



Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management – JA6138

Note: The Centers for Medicare & Medicaid Services (CMS) has issued Change Request (CR) 6313 as a replacement for CR6138. CR6313 reflects additional International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes involved with this issue. Those codes were inadvertently omitted from CR6138. Since MLN Matters article MM6138 was based on CR6138, it is being rescinded and replaced by MM6313. Providers should refer to MM6313, which is available at <http://www.cms.hhs.gov/MLNMMattersArticles/downloads/MM6313.pdf> on the CMS website.

Related CR Release Date : July 25, 2008 **Revised**

Date Job Aid Revised: January 23, 2009

Effective Date: March 19, 2008

Implementation Date: August 25, 2008

Key Words	MM6138, CR6138, R1562CP, R90NCD, PT/INR, Anticoagulation, NCD, Home, Coverage
Contractors Affected	<ul style="list-style-type: none"> • Medicare Carriers • Fiscal Intermediaries (FIs) • Part A/B Medicare Administrative Contractors (A/B MACs)
Provider Types Affected	Physicians, providers and suppliers submitting claims to Medicare Carriers, FIs or A/B MACs for home PT and International Normalized Ratio (INR) anticoagulation management monitoring services provided to Medicare beneficiaries



- CMS received a formal, complete, written request for reconsideration to expand the population eligible for coverage of home PT/INR monitoring to patients on warfarin.
- CR6138 is a result of that request and alerts providers that effective for claims with dates of service on and after March 19, 2008, CMS revised its National Coverage Determination (NCD) limits and will expand the population eligible for home coverage of 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.

- Effective for claims with dates of service on and after March 19, 2008, CMS revised its NCD to provide for home coverage of 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 monitoring and the home testing must be prescribed by a treating physician as provided at 42 Code of Federal Regulations (CFR) 410.32(a) and all of the following requirements must be met:
 1. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device;
 2. 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;
 3. 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
 4. Self-testing with the device should not occur more frequently than once a week.

Note: Applicable Healthcare Common Procedure Coding System Codes G0248, G0249, and G0250 will continue to be used for claims processing purposes for PT/INR. With the July 2008 Outpatient Code Editor and Medicare Physician Fee Schedule updates, the descriptors of these codes will change to reflect the revised coverage policy.

Provider Needs to Know...

- The following revised descriptors reflect the expanded NCD criteria and are effective for services on or after March 19, 2008 as follows:
 - **Long Descriptor 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;
 - **Short Descriptor G0248:** Demonstrate use home INR mon;
 - **Long Descriptor 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;
 - **Short Descriptor G0249:** Provide INR test mater/equipm;
 - **Long Descriptor 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

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- the home INR monitoring; not occurring more frequently than once a week; and
 - **Short Descriptor G0250:** MD INR test review inter mgmt.
 - Providers should also be aware of the following:
 - Test materials continue to include 4 tests. Frequency of reporting requirements remain the same;
 - Porcine valves are not included in this NCD, so Medicare will not make payment on home INR monitoring for patients with porcine valves unless covered by local Medicare contractors; and
 - This NCD is distinct from and makes no changes to the PT clinical laboratory NCD at Section 190.17, of the *NCD Manual*.
 - The following are applicable diagnosis codes to be used when submitting claims to Medicare contractors:
 - For services furnished on or after March 19, 2008, the applicable ICD-9-CM diagnosis codes for this benefit are:
 - V43.3 (organ or tissue replaced by other means; heart valve);
 - 289.81 (primary hypercoagulable state);
 - 451.0-451.9 (phlebitis & thrombophlebitis);
 - 453.0-453.3 (other venous embolism & thrombosis);
 - 415.11-415.19 (pulmonary embolism & infarction); or
 - 427.31 (atrial fibrillation (established) (paroxysmal)).
 - Medicare contractors will deny claims for PT/INR monitoring services that are not delivered in accordance with CR6138. Denied claims are subject to appeal.
 - When denying such claims, the Medicare Carrier, FI or A/B MAC will use the following codes:
 - Remittance Advice Remark Code N386, "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp> on the CMS website. If a provider does not have Web access, they may contact the contractor to request a copy of the NCD."
 - Claim Adjustment Reason Code 50 will be used: "These are non-covered services because this is not deemed a 'medical necessity' by the payer."
 - Medicare contractors will assign liability for the denied charges to provider unless documentation of an Advance Beneficiary Notice is present on the claim.
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Background

- The PT test is an in-vitro test to assess coagulation. PT testing and its normalized correlate, the INR, are the standard measurements for therapeutic effectiveness of warfarin therapy.
- Warfarin, Coumadin®, and others are self-administered, oral anticoagulant, or blood thinner, medications that affect a person's Vitamin K-dependent clotting factors.
- Currently, Medicare's NCD at 190.11 of the *NCD Manual* limits coverage of home PT/INR monitoring to anticoagulation management for patients with mechanical heart valves who are on warfarin.
- The monitoring and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a) (See http://www.cms.hhs.gov/ClinicalLabFeeSched/downloads/410_32.pdf on the CMS website.) and 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;
 - The patient must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
 - Self-testing with the device should not occur more frequently than once a week.

Operational Impact

The Medicare contractor will not search for claims but will adjust inappropriately denied claims with dates of service March 19, 2008, through the implementation date of CR6138 that are brought to their attention

Reference Materials

The related MLN Matters article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6138.pdf> on the CMS website.

CR6138 was issued in two transmittals: one for the *NCD Manual* and one for the *Medicare Claims Processing Manual*. These transmittals are available at <http://www.cms.hhs.gov/Transmittals/downloads/R90NCD.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R1562CP.pdf>, respectively, on the CMS website.