DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-12-2316

In the case of	**Claim for**
Cancer Care Associates (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiary)	**** (HIC Number)
TrailBlazer Health Enterprises (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated June 8, 2012, which concerned Medicare coverage for levoleucovorin calcium injections (HCPCS code J0641) furnished to the beneficiary on November 10 and 22, and December 7, 2010 and the discarded portion of the drug remaining in a single-use product after administering what is reasonable and necessary for the patient's condition ("the wastage") (HCPCS code J0641-JW).[1] The ALJ denied coverage finding that the items were not reasonable and necessary under section 1862 of the Social Security Act (Act). The ALJ also found the appellant liable for the non-covered charges under section 1879 of the Act. The appellant has asked the Medicare Appeals Council (Council) to review this action. We enter the appellant's request for review into the record as Exhibit (Exh.) MAC-1.

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

[1] The Centers for Medicare & Medicaid Services (CMS) has developed the Healthcare Common Procedural Coding System (HCPCS) to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40.

review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c).

After review of the record, the Council finds no basis to alter the ALJ's conclusions with regard to coverage and liability. However, as set forth below, the Council modifies the ALJ's decision to provide a different rationale for denying coverage.

BACKGROUND

The appellant requests the Council's review of the ALJ's denial of coverage for levoleucovorin calcium injections furnished to the beneficiary on November 10 and 22, and December 7, 2010, and for the resulting wastage. For the claims at issue on this appeal, the Medicare contractor denied coverage initially and in three individual redeterminations. *See* Exh. 1, at 72-75, 82-100. The Qualified Independent Contractor (QIC) also denied coverage for the claims at issue, finding there was insufficient evidence to override the local coverage determination's (LCD's) coverage limitations for this drug and to support its off-label use under the guidelines set forth in the Medicare Benefit Policy Manual. Exh. 1, at 16-21. Both the Medicare contractor and the QIC found the appellant liable for the non-covered charges. Exh. 1, at 22, 74, 82, 86.

The appellant then requested an "on the record review" by an ALJ. Exh. 1, at 1. The ALJ issued an unfavorable decision, finding that the use of levoleucovorin calcium injections in this case is an "off-label" use, levoleucovorin is categorized as a class III drug in the Medicare compendia DrugDex, levoleucovorin is not recommended for pancreatic cancer (the beneficiary's diagnosis), and the appellant has not produced any peer-reviewed medical literature to support the use of levoleucovorin calcium injections for the treatment of pancreatic cancer. Dec. at 8. Based on those reasons, the ALJ concluded that the requirements for coverage are not met. *Id.* The ALJ found the appellant liable for the non-covered charges. *Id.*

AUTHORITIES

ALJs and the Council are bound by statutes, regulations, national coverage determinations (NCDs), and CMS Rulings. 42 C.F.R. §§ 405.1060(a)(4) and 405.1063. Neither an ALJ nor the Council is bound by an LCD or Medicare program guidance such as program memoranda and manual instructions, "but will give

substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). If an ALJ or the Council declines to follow a policy in a particular case, the ALJ or Council decision must explain the reasons why the policy was not followed. *Id.* § 405.1062(b). Moreover, an ALJ or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect. *Id.* An ALJ or the Council may not set aside or review the validity of an LCD for purposes of a claim appeal. *Id.* § 405.1062(c).

LCD L26785 is applicable to the claims at issue in this case. That LCD lists specific diagnosis codes that support a finding of medical necessity for leucovorin and levoleucovorin calcium injections.

DISCUSSION

The appellant asserts that "[d]ue to the nationwide drug shortage of leucovorin, levoleucovorin was used in place of Leucovorin. Leucovorin is covered in the CMS LCD's for the diagnosis of pancreatic cancer (157.0)." Exh. MAC-1. The appellant further asserts that this substitution is widely accepted in the medical community because these two drugs are almost identical in molecular structure. *Id.* We note, in fact, that LCD L26785 was revised in 2009 to add coverage criteria for levoleucovorin calcium. In the revised LCD, the Medicare contractor indicated that the limited coverage for levoleucovorin calcium is identical to that for leucovorin calcium. LCD L26785, Revision 1 (effective Jan. 1, 2009).

