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MLN Matters Number: MM5699

Related Change Request (CR) #: 5699

Related CR Release Date: January 11, 2008

Effective Date: January 1, 2008

Related CR Transmittal #: R1412CP

Implementation Date: April 7, 2008

Reporting of Hematocrit or Hemoglobin Levels on All Claims for the Administration of Erythropoiesis Stimulating Agents (ESAs), Implementation of New Modifiers for Non-ESRD ESA Indications, and Reporting of Hematocrit or Hemoglobin Levels on all Non-ESRD, Non-ESA Claims Requesting Payment for Anti-Anemia Drugs

Note: This article was updated on June 15, 2013, to reflect current Web addresses. This article was previously revised on May 16, 2008, to delete the words “decimal implied” in the third bullet item on page 3 that discusses reporting of the MEA segment. The values for the most recent numeric test result should be reported with decimals. All other information remains the same.

Provider Types Affected

Physicians, providers, and suppliers who bill Medicare contractors (carriers, including durable medical equipment Medicare administrative contractors (DME MACs), fiscal intermediaries (FIs), Competitive Acquisition Plan (CAP) Designated Carriers, and A/B Medicare administrative contractors (A/B MACs)) for providing ESAs and related anti-anemia administration services to Medicare beneficiaries.

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Impact on Providers

Effective for services on or after January 1, 2008, you must report the most recent hemoglobin or hematocrit levels on any claim for a Medicare patient receiving: (1) ESA administrations, or (2) Part B anti-anemia drugs other than ESAs used in the treatment of cancer that are not self-administered. In addition, non-ESRD claims for the administration of ESAs must also contain one of three new Healthcare Common Procedure Coding System (HCPCS) modifiers effective January 1, 2008. Failure to report this information will result in your claim being returned as unprocessed. **(Note that renal dialysis facilities are already reporting this information on claim types 72X, so CR5699 applies to providers billing with other types of bills.)** See the rest of this article for reporting details.

Background

Medicare Part B provides payment for certain drugs used to treat anemia caused by the cancer itself or by various anti-cancer treatments, including chemotherapy, radiation, and surgical therapy. The treatment of anemia in cancer patients commonly includes the use of drugs, specifically ESAs such as recombinant erythropoietin and darbepoetin. Emerging data and recent research has raised the possibility that ESAs administered for a number of clinical indications may be associated with significant adverse effects, including a higher risk of mortality in some populations.

Most recently, section 110 of Division B of the Tax Relief and Health Care Act (TRHCA) of 2006 directs the Secretary to amend Section 1842 of the Social Security Act by adding at the end the following new subsection: *"Each request for payment, or bill submitted, for a drug furnished to an individual for the treatment of anemia in connection with the treatment of cancer shall include (in a form and manner specified by the Secretary) information on the hemoglobin or hematocrit levels for the individual."*

In light of the health and safety factors and the TRHCA legislation, effective January 1, 2008, the Centers for Medicare & Medicaid Services (CMS) is implementing an expanded reporting requirement for all claims billing for administrations of an ESA. Hematocrit and /or hemoglobin readings are already required for ESRD claims for administrations of an ESA. Effective with the implementation of change request (CR) 5699, all other claims for ESA administrations will also require the reporting of the most recent hematocrit or hemoglobin reading, along with one of three new HCPCS modifiers effective January 1, 2008.

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In addition, CR 5699 requires the reporting of the most recent hematocrit or hemoglobin readings on all claims for the administration of Part B anti-anemia drugs OTHER THAN ESAs used in the treatment of cancer that are not self-administered.

