Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	
LCD Appeal of Non-coverage of Intravenous Immunoglobulin (LCD Database ID No. L9245)	DATE: January 8, 2007
	Civil Remedies CR1426
	App. Div. Docket No. A-06-70
	Decision No. 2059

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Four aggrieved parties appealed of the decision of Administrative Law Judge (ALJ) Keith W. Sickendick that determined that the local coverage determination (LCD) entitled "Intravenous Immunoglobulin" was complete and adequate under the applicable reasonableness standard to support the validity of the LCD provisions at issue. In re CMS LCD Complaint: Non-Coverage of Transfer Factor, DAB CR1428 (2006) (ALJ Decision). For the reasons explained more fully below, we find no material error in the ALJ Decision. We therefore uphold the decision in its entirety.

Applicable Legal Authority

Section 1869(f)(2)(B) of the Social Security Act[1] (Act) defines an LCD as "a determination by a fiscal intermediary or a carrier

[1] The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

under part A or part B [of the Medicare program], as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A)."[2] With certain exceptions not relevant here, section 1862(a)(1)(A) of the Act specifies that no Medicare payment may be made for items and services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." The coverage exclusion in section 1862(a)(1)(A) is sometimes referred to as the "medical necessity" standard. An LCD is issued by a Medicare contractor in a particular region and applies the medical necessity standard for that region but is not binding beyond the issuing contractor. By contrast, a national coverage determination (NCD) is issued by the Centers for Medicare & Medicaid Services (CMS) and is binding nationwide. In reviewing appeals of specific claims denials (a process separate from this review of the LCD policy's validity), an ALJ is not bound by an LCD, but is bound by all applicable NCDs. 42 C.F.R. § 405.1062(a).

Section 1869(f)(2) of the Act created a new channel for review of the validity of LCDs issued by Medicare contractors.[3] These challenges address the validity of the LCD policy itself rather than its applicability to particular claims. Beneficiaries in need of an item or service for which coverage is denied under an LCD may challenge the policy before an ALJ. An ALJ reviewing any LCD is to defer to "reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law" by CMS and its contractors. Section 1869(f)(2)(A)(i)(III) of the Act. This deferential standard is sometimes referred to as the "reasonableness" test or standard. Where the ALJ determines that the LCD record "is incomplete or lacks adequate information to support the validity" of the LCD, the ALJ shall then permit discovery and the taking of evidence before reaching a determination on the validity of the LCD. Section 1869(f)(2)(A)(i)(I) of the Act.

Procedural regulations governing the ALJ LCD review process and the appeal process to the Board are set out at 42 C.F.R. Part 426.

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[2] Fiscal intermediaries and carriers are collectively referred to here as Medicare contractors.

[3] Section 1869(f) was added to the Act by section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

Case Background

Four aggrieved parties (complainants) initiated this case by filing a complaint that was received by the ALJ on July 11, 2005 seeking review of an LCD issued by Blue Cross Blue Shield of Kansas (contractor), which was authorized by CMS to issue LCDs. The ALJ found the complaint acceptable, in that it met applicable requirements, and ordered the contractor to produce the LCD record. The parties submitted briefs and exhibits as described on page 2 of the ALJ Decision.

All four complainants are treated by a single physician and had similar clinical conditions.[4] It is undisputed that all four suffer from secondary immunodeficiencies, Acquired Immune Deficiency Syndrome (AIDS), chronic sinusitis and other recurrent infections, as well as other diagnoses. Three were receiving anti-retroviral therapy (ART). All four were treated with infusions of intravenous immunoglobulin (IV Ig). Upon the issuance of the contested LCD, the physician discontinued IV Ig infusions for all four of the patients because of non-coverage by Medicare. Complainants alleged that all four experienced "significant and debilitating health problems" thereafter. Complainant's Appeal Br. at 2-5. One complainant was later able to obtain private insurance and return to IV Ig treatment with alleged "marked improvement in his health." Id. at 3.

The LCD text at issue[5] reads in relevant part as follows:

> **Limitations:**
>
> **Secondary Immunodeficiencies**
>
> Low immunoglobulin levels or failure of antibodies to rise to an antigen challenge occurs sometimes in patients who do not have primary B-cell disorders. These changes may be the result of several systemic illnesses, malignancies, viral infections or drugs. In these disorders a state of secondary immunodeficiency

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[4] See patient summaries on pages 1-5 of Complainants' Appeal Brief.

[5] The record contains two versions of the LCD with differing revision effective dates, but the ALJ noted, and neither party disputed before us, that the relevant provisions appear identical. See ALJ Decision at 6, n.3, and record citations therein.

