Correction to Prothrombin Time / International Normalized Ratio (PT/INR) Monitoring for Home Anticoagulation Management – JA6313

| Related CR Release Date: | January 8, 2009 |
| Date Job Aid Revised:   | January 22, 2009 |
| Effective Date:         | March 19, 2008  |
| Implementation Date:    | February 9, 2009 |

**Key Words**

MM6313, CR6313, R1663CP, PT, INR, Prothrombin, Monitoring, Home, Anticoagulation

**Contractors Affected**

- 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 INR anticoagulation management monitoring services provided to Medicare beneficiaries

**Issue**

- It contains no other changes. However, its content is repeated for convenience as a reference document.
In response to a formal, complete, written request for reconsideration to expand the population eligible for coverage of home PT/INR monitoring to patients on warfarin, the Centers for Medicare & Medicaid Services (CMS) revised its National Coverage Determination (NCD) on PT/INR Monitoring for Home Anticoagulation Management to expand the population eligible for coverage of home PT/INR monitoring to patients on warfarin.

**Effective for claims with dates of service on and after March 19, 2008,** Medicare now covers the use of home PT/INR monitoring for chronic, oral anticoagulation management for patients with:

- Mechanical heart valves,
- Chronic atrial fibrillation, and
- Venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin.

This coverage includes the ICD-9-CM codes listed in the table that starts on page 2 of MLN Matters article MM6313.

The monitor and the home testing must be prescribed by a treating physician as provided at 42 Code of Federal Regulations 410.32(a) (See [http://www.cms.hhs.gov/ClinicalLabFeeSched/downloads/410_32.pdf](http://www.cms.hhs.gov/ClinicalLabFeeSched/downloads/410_32.pdf) on the CMS website.).

In addition, 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;
- 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;
- 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.

**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.

The following 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 the home INR monitoring; not occurring more frequently than once a week; and
- **Short Descriptor G0250**: MD INR test revie inter mgmt.

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<td>1. Test materials continue to include 4 tests. Frequency of reporting requirements will remain the same.</td>
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<td>2. Porcine valves are not included in this NCD. Therefore, Medicare will not make payment on Home INR Monitoring for patients with porcine valves unless covered by local Medicare contractors.</td>
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<td>3. This NCD is distinct from, and makes no changes to, the PT clinical laboratory NCD at Section 190.17 of the NCD Manual.</td>
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- Medicare contractors will deny claims for PT/INR monitoring services that are not delivered in accordance CR6313. However, denied claims are subject to appeal, and medical review override of denials for appeal purposes will be allowed.
- When denying such claims, Medicare Carriers, FIs or MACs will use the following codes:
  - **Medicare Summary Notice 15.20**: “The following policies (NCD 190.11) were used when we made this decision.”
  - **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](http://www.cms.hhs.gov/mcd/search.asp) on the CMS website. If you do not have Web access, you may contact the contractor to request a copy of the NCD.”
  - **Claim Adjustment Reason Code 50**: “These are non-covered services because this is not deemed a ‘medical necessity’ by the payer.”
Warfarin, Coumadin®, and others, are self-administered, oral anticoagulant medications that affect a person’s Vitamin K-dependent clotting factors. The PT test (an in-vitro test to assess coagulation) and its normalized correlate, the INR are the standard measurements for therapeutic effectiveness of warfarin therapy.

Medicare contractors will adjust claims already processed and inappropriately denied prior to the implementation of CR6313, but only if such claims are brought to their attention.

The related MLN Matters article can be found at http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6313.pdf on the CMS website.

The official instruction (CR6313) issued regarding this change may be found at http://www.cms.hhs.gov/Transmittals/downloads/R1663CP.pdf on the CMS website.

The revised *Medicare Claims Processing Manual*, Chapter 32 (Billing Requirements for Special Services), Section 60 (Coverage and Billing for Home Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management), Subsections 4.1 (Allowable Covered Diagnosis Codes) and 5.2 (Applicable Diagnosis Codes for Carriers) can be found as an attachment to that CR.