenue Codes, § 60.4.1 Allowable Covered Diagnosis Codes, § 60.4.2 Healthcare Common Procedure Coding System (HCPCS) for Intermediaries, § 60.5.2 Applicable Diagnosis Codes for Carriers, § 60.6 Carrier Claim Requirements

CMS Transmittals
Transmittal 90, Change Request 6138, Dated 07/25/2008 (Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management)
Transmittal 280, Change Request 6282, Dated 12/31/2008 (Incorporation of Recent Regulatory Revisions pertinent to Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)
Transmittal 1165, Change Request 8109, Dated 01/18/2013 (International Classification of Diseases (ICD)-10 Conversion from ICD-9 and Related Code Infrastructure of the Medicare Shared Systems as They Relate to CMS National Coverage Determinations (NCDs) (CR)
Transmittal 1562, Change Request 6138, Dated 07/25/2008 (Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management
Transmittal 1580, Change Request 9252, Dated 12/02/2015 (ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs) - 3rd Maintenance CR
Transmittal 1663, Change Request 6313, Dated 01/08/2009 (Correction to Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management)

MLN Matters
Article MM6138, Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management
Article MM6313, Correction to Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management

Others
Appropriate Billing of INR testing by Independent Diagnostic Testing Facilities - Retired

GUIDELINE HISTORY/REVISION INFORMATION

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<tr>
<th>Date</th>
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<tbody>
<tr>
<td>05/10/2017</td>
<td>• Annual review</td>
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