The appellant also argues that the chemotherapy regimen FOLFIRINOX, which includes leucovorin or levoleucovorin, has a category 1 recommendation in NCCN, and a category 2B (sic, should read IIb) recommendation in DrugDex, as well as being the drug of choice in the AFHS compendia. However, we find that the appellant has submitted no evidence from the NCCN, Drugdex or the AFHS compendia to support this argument. An incomplete extract from the NCCN submitted regarding leucovorin lacks any headings or explanation of the columns (and, at best, only appears to reference a 2B recommendation.) Exh. 1 at 56. It is not possible to decipher the printout without this missing key. The appellant has the burden of proof in submitting evidence in each appeal.

The appellant asserts that the ALJ received all pertinent medical information as well as detailed progress notes to rule on this case outside the LCD. Exh. MAC-1, at 2. The ALJ identified the applicable LCD for leucovorin and levoleucovorin calcium in his decision and states that he considered it and gave substantial deference to it. *See* Dec. at 6. However, it is not clear that the ALJ applied it to his analysis of the decision. *See id.* at 8. As stated above, the applicable LCD in this case is L26785. The diagnosis code for pancreatic cancer, however, is not listed in the LCD in effect on the dates of service at issue as one which supports a finding of medical necessity for levoleucovorin and leucovorin calcium injections.

The Council notes that the applicable LCD has been revised. The revised provisions took effect on August 13, 2012, more than 18 months after the dates of service at issue. The revised language adds the diagnosis code for pancreatic cancer to the list of diagnosis codes that support medical necessity. *See* LCD L26785, Revision 8(effective Aug. 13, 2012). However, we cannot apply LCDs retrospectively. Therefore, we must apply the LCD in effect on the dates of service at issue, which does not list the diagnosis code for pancreatic cancer among those that support a finding of medical necessity.

The LCD states the following under the section titled "ICD-9 Codes that DO NOT Support Medical Necessity": "All those not listed under the 'ICD-9 Codes that Support Medical Necessity' section of this LCD." *Id.* (Emphasis in original). The language used in the LCD does not leave room for exceptions. We find no basis for not giving substantial deference to the LCD. Accordingly, we find that the coverage criteria in the LCD are not met, and thus the levoleucovorin calcium injections as well as the wastage at issue are not medically reasonable and necessary.

The appellant also asserts that the ALJ did not take the time to carefully review the information provided to him based on the fact that the appellant did not appeal a claim for oxaliplatin, and the appellant asserts that the ALJ ruled on this claim. Exh. MAC-1, at 2. The appellant asserts that this oversight leads the appellant to believe that this case was not given deferential review to rule on this complicated matter. *Id.*

We find this assertion is without merit. The ALJ did not rule on the oxaliplatin claim. *See* Dec. at 2, 8-9. The ALJ's only reference to the oxaliplatin claim is in the procedural history

section of his decision, in which he states that the oxaliplatin claim was denied initially and on redetermination but was granted payment by the QIC. Dec. at 1. There is no further mention of the oxaliplatin claim in the ALJ's decision, and the ALJ did not rule on this claim. *See* Dec. at 2-9.

The appellant further asserts that other ALJs who ruled on other dates of service for this same beneficiary have issued fully favorable decisions based on the same information that was provided to the ALJ in the instant case. *Id.* Just as the Council's review of the ALJ's decision is a *de novo* review, the ALJ also conducts a *de novo* review. 42 C.F.R. § 405.1000(d). Medicare administrative appeal decisions have no precedential value. 70 Fed. Reg. 11420, 11449 (Mar. 8, 2005). Thus, a previous ALJ decision is not binding on any subsequent decision issued by an ALJ or the Council. Further, review of the other ALJ's decision as submitted for the first time with the request for review suggests that the appellant submitted material information from the compendia which are absent in this case. Again, the appellant is responsible for submitting evidence in the record in each case.[2]

With regard to liability, the ALJ found the appellant liable for the non-covered costs under section 1879 of the Act. The appellant does not contest the ALJ's determination on liability. Accordingly, the Council affirms the ALJ's findings and conclusions regarding liability without any further discussion.

DECISION

For the above stated reasons, the Council finds that the items at issue are not medically reasonable and necessary, and thus are not covered under section 1862(a)(1)(A) of the Act. Further, the Council finds the appellant liable for the cost of the non-covered items under section 1879 of the Act.

[2] The appellant did submit news reports of papers presented at professional conferences in June 2010. Exh. at 5-9. These papers, which revealed some treatment promise but significant toxic side-effects, were not indicated to have been published in a peer-reviewed journal.

The Council modifies the ALJ's decision in accordance with the foregoing discussion.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ Constance B. Tobias, Chair
Departmental Appeals Board

Date: April 19, 2013