DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

ORDER OF MEDICARE APPEALS COUNCIL
REMANDING CASE TO ADMINISTRATIVE LAW JUDGE

In the case of	**Claim for**
Texas Oncology (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiary)	**** (HIC Number)
Trailblazer Health Enterprises, Inc. (Contractor)	**** (ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated June 2, 2009, because there is an error of law material to the outcome of the claim. The ALJ found that Camptosar (irinotecan) the supplier furnished the beneficiary on July 23, 2008; July 30, 2008; August 20, 2008; September 3, 2008; and September 10, 2008, satisfied the requirements of Local Coverage Determination (LCD) A46312.

The Council has considered the record before the ALJ and the memorandum dated July 29, 2009, from the Centers for Medicare & Medicaid Services (CMS), which has been entered into the record as Exhibit (Exh.) MAC-1. The Council hereby vacates the hearing decision and remands this case to an ALJ for further proceedings, including a new decision. *See* 42 C.F.R. § 405.1110(d).

BACKGROUND

The beneficiary, ***, is a 66 year old woman with a diagnosis of malignant neoplasm of the intrahepatic bile duct first discovered around April 2008.[1] *See, e.g.,* File for September 10,

[1] The ALJ's decision and the CMS memorandum both incorrectly refer to the beneficiary as ***.

2008. Exh. 2.[2] She is not a candidate for surgical resection. She received chemotherapy combining gemcitabine with irinotecan.

The irinotecan was billed with a JZ modifier, which denotes that the item is expected to be denied as not reasonable and necessary and an advance beneficiary notice (ABN) was not signed by the beneficiary. The claims were accordingly denied initially. On redetermination, the irinotecan was denied as not medically reasonable and necessary for the diagnosis.[3] The supplier was held liable under section 1879 of the Social Security Act (Act), because it should have known that the irinotecan was not covered pursuant to LCD 4I-92B.

On reconsideration, the Qualified Independent Contractor (QIC) identified irinotecan for the beneficiary's diagnosis as an off-label use not approved by the Food and Drug Administration (FDA).[4] The QIC also noted that the contractor's LCD indicated that irinotecan is not covered for advanced cholangiocarcinoma. The reconsiderations also cited the applicable provisions of section 1861(t)(2) of the Act, which govern the determination of medical necessity for off-label chemotherapy, and the implementing CMS manual provisions in the Medicare Benefit Policy Manual (MBPM), Pub. 100-02, chapter 15, section 50.4.5. The QIC found no approved use of irinotecan in approved compendia. Accordingly, the irinotecan was not medically reasonable and necessary.

The QIC further noted that the appellant submitted some medical literature, but the articles were eliminated from consideration because:

1) The literature was not from a publication approved by the Secretary as listed in the MBPM section 50.4.2. This also excluded abstracts.

2) The literature was not relevant to the regimen of chemotherapy at issue.

3) Literature published after the date of service is not applicable.

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[2] The record consists of a Master File, and individual files for each date of service.
[3] See Exh. 1 in the individual files.
[4] See Exh. 1 in the Master File. The QIC issued a reconsideration for each date of service.

The reconsiderations also advised the supplier that all evidence that is not submitted prior to the issuance of the reconsideration will not be considered at the ALJ level, unless the appellant demonstrates good cause as to why the evidence was not submitted previously.

The appellant requested an ALJ hearing, and submitted additional medical literature to the ALJ. The QIC submitted a position paper to the ALJ. The QIC stated that the appellant had only previously submitted two abstracts from the medical literature – a study at Tenon Hospital in Paris, France, and a study at the Freiburg University Hospital. The QIC asserted that the appellant had no good cause for submitting any new evidence to the ALJ.

In his recitation of the applicable legal authorities, the ALJ included the relevant provisions of section 1861(t)(2) of the Act. Dec. at 3-4. The ALJ also stated that he had considered and gave substantial deference to LCD L25118 – Camptosar. *Id.* at 5. The ALJ's analysis in its entirety provides:

> The prior decisions determined that the chemotherapy drug (Camptosar) could not be paid due to a lack of medical necessity. The undersigned also finds the medical documentation contained in the file to be sufficient to show that the drugs was (sic) medically necessary and reasonable.
>
> The provider, supplier, or beneficiary is responsible to supply sufficient information to determine whether payment is due and the amount of payment. The LCD sets forth specific requirements in order for Camptosar to be covered. In this case, the Appellant did provide sufficient medical records and documentation to satisfy the LCD A46312 requirement. The medical record shows that the beneficiary had a bile duct tumor and was receiving chemotherapy. The beneficiary was administered camptosar by Dr. *** on the dates of services (sic). (See Ex. 1, page 2).
>
> The medical evidence is sufficient to support that the Camptosar drug provided to treat the beneficiary by the appellant was reasonable and necessary.