> exists. This state may also lead to recurrent infections and laboratory immunoglobulin abnormalities.
>
> Secondary immunodeficiencies or hypogammaglobulinemia, in isolation, will not be covered unless the immunodeficiency is the result of chronic lymphocytic leukemia or childhood Human Immunodeficiency Virus (HIV) infection.

Complainants' Ex. B, at 4. Thus, the contractor provided for coverage of IV Ig treatment for primary immunodeficiencies subject to a variety of requirements for monitoring, dosing, and ascertaining continuing necessity. As to secondary immunodeficiencies, the contractor denied coverage except as to two named conditions, neither of them applicable to any of the complainants.

ALJ Decision

The ALJ determined that the record of the LCD provision at issue was "complete and adequate" to support its validity "under the reasonableness standard." ALJ Decision at 1, 6. He therefore concluded that the review process was complete and that he need not proceed to the taking of evidence. Id. at 15. The ALJ noted that complainants framed the "core controversy" as arising from the provision in the LCD that "explicitly denies off-label immune globulin therapy to persons, like appellants, with illness arising out of secondary humoral immunodeficiencies not the result of chronic lymphocytic leukemia or childhood HIV infection . . . ." ALJ Decision at 6, quoting Complaint at 7; see also Notice of appeal at 6. His analysis focused on whether this provision met the reasonableness test based on the LCD record provided by the contractor and the evidence submitted by the complainants bearing on whether the record is adequate and complete so as to support the validity of the provision. Id. at 8.[6]

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[6] We note that certain statements in the ALJ Decision might be read to suggest that the ALJ erroneously considered only the validity of the LCD provision when it was issued. See ALJ Decision at 8, n.4. (noting that evidence submitted by complainants may appropriately be considered "when determining whether the evidence the Contractor relied upon **when** promulgating the LCD is adequate to support the validity of the LCD provisions under the reasonableness standard.")(Emphasis added). This would be erroneous since the LCD record may have become incomplete or

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In that process, the ALJ considered the complainants' argument that the CMS Program Integrity Manual (PIM, in the record as Complainants' Exhibit H) required coverage of IV Ig because the treatment is medically necessary for their conditions. ALJ Decision at 8. Since it is undisputed that effectiveness is a required component of medical necessity, the ALJ looked at the evidence in the LCD record and that proffered by complainants to show effectiveness. Id., citing PIM § 13.5.1. First, the ALJ noted that the complainants recognized that "large scale studies involving placebo controlled trials evaluating the effectiveness of IVIg in secondary humoral immunodeficiency have not been performed" and are unlikely to be conducted in the future. Id., quoting Complaint at 8. The ALJ then reviewed the seven documents/articles that the contractor included in its sources of information and basis for decision in the LCD record. ALJ Decision at 9-11.

He also reviewed the material offered by the complainants, which included letters from the authors of two studies cited in the LCD record denying that their articles supported the contractor's LCD (Drs. Jaffe and Ballow), two other studies which he discussed in detail, and letters from two physicians reporting their success in using IV Ig with patients with secondary humoral immunodeficiency. ALJ Decision at 10-13. The ALJ concluded that none of these documents established that the contractor could not rationally rely on the evidence in the LCD record as complete and adequate to support the LCD. He found that, although Dr. Jaffe opined that a trial use of IV Ig might greatly benefit certain

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[6](...continued)
inadequate to support the validity of the LCD as a result of scientific or clinical developments which occurred after its promulgation and which, thus, could not have been considered by the contractor at the time of promulgation. 68 Fed. Reg. 63,692, 63,700 (Nov. 7, 2003). The ALJ Decision as a whole makes evident, however, that in fact the ALJ properly considered whether the existing LCD record is complete and adequate to support the current validity of the challenged provisions, in light of the argument and evidence to the contrary proffered at this stage by complainants. Thus, the ALJ treated as material and relevant any evidence from the complainants that reflected on the weight of the record relied upon by the contractor (without regard to whether the complainants' evidence was available at the time the LCD was promulgated). ALJ Decision at 8. Further, the ALJ considered throughout whether the usage for which the complainants sought coverage is effective, that is, in the present tense.

