Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	Date: August 24, 2007
In re CMS LCD COMPLAINT:	)	
Local Coverage Determination:	)	
OXALIPLATIN (ELOXATIN®),	)	Docket No. C-06-656
LCD Database ID Number L13743.	)	Decision No. CR1639
	)	

DECISION

I issue this decision deciding the hearing request brought by an aggrieved Medicare beneficiary (AB) challenging Local Coverage Determination (LCD) L13743, issued by the local New Jersey Medicare Contractor, Empire Medical Services (Empire), refusing coverage and payment by the Medicare program for treatment with oxaliplatin (Eloxatin) for the AB's transitional cell carcinoma of the bladder. I find the record of the LCD is complete and adequate to support the validity of the LCD and, thus, conclude that the LCD is reasonable.

I. Background and Undisputed Facts

I hear and decide this case pursuant to regulations governing challenges to LCDs published at 42 C.F.R. Part 426, Subparts C and D.

The following facts appear undisputed and I accept them as true. The AB was diagnosed with bladder carcinoma. He initially had chemotherapy and it appeared that the bladder carcinoma was responding. A recurrence was noted and in May 2005 he had a radical cystoprostectomy, bilateral lymph node dissection and ileoconduit urinary diversion. When certain neoadjuvant and adjuvant chemotherapy did not bring about expected results, it was decided in November 2005 to change the protocol of his treatment and start chemotherapy with oxaliplatin (Eloxatin®). He had an excellent response through March 2006, but that regimen ended in April 2006 when the markers began to increase again.

While oxaliplatin is indicated for colorectal cancer, it was used for the AB's bladder cancer because he was not responding to traditional therapy and there had been some indication in clinical trials that oxaliplatin might be beneficial in the treatment of bladder cancer as well.

Claims were made for this treatment under Medicare Part B by the AB's doctor, but those claims were denied by the Medicare Carrier, Empire, due to LCD L13743, which does not cover bladder cancer as a coverable diagnosis that supports the use of oxaliplatin.

The AB submitted a hearing request with various attachments. I directed the intermediary to provide me with a copy of its LCD record. Empire submitted its LCD record under cover of a letter dated October 12, 2006 (although not received in my office until November 15, 2006). I provided the AB with the opportunity to comment on the LCD record and to provide supplemental evidence if he wished within 30 days of his receipt of that record. When I did not receive a response from the AB, I sent another letter indicating he could have until January 26, 2007 to submit his written response. No response or communication was received.

Therefore, I find the record of this case to be closed. The record consists of the AB's request for review of the LCD with Attachments 1-6, and the submission of the LCD record for this LCD complaint from Empire.

II. Discussion

A. Applicable Law

An LCD, as defined by the Social Security Act (Act), is "a determination by a fiscal intermediary or a carrier . . . respecting whether or not a particular item or service is covered" within the area covered by the contractor. Act, section 1869(f)(2)(B) (42 U.S.C. § 1395ff(f)(2)(B)).

The Secretary of the Department of Health and Human Services promulgated regulations pursuant to sections 1102 and 1871 of the Act (42 U.S.C. §§ 1302 and 1395hh), implementing sections 1869(f)(1) and (f)(2) of the Act. 42 C.F.R. § 426.100. The regulations are found at 42 C.F.R. Part 426. The procedures for review of an LCD are in 42 C.F.R. Part 426, Subpart D (42 C.F.R. § 426.400 *et. seq*.).

The reasonableness standard is defined at 42 C.F.R. § 426.110, as:

> [T]he standard that an ALJ or the Board must apply when conducting an LCD or an NCD [national coverage determination] review. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Board.

