

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of

Health & Oncology Services,
Inc.

(Appellant)

(Beneficiary)

AdminaStar Federal

(Contractor)

Claim for

Supplementary Medical
Insurance Benefits (Part B)

(HIC Number)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated May 6, 2009, which concerned coverage 70 units of the drug bevacizumab 10 mg. (brand name: Avastin) furnished to the beneficiary on August 5, 2008 for treatment of ovarian cancer. The ALJ determined that the drug could not be covered because the appellant had not submitted the administration record for the drug showing that it had actually been supplied. The ALJ found the appellant liable for the cost of the non-covered services. 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. 42 C.F.R. § 405.1112(c). As set forth below, the Council reverses the ALJ's decision.

BACKGROUND

The appellant furnished an injection of the chemotherapy drug, Avastin, to the beneficiary on the date of service at issue. The appellant billed Medicare, using HCPCS procedural code J9035 and ICD-9 diagnosis code of 183.0. Code J9035 is the code used

for billing a 10 mg. injection of bevacizumab, and code 183.0 is used to designate a malignant neoplasm of the ovary. The appellant administered 700 mg., and billed for 70 units of J9305. Payment was denied on initial determination. On November 10, 2008, the claim was denied on reconsideration, stating only that "[t]he medical facts provided do not warrant payment for procedure code J9035, according to Medicare guidelines." Exh. 1, at 2. No other explanation was given.

On reconsideration, a qualified independent contractor (QIC) again denied coverage. The QIC noted that the appellant submitted a letter from the treating physician stating that the patient had ovarian cancer and had been treated in the past with other chemotherapy drugs. The QIC noted that the appellant argued that the National Comprehensive Cancer Network (NCCN) had approved the use of Avastin to treat ovarian cancer and that the appellant had submitted literature supporting such assertion. The QIC further noted that the appellant had submitted multiple laboratory test results and progress notes for the beneficiary for other dates of service. However, the QIC found that the drug could not be covered because "the medication administration record for the service at issue was not submitted to support performance of the service. Medical records must document the service that was provided and support the medical necessity for performing it." Exh. 2, at 3.

On further appeal to an ALJ, the appellant submitted the administration record for the drug for the date of service at issue. However, the ALJ excluded the document from the record, noting that such document should have been submitted at an earlier level of review. The ALJ found that the appellant failed to show good cause for the late filing of the document. ALJ Dec. at 2. The ALJ then found that the drug was not covered because "the Appellant has failed to submit a copy of the administration record for the date of service at issue. Without a copy of the administration record, this reviewer cannot find that the Appellant provided the service at issue." ALJ Dec. at 4.

The appellant then filed a request for review with the Council, noting that the administration record at issue had been submitted to the ALJ but had been excluded from the record.

RELEVANT PROVISIONS

Section 1833(e) of the Social Security Act (Act) states:

No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

With regard to submitting such documentation during the appeals process, the regulations provide that a reconsideration decision must include the following:

If the notice of redetermination indicated that specific documentation should be submitted with the reconsideration request, and the documentation was not submitted with the request for reconsideration, the summary must indicate how the missing documentation affected the reconsideration...

42 C.F.R. § 405.976(b)(5)(i).

The regulations for appeals before an ALJ provide that --

[a]ny evidence submitted by a provider, supplier or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see § 405.1028).

The regulations further provide that an ALJ will examine any new evidence submitted for the first time to the ALJ to determine if the provider or supplier has good cause for late filing of the evidence. If the ALJ does not find good cause for the late submission, the ALJ must exclude the evidence from the proceedings and may not consider it in making a decision. 42 C.F.R. § 405.1028. The regulation specifically states that an ALJ will find good cause, for example, "when the new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration." 42 C.F.R. § 405.1028(b).

DISCUSSION

The Council has determined that the appellant established good cause for submitting the drug administration record for the first time at the ALJ level. The redetermination notified the appellant only that "medical facts" did not warrant payment for the procedure code at issue. On appeal to the QIC, the appellant submitted documentation establishing the factual basis supporting coverage of the service, i.e., that the beneficiary had a diagnosis of cancer and had tried multiple other chemotherapy drugs. The QIC reconsideration decision noted, for the first time, that the *documentation* was insufficient because the appellant had not specifically submitted the actual drug administration record. This was essentially a newly-identified issue at the QIC level, as the appellant had been informed that the basis for denial below was that the "medical facts" did not support coverage.¹ The appellant submitted the administration record at the next level of appeal, before the ALJ. For these reasons, the Council has determined that the appellant had good cause for submitting the administration record for the first time at the ALJ level, and the Council hereby admits the administration record into the record in this case. However, in the future, the appellant should submit all documentation supporting coverage, including drug administration records, with the request for reconsideration.

The administration record which the Council has admitted into the record supports that 700 mg. of the drug Avastin was furnished by injection to the beneficiary on August 5, 2008. The record, as compiled by the ALJ, establishes that the beneficiary had ovarian cancer and had tried other chemotherapy drugs unsuccessfully prior to Avastin. The Council has reviewed the local coverage policy of National Government Services, Inc., the applicable Medicare Administrative Contractor (MAC). That policy is articulated in Article A46095, entitled "Article for BEVACIZUMAB (e.g., Avastin) - Related to LCD L25820 (A46095)." Such policy states that Avastin is covered for diagnoses of "malignant neoplasm of the ovary."

¹ The Council notes that the contractor's policy for usage of drug and biologicals, LCD L25820, lists only that medical records must contain documentation that fully supports the medical necessity for the services, and that such documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. The LCD does not specifically reference drug administration records.

DECISION

For the reasons stated above, it is the decision of the Medicare Appeals Council that the 700 mg. Avastin injection furnished by the appellant to the beneficiary on August 5, 2008 for the treatment of ovarian cancer is covered.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

Date: September 21, 2009