What you Need to Know

CR 5699, from which this article is taken, instructs all providers and suppliers that:

1. Effective January 1, 2008, all claims billing for the administration of an ESA with HCPCS codes J0881, J0882, J0885, J0886 and Q4081 must report the most recent hematocrit or hemoglobin reading available when the billed ESA dose was administered. Facilities should bill at a frequency that allows for the reporting of the most recent hematocrit or hemoglobin reading prior to the start of the billing period that is applicable to the administrations billed on the claim. For new patients this would be the most recent reading prior to the onset of treatment. Note that a provider may have to submit more than one claim for the month if there were multiple readings that were applicable to the administrations given during the month. Claims submitted prior to the publication of change request 5699 that were not completed per the instructions in change request 5699 should be re-submitted.
- For institutional claims, the hemoglobin reading is reported with a value code 48 and a hematocrit reading is reported with the value code 49. Such claims for ESAs not reporting a value code 48 or 49 will be returned to the provider.
 - Effective for services on or after January 1, 2008, for professional paper claims, test results are reported in item 19 of the Form CMS-1500 claim form. For professional electronic claims (837P) billed to carriers or A/B MACs, providers report the hemoglobin or hematocrit readings in Loop 2400 MEA segment. The specifics are MEA01=TR (for test results), MEA02=R1 (for hemoglobin) or R2 (for hematocrit), and MEA03=the test results. The test results should be entered as follows: TR= test results, R1=hemoglobin or R2=hematocrit (a 2-byte alpha-numeric element), and the most recent numeric test result (a 3-byte numeric element [xx.x]). Results exceeding 3-byte numeric elements (10.50) are reported as 10.5.

Examples: If the most recent hemoglobin test results are 10.50, providers should enter: TR/R1/10.5, or, if the most recent hematocrit results are 32.3, providers would enter: TR/R2/32.3.

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- Effective for dates of service on and after January 1, 2008, contractors will return to provider paper and electronic professional claims, or return as unprocessable paper and electronic institutional claims for ESAs when the most recent hemoglobin or hematocrit test results are not reported.
 - When Medicare returns a claim as unprocessable for ESAs with HCPCS codes J0881, J0882, J0885, J0886, or Q4081 for failure to report the most recent hemoglobin or hematocrit test results, it will include Claim Adjustment Reason Code 16 (Claim/service lacks information which is needed for adjudication.) and Remittance Advice Code MA130 (Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with complete/correct information.)
2. Effective January 1, 2008, all non-ESRD ESA claims billing HCPCS J0881 and J0885 must begin reporting one (**and only one**) of the following three modifiers on the same line as the ESA HCPCS:
- EA: ESA, anemia, chemo-induced;
 - EB: ESA, anemia, radio-induced; or
 - EC: ESA, anemia, non-chemo/radio
- Non-ESRD ESA institutional claims that do not report one of the above three modifiers along with HCPCS J0881 or J0885 will be returned to the provider.
 - Non-ESRD ESA professional claims that are billed without one of the three required modifiers as line items along with HCPCS J0881 or J0885 will be returned as unprocessable with reason code 4 and remark code MA130. If more than one modifier is reported, the claim will be returned with reason code 125 and remark code N63.
3. Effective January 1, 2008, all non-ESRD, non-ESA claims billing for the administration of Part B anti-anemia drugs used in the treatment of cancer that are not self-administered must report the most recent hematocrit or hemoglobin reading. Facilities should bill at a frequency that allows for the reporting of the most recent hematocrit or hemoglobin reading prior to the start of the billing period that is applicable to the administrations billed on the claim. For new patients this would be the most recent reading prior to the onset of

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treatment. Note that a provider may have to submit more than one claim for the month if there were multiple readings that were applicable to the administrations given during the month.

- Institutional claims that do not report the most recent hematocrit or hemoglobin reading will be returned to the provider.
- Professional claims that do not report the most recent hematocrit or hemoglobin reading will be returned as unprocessable using Reason Code 16, and Remarks Codes MA130 and N395
- Your Medicare contractor will not search for claims with dates of service on or after January 1, 2008, processed prior to implementation of this CR, but will adjust such claims when you bring them to the attention of your contractor.

Additional Information

For complete details regarding this CR please see the official instruction (CR5699) issued to your Medicare carrier, FI, DME MAC, CAP Designated Carrier, and A/B MAC. That instruction may be viewed by going to <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1412CP.pdf> on the CMS website.

If you have questions, please contact your Medicare carrier, FI, DME MAC, CAP Designated Carrier, or A/B MAC at their toll-free number which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS Website.

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