The CMS memorandum asserts that the ALJ did not apply the governing provisions of section 1861(t)(2) of the Act, or

the implementing manual provisions in the MBPM, chapter 15, section 50.4.5. The memorandum also asserts that the applicable LCD for the contractor is L26746, which provides that irinotecan is not covered for cancer of the bile ducts. That LCD is stated to be the same as LCD 4I-92B cited in the redeterminations. The memorandum also represents that LCD A46312 cited by the ALJ is from another contractor, but is substantively the same as LCD L26476.

LEGAL PRINCIPLES

Coverage Provisions

Section 1861(t) of the Social Security Act (Act) defines "drugs and biologicals" for purposes of the Medicare coverage issue in this case. Subsection 1861(t)(2)(A) notes that the term "drugs" includes "drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph(B))." Section 1861(t)(2), subparagraph (B) provides that the term "medically accepted indication" with respect to the use of a drug includes:

> any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if –
>
> (i) the drug has been approved by the Food and Drug Administration; and
>
> (ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service – Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia – Drug Information, and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

> (II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses for drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

Section 1861(t)(2)(B) of the Act.

The criteria referenced at section 1862(t)(2)(B) of the Act are found in the MBPM, chapter 15, section 50.4.5 – Unlabeled Use for Anti-Cancer Drugs.[5] In pertinent part, the Manual provides –

> Effective January 1, 1994, unlabeled uses of FDA approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen for a medically accepted indication are evaluated under the conditions described in this paragraph. A regimen is a combination of anti-cancer agents which has been clinically recognized for the treatment of a specific type of cancer. . .
>
> In addition to listing the combination of drugs for a type of cancer, there may be a different regimen or combinations which are used at different times in the history of the cancer . . . A protocol may specify the combination of drugs, doses, and schedules for administering drugs. For purposes of this provision, a cancer treatment regimen includes drugs used to treat toxicities or side effects of the cancer treatment regimen when the drug is administered incident to a chemotherapy treatment.

Further, chapter 15, section 50.4.5.D, A Use Supported by Clinical Research That Appears in Peer Reviewed Medical Literature, applies to unlabeled uses which do not appear in any

[5] Effective October 1, 2003, CMS established a new manual system accessible on the internet at: www.cms.hhs.gov/manuals.

of the prescribed compendia or are listed as insufficient data or investigational. In pertinent part, section 50.4.5.D provides --

> In determining whether there is supportive clinical evidence for a particular use of a drug, carrier medical staff (in consultation with local medical specialty groups) will evaluate the quality of the evidence published in peer reviewed medical literature. When evaluating this literature, they will consider (among other things) the following:
>
> • The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate. While a 20% response rate may be adequate for highly prevalent disease states, a lower rate may be adequate for rare diseases or highly unresponsive conditions.
>
> • The effect on a patient's well-being and other responses to therapy that indicate effectiveness, e.g., a significant increase in survival rate or life expectancy or an objective and significant decrease in the size of the tumor or a reduction in symptoms related to the tumor. Stabilization is not considered a response to the therapy….

The Manual then identifies twenty-six peer reviewed publications to be used by a carrier in assessing clinical research purporting to support Medicare coverage for a drug use.

Procedural Regulations

The regulations at 42 C.F.R. § 405.966(a) provide that when a party files a request for reconsideration by a Qualified Independent Contractor (QIC), it should present evidence and allegations of fact or law related to the issue in dispute and explain why it disagrees with the initial determination and/or redetermination. Absent good cause, failure to submit all evidence prior to the issuance of the reconsideration precludes subsequent consideration of the evidence. 42 C.F.R. § 405.966(a)(2).

Any evidence submitted by a provider, supplier, or a beneficiary represented by a provider or supplier that was 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. 42 C.F.R. § 405.1018(c). Further, pursuant to 42 C.F.R. § 405.1028 an ALJ is required to examine any new evidence submitted with the request for hearing, unless the appellant is an unrepresented beneficiary, to determine if the appellant had good cause for submitting the evidence for the first time at the ALJ level. If the ALJ determines that good cause does not exist for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceedings and may not consider it in reaching a decision. 42 C.F.R. § 405.1028(c).

