

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-1918

In the case of

Harlan Appalachian Regional
Hospital

(Appellant)

(Beneficiary)

National Government Services

(Contractor)

Claim for

Supplementary Medical
Insurance (Part B of A)

(HIC Number)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated June 7, 2011, which concerned Medicare coverage for an epoetin alfa, non-ESRD injection (brand name: Procrit®) (HCPCS billing code J0885),¹ furnished to the beneficiary on April 8, 2010. The ALJ determined that the appellant had not furnished sufficient documentation to establish that the Procrit injection was medically reasonable and necessary; specifically, the appellant had not submitted a bone marrow report as required for coverage under the applicable local coverage determination (LCD). The ALJ further found the appellant financially liable for the non-covered costs. The appellant has asked the Medicare Appeals Council (Council) to review this action.

The Council reviews the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary.

¹ HCPCS, the Healthcare Common Procedure Coding System, is a coding system developed by the Centers for Medicare & Medicaid Services (CMS) for processing, screening, identifying and paying Medicare claims. See 42 C.F.R. §§ 414.2 and 414.40.

42 C.F.R. § 405.1112(c). The Council has considered the record ² and exceptions but finds no basis to disturb the ALJ decision.

On all dates relevant to the date of service at issue, the beneficiary was diagnosed with red cell aplasia and low grade myelodysplastic syndrome. A laboratory test taken on the date of service at issue indicated the beneficiary had a hemoglobin (HGB) level of 9.2 g/dL and a hematocrit (HCT) of 28.5%. Exh. 3, at 41-42. On April 8, 2010, the beneficiary received a single injection of epoetin alfa (Procrit), 40,000 units. Exh. 3, at 40.

The LCD for Erythropoiesis Stimulating Agents (ESA), L25211, in effect on the date of service, states that ESA will be covered for patients with myelodysplastic syndrome who have: (1) myelodysplasia with less than 10% blasts, (2) pretreatment erythropoietin levels of 500 or less, and (3) anemia with hemoglobin (HGB) less than 10 g/DL and hematocrit (HCT) of less than 30% at the time of initiation of the ESA. Exh. 7, at 8. The documentation section of the LCD specifically states:

For patients on ESA therapy for [myelodysplastic syndrome] MDS, initiated prior to 12/01/2007, National Government Services requires that a physician's statement that the patient does have MDS be included in the medical record. **For ESA therapy initiated on or after 12/01/2007, a copy of the actual bone marrow report must be included in the medical record. MDS cannot be diagnosed definitively without a bone marrow biopsy.**

(Emphasis added.)²

The appellant submitted to the ALJ a copy of the version of LCD 25211 in effect on April 8, 2010, accompanied by a May 19, 2011 cover letter. See exh. 7. However, while the appellant submitted the first ten pages of the LCD, the appellant did not submit the last few pages, which includes the documentation section quoted above requiring submission of a bone marrow report. The appellant argued to the ALJ that a bone marrow report wasn't required by the LCD, and then argued before both the ALJ and the Council that it had submitted sufficient documentation establishing medical reasonableness and necessity for the injection at issue.

² Local Coverage Determinations are available at <http://www.cms.gov/medicare-coverage-database> (last visited 06/11/2012.)

ALJs and the Council are not bound by LCDs, but must give them ³ substantial deference where they are applicable to a case. If an ALJ or the Council declines to follow an LCD, the ALJ or Council must explain the reasons why the policy was not followed. 42 C.F.R. § 405.1062(a),(b).

The Council finds no basis to depart from LCD 25211 in this case. The appellant is incorrect with regard to the requirement of a bone marrow report, as such report has been required by the plain language of the LCD since December 1, 2007. While a blood test report for the date of service at issue indicates that the beneficiary met the requirements of a HGB less than 10 g/DL and a HCT less than 30%, the policy also requires that a bone marrow report be submitted to verify the diagnosis of MDS. The record before the Council indicates that a bone marrow specimen was submitted for cytogenetics testing on December 17, 2007; however, there is no report from that testing in the record to verify an MDS diagnosis. Exh. 3, at 35. Moreover, this order for a bone marrow test was issued more than two years prior to the date of service at issue and may not be medically relevant to the date of service at issue.

The Council therefore adopts the ALJ decision.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

Date: June 13,2012