Further definition of the reasonableness standard is provided by the notice of final rule making at 68 Fed. Reg. 63,692, 63,703-04 (2003). The drafters of the regulation discussed the reasonableness standard adopted as follows:

> We are using the statutory language from sections 1869(f)(1)(A)(iii) and (f)(2)(A)(i)(I) of the Act, which instructs adjudicators to defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary. The logical corollary is that the ALJs and the Board must accord deference if the contractor's or CMS's findings of fact, interpretations of law, and application of fact to law are reasonable. The concept of deference is one that is generally applied by courts to administrative decision making, in recognition of the expertise of a program agency. Thus, we view the statute as setting out a reasonableness standard that recognizes the expertise of the contractors and CMS in the Medicare program--specifically, in the area of coverage requiring the exercise of clinical or scientific judgment. So long as the outcome is one that could be reached by a rational person, based on the evidence in the record as a whole (including logical inferences drawn from that evidence), the determination must be upheld. This is not simply based on the quantity of the evidence submitted, but also includes an evaluation of the persuasiveness of the material. If the contractor or CMS has a logical reason as to why some evidence is given more weight than other

> evidence, the ALJs and the Board may not overturn the determination simply because they would have accorded more weight to the evidence in support of coverage. In some situations, different judgments by different contractors may be supportable, especially if explained by differences such as the ready availability of qualified medical professionals in one contractor's area, but not in another. Moreover, an ALJ or the Board may not determine that an LCD is unreasonable solely on the basis that another Medicare contractor has issued an LCD that permits coverage of the service at issue, under the clinical circumstances presented by the complaint. For legal interpretations, the reasonableness standard would not be met if an interpretation is in direct conflict with the plain language of the statute or regulation being interpreted. Moreover, an interpretation in an LCD would not meet the reasonableness standard if it directly conflicts with an NCD or with a CMS Ruling. So long as an interpretation is one of the readings permitted by the plain language of the law and can be reconciled with relevant policy, however, it must be upheld, even if the ALJ or the Board might have reached a different result if interpreting the statute or regulation in the first instance.

Id.

B. The LCD

The LCD provides as follows:

> **Indications and Limitations of Coverage and/or Medical Necessity**
> Oxaliplatin for injection (Eloxatin™) is an organoplatinum complex used as antineoplastic agent.
>
> **Indications**
> FDA Labeled Indication:
>
> 1. ELOXATIN, used in combination with infusional 5-FU/LV, is indicated for the treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed

during or within 6 months of completion of first-line therapy, with the combination of bolus 5-FU/LV irinotecan.

2. Effective 01/09/2004, the FDA has approved the use of oxaliplatin as first line therapy in combination with infusional 5-FU/LV for the treatment of patients with advanced metastatic carcinoma of the colon or rectum.

3. Effective 05/01/2004, coverage is extended to include patients receiving oral capecitabine as an alternative to infusional 5-FU, in combination with oxaliplatin.

4. Effective 11/04/2004, the FDA has approved oxaliplatin for use as an adjuvant therapy in patients with stage 3 colon cancer who have undergone resection of the primary tumor, when used in combination with infusional 5-FU and leucovorin. Empire Medicare Services will also reimburse the oxaliplatin when given with 5-FU and capecitabine.

5. Effective December 1, 2005, oxaliplatin has been approved for use as an adjuvant therapy in patients with stage II colon cancer, in combination with 5-fluorouracil/leucovorin.

6. Effective May 1, 2005, oxaliplatin is covered for the off-label indication of patients with malignant neoplasm of the stomach.

Limitations

1. Oxaliplatin is not covered for any indications other than those specifically listed above in the Indications section of this LCD.

LCD for Oxaliplatin (ELOXATIN®), L13743, Contractor: National Government Services, Inc. (formerly known as Empire Medicare Services).

The LCD precludes reimbursement under Medicare Part B for use of this drug for outpatient chemotherapy for any indications other than those specifically listed. In this case, Empire denied coverage for its use in chemotherapy for a patient with bladder cancer, an off-label use.

C. Issue

The issue in this case is whether the LCD unreasonably prohibits Part B Medicare reimbursement for coverage of oxaliplatin for the treatment of patients with bladder cancer.

