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January 17, 2008

Liz Richter
Acting Director, Center for Medicare
Management
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Richter:

I am writing on behalf of the American Society of Clinical Oncology (ASCO) regarding Transmittal 1413, dated January 14, 2008, "Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions." ASCO is the national organization representing physicians who specialize in the treatment of cancer, and Medicare coverage of ESAs is extremely important to our patients. We are concerned that the Transmittal does not accurately reflect the National Coverage Determination (NCD) on use of ESAs and may therefore cause confusion. In addition, we are seeking clarification of two other provisions in the Transmittal.

The primary problem with the Transmittal is Business Requirement No. 5818.3, which provides that claims for ESA use will be denied "when a hemoglobin 10.0g/dL or greater or hematocrit 30.0% or greater is reported." This instruction to the contractors is not consistent with the NCD.

Under the NCD, there is an initiation period that consists of the first four weeks of treatment. If the patient's hemoglobin or hematocrit is below the specified threshold at the beginning of that period, ESA use is covered for the entire four-week initiation period unless there is a rapid rise in the hemoglobin or hematocrit meeting specified criteria. Under the Transmittal, however, contractors have in effect been instructed to deny claims at any time during the four-week period if the reported hemoglobin or hematocrit exceeds the value required for initiation of therapy. This erroneous instruction will cause claims to be denied even if they reflect ESA use that is consistent with the NCD, and we request that the Transmittal be corrected immediately.

We also would like clarification of the new provision in the Claims Processing Manual that states, "Medicare contractors have the discretion to conduct medical review of claims and reverse the automated adjudication if the medical review results in a determination of clinical necessity." This concept is also reflected in Business Requirement No. 5818.5.1, which states, "Denials are subject to appeal and SSMs shall allow for medical review override of denials for appeal purposes."



These provisions appear to allow coverage of ESA use if the use is clinically necessary in circumstances that would otherwise be noncovered under the NCD. If that is the intention, ASCO applauds their inclusion. In certain situations, ESA use may be clinically appropriate for individual patients even though not contemplated by the general provisions of the NCD. We would appreciate CMS confirming our interpretation of these provisions.

Finally, we would like clarification of the implementation schedule, and in that respect we have several questions. First, if physicians begin using the new modifiers and submitting hemoglobin/hematocrit information at this time, will those claims be successfully handled by the contractors' current automated systems or will they be subject to hand-processing until the contractors have implemented the new processing requirements? Second, do we correctly interpret the Transmittal as instructing the contractors not to audit or otherwise review claims processed before they have implemented the requirements of the Transmittal unless a specific processed claim is brought to their attention? If so, can you provide assurance that Recovery Audit Contractors would be similarly constrained in their ability to audit these claims?

Thank you for your consideration of this request. Please contact us if you need any further information.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, M.D.

cc: Barry Straube, MD
Louis Jacques, MD