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.

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>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<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>
</tr>
<tr>
<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>
</tr>
<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>
</tr>
</tbody>
</table>

**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.

**PURPOSE**

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
• Medicare coding or billing requirements, and/or
• Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.
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 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 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)
Transmittal 2076, Change Request 10622, Dated 05/04/2018, (International Code of Diseases, Tenth Revision (ICD-10) and Other Coding Revisions to National Coverage Determinations (NCDs))

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

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>05/09/2018</td>
<td>• Annual review</td>
</tr>
<tr>
<td></td>
<td>• Updated policy title; previously titled Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Treatment (NCD 190.11)</td>
</tr>
</tbody>
</table>

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

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 member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.
You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.