patients with secondary immunodeficiency for whom clinical and laboratory evidence supports the inability to make functional antibodies, Dr. Jaffe did not point to any study or publication to support her opinion. Id. at 10. Dr. Ballow also acknowledged the absence of well-controlled studies in HIV-positive (HIV+) adults with recurrent infection and suggests "extrapolating from controlled trials in children," according to the ALJ. Id. at 11. Dr. Ballow did identify a study conducted by Michael G. Kiehl, M.D., et al. (Kiehl study), which the ALJ considered in some detail. The Kiehl study analyzed data on 127 HIV+ adults (57 as controls) in an open study and was stopped early due to favorable results in terms of reduction in several measures of infection recurrence. Id. at 12. The ALJ concluded that this study did not suffice to show that the LCD was not reasonably based on a complete and adequate record, noting that the authors claimed only that the study provided evidence to argue for the utility of a later double-blinded, placebo-controlled study of the benefits of IV Ig. Id. at 13. No such study was ever conducted as far as is known from the record before the ALJ. The ALJ also relied on an article submitted by the contractor which questioned the Kiehl data and its significance. Id., citing BABS Ex. H.[7] The letters from individual treating physicians were rejected by the ALJ as merely anecdotal evidence without sufficient weight to undermine the validity of the LCD. Id.

The ALJ found that he need not resolve a disagreement between the parties about the interpretation of 67 LCDs of other contractors. ALJ Decision at 14. Complainants read the majority of the LCDs to provide some "off-label" use of IV Ig for various immunodeficient states without requiring that they be the result of primary immunodeficiency. Id., citing Complaint at 13, 23-26. The contractor pointed to other coverage limitations in the various LCDs and alleged that 39 of them limit coverage of HIV patients to those under age 13 while four others allow no coverage for HIV patients of any age. Id., citing BABS Response at 21-23.

The ALJ further recognized that the complainants objected to other provisions of the LCD dealing with limitations on IV Ig treatment in primary humoral immunodeficiencies. ALJ Decision at 13-14. He found that complainants failed to show that they were

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[7] In considering what weight to give to evidence proffered by complainants to show that the record was incomplete or inadequate, the ALJ correctly considered evidence proffered by the contractor in response, in addition to the materials in the contractor's LCD record.

aggrieved parties as to those provisions, since none of them claimed to suffer from primary immunodeficiencies. Id. at 14. The ALJ also rejected complainants' arguments that the LCD was not promulgated in the manner required by the PIM as beyond the scope of the ALJ's review. Id. at 15.

Issues on appeal

Complainants raise a procedural issue which we address first about the ALJ's treatment of certain documents excluded from the LCD record provided to complainants by the contractor but filed with the ALJ. Notice of appeal at 4. Complainants then allege the following four errors in the ALJ Decision:

> 1. That the ALJ erred in finding that IV Ig is not effective in secondary humoral immunodeficiency;
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> 2. That the ALJ erred in failing to address complainants' objections to other provisions in the LCD;
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> 3. That the ALJ erred in failing to resolve the dispute about the LCDs of other contractors on IV Ig usage; and
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> 4. That the ALJ erred in failing to give due consideration to the contention that the contractor failed to follow PIM guidelines in promulgating the LCD.

Notice of appeal at 5, 27, 34, 35.

Standard of Review

The Board reviews ALJ decisions on LCD appeals to determine whether the ALJ decision contains any material error. 42 C.F.R. § 426.476(b). Harmless error is not a basis for reversing an ALJ decision under the regulations. 42 C.F.R. § 426.472(b)(4).

Analysis

1. The ALJ did not err in his treatment of the excluded documents.

The regulations specify that the LCD record provided by the contractor to the aggrieved party and the LCD record provided by the contractor to the ALJ may differ. 42 C.F.R. §§ 426.418(b) and 426.419. Specifically, the LCD record furnished to the ALJ,

but not that furnished to the aggrieved party, is to include "[p]roprietary data or privileged information." Id. Such materials considered by the contractor in promulgating the LCD are to be filed with the ALJ under seal. 42 C.F.R. § 426.418(b). The preamble explains the purpose of these provisions as follows:

> These sections have been added in response to comments, and to facilitate the review process when privileged or proprietary data is submitted. Generally, an LCD or NCD record is composed of documents and materials that the contractor or we considered during the development of the LCD or NCD. . . . In the cases where comments are submitted, a "comment and response" summary document is sufficient for inclusion in the LCD record. In §426.418(b) and §426.518(b), we do not include privileged information or proprietary data, or any new evidence, as part of the record furnished to the aggrieved party. In §426.419 and §426.519, we state that official records presented to the Board may contain proprietary data or privileged information, if the information was considered in reaching the LCD or NCD under review. In these instances, the proprietary data and privileged information is filed under seal and is protected from inappropriate disclosure according to all applicable statutes and regulations, or common law privileges.