D. Findings Pursuant to 42 C.F.R. §§ 426.450 through 426.457

I make findings to support my decision in this case. I set forth each finding below as a separate heading. I discuss each finding in detail.

1. The LCD record is complete and adequate to support the validity of the LCD provisions at issue and I find the LCD is reasonable under the reasonableness standard.

The AB is disputing the determination by Medicare not to cover the use of chemotherapy treatment with oxaliplatin for his bladder cancer. The statements of the AB and his physician, as well as the other materials submitted with his complaint, indicate that oxaliplatin is not labeled for use or indicated for patients with bladder cancer. Essentially, the AB is requesting that I find the LCD unreasonable because it does not recognize as appropriate the off-label use in this instance for bladder cancer.

My focus is upon the LCD challenged by the AB and whether or not the LCD record is complete and adequate to support the validity of the LCD provisions under the reasonableness standard. I find that the LCD is reasonable and consistent with longstanding CMS policy.

Medicare policy recognizes that often medical science progresses rapidly and what one day may be considered experimental, may later be considered acceptable treatment after studies show that a procedure or drug regimen is effective. Anti-cancer chemotherapeutic agents are eligible for coverage when used in accordance with Food and Drug Administration (FDA)-approved labeling, when the off-label use is supported in one of the authoritative drug compendia listed in section 1861(t)(2)(B)(ii)(I) of the Act, or when the Medicare Carrier/Contractor determines an off-label use is medically accepted based on guidance provided by the Secretary (section 1861(t)(2)(b)(ii)(II) of the Act). *See* Medicare Benefit Policy Manual, CMS Publication 100-2, Chapter 15, Section 50.4.5. Also, there is an NCD that states that oxaliplatin will be covered for off-label use only when it is being used in specific clinical trials identified by CMS for coverage. Medicare NCD Manual Part 2, section 110.17 (effective January 28, 2005), CMS Publication 100-03. That

section specifically lists the clinical trials for which its use is approved and it does not include any trials for bladder cancer and the LCD record here does not support that its use for the aggrieved party was pursuant to any CMS-approved clinical trials. That section further states –

> This policy does not alter Medicare coverage for items and services that may be covered or non-covered . . . The existing requirements for coverage for oxaliplatin for FDA-approved indications are not modified . . . Contractors shall continue to make reasonable and necessary coverage determinations under section 1861(t)(2)(b)(ii)(II) of the [Social Security] Act based on guidance provided by the Secretary for medically accepted uses of off-label indications of oxaliplatin . . . provided outside of the identified clinical trials . . . .

Medicare NCD Manual, Part 2, Section 110.17.C.

In this case, there is no dispute that oxaliplatin is not FDA-approved for the AB's type of bladder cancer; it is also clear from the LCD record that the off-label use for bladder cancer is not supported by one of the authoritative drug compendia listed under section 1861(t)(2)(B) of the Act. Thus, the only issue before me is whether the Medicare Contractor should have determined that the off-label use of oxaliplatin for the AB's bladder cancer is medically accepted. The LCD record indicates that the Medicare Contractor reviewed submitted literature and found that it did not support the use of oxaliplatin for pancreatic, bladder or refractory germ cell cancer. Therefore, the Contractor determined that the LCD would not be revised to include these conditions at this time. The Contractor further indicated that it would review any published peer-reviewed double-blinded and randomized studies which support extending coverage for such conditions. The AB submitted no response and provided no further evidence to show that any such peer-reviewed double-blinded and randomized studies have been done that support a finding that off-label use of this drug for bladder cancer is safe and effective.

I therefore find that the LCD at issue here is valid and reasonable under the reasonableness standard.

2. The review process is complete upon issuance of this decision.

Since I find that the LCD record is complete and adequate to support the validity of the challenged LCD under the reasonableness standard, "issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process." 42 C.F.R. § 426.425(c)(2).

/s/
Alfonso J. Montano
Administrative Law Judge