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

Key Words
MM5699, CR5699, R1412CP, Hematocrit, Hemoglobin, ESA, Anemia

Provider Types Affected
Physicians, providers, and suppliers who bill Medicare Carriers, including Durable Medical Equipment Medicare Administrative Contractors (DME MACs), Fiscal Intermediaries (FIs), Competitive Acquisition Plan (CAP) Designated Carriers, and Part A/B MACs for providing ESAs and related anti-anemia administration services to Medicare beneficiaries

Note: MLN Matters article MM5699 was revised on May 16, 2008, to delete the words “decimal implied” in the bullet item that discusses reporting of the MEA segment (last bullet below in bold). The values for the most recent numeric test result should be reported with decimals. All other information remains the same.

Key Points
- The effective date of the instruction is January 1, 2008.
- The implementation date is April 7, 2008.
- 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.
- Recently published data regarding the use of ESAs have raised safety concerns.
- 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 Healthcare Common Procedure Coding System (HCPCS) modifiers effective January 1, 2008.

• In addition, CR5699 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.

CR5699 Instructions to All Providers and Suppliers

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.

Note: Claims submitted prior to the publication of CR5699 that were not completed per the instructions in CR5699 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 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-position 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.

• 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 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 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

• Medicare contractors 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 brought to their attention.

Important Links

The related MLN Matters article can be found at http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5699.pdf on the CMS website.

The official instruction (CR5699) regarding this change may be viewed at http://www.cms.hhs.gov/Transmittals/downloads/R1412CP.pdf on the CMS website.