68 Fed. Reg. at 63,709.

These provisions were based in part on CMS's analysis of section 1862(a) of the Social Security Act. 68 Fed. Reg. at 63,701-02. That section discusses the procedures to be used by the Secretary in developing an NCD and provides that the Secretary shall "make available to the public the data (other than proprietary data) considered in making the determination." Id. CMS reasoned that Congress would not have intended to protect such information in the promulgation of a coverage policy only to have it publically released in a later challenge to the policy. Id. at 63,702. CMS recognized that the exclusion of certain information from the record provided to aggrieved parties raised a "tension" between the availability of discovery in the challenge process and the importance of confidentiality in encouraging manufacturers and others to "submit evidence that would be useful in making LCDs/NCDs" without fearing disclosure of proprietary or confidential material in a subsequent appeal. Id. CMS resolved this tension by providing for submission under seal of proprietary or privileged documents to the ALJ, barring disclosure to the public by the ALJ (or the Board), and requiring

the adjudicator to state whether documents admitted under seal as privileged or proprietary "were material and what role they played in the determination." 68 Fed. Reg. 63,711; see also 42 C.F.R. §§ 426.440(c), 426.450(b)(5).

Pursuant to these provisions, the contractor identified certain documents in the LCD record furnished to the ALJ as "excluded" from the LCD record furnished to the complainants. Complainants challenged the exclusion of statements from four clinical experts from the LCD record as furnished to them and requested that the ALJ either compel the release of those statements or require the contractor to explain why they qualify as proprietary and privileged. ALJ Decision at 7. The ALJ reviewed the statements and concluded that none were "material to a determination that the LCD record is not adequate to support the validity of the LCD provisions challenged" here. Id. at 8. He therefore concluded that he need not determine whether the documents should have been released to complainants, and retained the documents in the record forwarded on appeal for our review, identifying those which were excluded from release. Id.

We find no material error in the ALJ's treatment of the excluded documents. The complainants did not contest the exclusion of three of the items. The four items sought by complainants were identified as documents 3-6 on the contractor's index of excluded documents and described as statements from local clinical experts with the dates of the statements and the location of the expert noted. They consist of correspondence with physicians concerning their experience and opinions regarding the use of IV Ig in adult HIV+ patients generally, the drafting of the LCD policy in that regard, and the utilization of this therapy. As the ALJ stated, nothing in the letters is material in the sense that including them in the record would in no way alter the outcome of the matter and that they would not provide any support to complainant's position if released.[8]

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[8] The regulation requires that the ALJ prepare a sealed statement explaining why the excluded documents are not material, since the ALJ decision may not disclose the substance or the contents of the documents. No such statement appears in the record as forwarded to the Board. We do not consider this omission to constitute material error since our own review of the excluded documents makes evident that they are, in fact, not material to the issues properly resolved by the ALJ. We have prepared a sealed statement containing our reasoning which will be included under seal in the record forwarded to the court in

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2. The ALJ did not err in determining that the record was complete and adequate to support the contractor's LCD because the contractor could reasonably conclude that IV Ig has not been proven effective in secondary humoral immunodeficiency.

Complainants assert that the ALJ established an incorrect standard that only large-scale placebo trials using IV Ig in adult secondary HIV-related immunodeficiency could justify requiring coverage of the therapy. According to complainants, both costs and ethical constraints would likely prevent such trials of this treatment modality ever being performed. Notice of appeal at 6. The correct standard, complainants argue, is found in PIM provisions prescribing a "multi-faceted approach" to determining what therapy should be covered. Id. Complainants argue that this approach required asking the following four questions:

> 1) Are there other Medicare carriers that reimburse for treatment of secondary immunodeficiencies with immunoglobulin;
> 2) Are there scholarly articles or other outside documentation that this treatment is effective;
> 3) What are the opinions of immunologists familiar with the use of immune globulin in off-label secondary immunodeficiency; and
> 4) What is the community experience with this treatment?

Id. Complainants apparently believe that affirmative responses to any of the questions would make unreasonable the contractor's findings and conclusions underlying the LCD. Complainants do not, however, cite to any specific provision of the PIM for either their list of questions or their inference that any affirmative response compels coverage.[9] They do quote from the

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[8](...continued)
any later appeal of this decision.