An ALJ must make a complete record of the evidence including the documents used in making the decision under review, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits. 42 C.F.R. § 405.1042(a)(1) and (2). The CMS and its contractors may participate by submitting position papers for the record. 42 C.F.R. § 405.1010. The ALJ's decision must be based on evidence offered at the hearing or otherwise admitted into the record. 42 C.F.R. § 405.1046(a). The ALJ must also discuss on the record any evidence excluded under 42 C.F.R. § 405.1028, and include a justification for excluding the evidence. 42 C.F.R. § 405.1042(a)(2).

ALJs and the Council are not generally bound by LCDs, or CMS program guidance such as program memoranda or manual instructions. However, an ALJ or the Council must give such policies substantial deference if applicable in 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 rationale for not following that policy must be explained. 42 C.F.R. § 405.1062(b). In addition, section 1861(t)(2) of the Act provides that the Secretary shall identify the compendia and the acceptable publications for determining a use supported by clinical research that appears in peer reviewed medical literature. The MBPM, chapter 15, section 50.4.5, is the vehicle the Secretary uses to identify this material; the grant of authority under section 1861(t)(2) thus conveys legislative effect to that manual section.

DISCUSSION

Evidentiary Concerns

An ALJ must make a complete record of the evidence. The record will include marked as exhibits the documents used in making the decision under review, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ admits. 42 C.F.R. § 405.1042(a)(1) and (2). The ALJ's decision must be based on evidence offered at the hearing or otherwise admitted into the record. 42 C.F.R. § 405.1046(a).

The record in this case includes one Master File, and individual files for each date of service. During the hearing the ALJ admitted into evidence abstracts from several medical studies. *See* Exh. 2 Master File. However, the ALJ never ruled on whether the appellant had good cause for submitting additional evidence to the ALJ.

Further, each of the five individual files contains an assortment of paper-clipped pages, with an orange colored cover sheet that reads:

ATTACHMENT I

DOCUMENTATION SUBMITTED

FOLLOWING QIC RECONSIDERATION

ALJ NEEDS TO DETERMINE GOOD CAUSE FOR
DOCUMENTS TO BE MARKED INTO EVIDENCE

_____**INCLUDE** into Evidence as Exhibit #_____

_____**EXCLUDE** from Evidence as Good Cause not established

None of these cover sheets were completed, nor were the paper-clipped documents marked as evidence.

In addition, the Master File contains the QIC position paper. The ALJ did not enter this document into evidence. The appellant also submitted a decision by another ALJ dated March 19, 2009, for this same beneficiary. The ALJ did not mark this decision as an exhibit.

The ALJ thus did not appropriately rule on the admissibility of all evidence submitted, or enter into the record all documents that should have been admitted.

Coverage and Medical Necessity

The Council finds that the ALJ did not provide an analysis of whether the use of irinotecan in this case met the requirements for off-label use of an anti-cancer drug as provided in Section 1861(t)(2)(B) of the Act, and the MBPM, chapter 15, section 50.4.5. The ALJ erred in basing his decision solely on unidentified provisions of an LCD, without considering whether there is supportive clinical evidence for this particular use of irinotecan.

Moreover, the ALJ's decision cites both LCD L25118 and LCD A46312 as the applicable LCDs. The decision does not cite any provisions from either LCD. Nor are copies of either LCD in the record. The CMS asserts that another LCD applies, LCD L26746, but does not cite any provisions of that LCD, or include a copy of the LCD for the record.

The record thus lacks evidence regarding which LCD applies, and the contents of that LCD.

REMAND INSTRUCTIONS

On remand the ALJ shall rule on whether the appellant had good cause to submit new evidence, and shall enter all appropriate evidence into the record. The ALJ shall determine which LCD applies to this case, and shall enter a copy into the record.

The ALJ shall the determine whether irinotecan provided as part of a combined chemotherapy regimen with gemcitabine is a medically accepted indication as provided in section 1861(t)(2)(B) of the Act, and MBPM, chapter 15, section 50.4.5.

The ALJ may take further action not inconsistent with this order.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ Susan S. Yim
Administrative Appeals Judge

Date: October 21, 2009