[9] Section 13.1.3 of the PIM discusses the process of LCD development and advises that contractors develop LCDs "by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community." This discussion of process does not create the four-question test that complainants propose, however. Section 13.1.3 also references section 13.7.1,

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PIM section defining "reasonable and necessary" to encompass whether a proposed therapy is "[s]afe and effective," "[n]ot experimental or investigational," and appropriate as furnished for the use. Id. at 9, quoting PIM § 13.5.1. They then argue that IV Ig therapy for the use at issue meets the PIM definition of "reasonable and necessary."

Complainants are mistaken in their claims that the ALJ's conclusion on the effectiveness of IV Ig therapy in these clinical conditions was based on the premise that only "gold standard" scientific studies were relevant. The ALJ did note that complainants' concession that no large placebo-controlled trials had been or likely would be performed "could" be sufficient to resolve the case. ALJ Decision at 9. He did not, however, resolve it based on that concession alone but instead went forward to a full analysis of the LCD record and the evidence offered by complainants. Id. Based on that analysis, the ALJ concluded that complainants failed to prove that the contractor could not reasonably have concluded that the use of IV Ig was ineffective for the use sought by complainants. We turn therefore to the parties' contentions concerning the ALJ's review of the medical evidence regarding effectiveness.

The contractor contends that complainants' articulation of the proper standard of review of the LCD fails to acknowledge the applicable reasonableness standard by which the ALJ is to evaluate the contractor's LCD. Contractor Br. at 11. We conclude, however, that the ALJ himself correctly recognized that his role was a deferential one, to determine whether the record supporting the LCD was such that a rational contractor could reasonably have reached the findings and conclusions underpinning the LCD. See, e.g., ALJ Decision at 8. To the extent the PIM definition of "reasonable and necessary" informed the ALJ's consideration of medical evidence about the use of IV Ig, the ALJ did not suggest that he was applying that guidance de novo himself but, rather, indicated that he was properly evaluating the contractor's bases for the findings and conclusions reflected in the LCD under the appropriate reasonableness standard.

The contractor also questions whether the PIM applies in this process at all, since it is not a law, regulation, ruling or NCD

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[9](...continued)
discussed infra, which does set out the evidentiary standards for contractors to use in evaluating the scientific validity of a proposed LCD. Those standards are quite different from the four-part test proposed by complainants.

binding on the ALJ but merely a set of guidelines provided by CMS for its contractors. Contractor's Br. at 12-13, citing 42 C.F.R. § 426.431(c). While the PIM is indeed not binding on the ALJ or the Board in evaluating the evidence supporting the validity of an LCD under the reasonableness standard, that does not imply that the ALJ should disregard CMS's guidance to its contractors. As the contractor argues, however, the relevant PIM provisions on what evidence should be considered in developing LCDs are quite different than those to which the complainants pointed in challenging the ALJ Decision.

The PIM expressly advises contractors to base their LCDs "on the strongest evidence available" and provides a hierarchy of evidence to be considered, as follows:

> In order of preference, LCDs shall be based on:
>
> > Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
> >
> > General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
> >
> > > Scientific data or research studies published in peer-reviewed medical journals;
> > >
> > > Consensus of expert medical opinion (i.e., recognized authorities in the field); or
> > >
> > > Medical opinion derived from consultations with medical associations or other health care experts.

PIM § 13.7.1. Contractors are specifically instructed not to rely on anecdotal evidence or testimonials. Id.

The contractor reports that it began its research as instructed with a search of the public scientific literature and identified seven relevant articles. Contractor Br. at 15. The ALJ discussed the substance of the articles in some detail, and we will not repeat his analysis here. See ALJ Decision at 9-11. The overarching conclusion to be derived from that analysis is that none of the articles purports to present large randomized clinical trials or other definitive studies supporting the use of IV Ig to treat recurrent sino-pulmonary infections in adult HIV+ patients. The 1995 consensus report on off-label uses of IV Ig,

cited by the ALJ at page 9, finds the use of IV Ig for adult patients with HIV to be unsupported, as does the 1999 report of the Centers for Disease Control, cited on the following page. The Jaffe (2001) and Ballow (2002) studies do not directly address IV Ig use for recurrent infections in HIV+ adults with secondary immunodeficiency.[10] Complainants argue that these studies do not support the "extreme restrictions" imposed by the LCD, but miss entirely the point that no definitive study supports the effectiveness of IV Ig therapy for recurrent infections due to secondary immunodeficiency related to HIV infection in adults.[11] Complainants themselves state that only the Jaffe article specifically addresses secondary immunodeficient states, and that article offers no data on adults with HIV or an opinion on the use of IV Ig in adults (although it does recommend its use in HIV+ children with demonstrated

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[10] As the ALJ correctly observed, the letters presented by complainants from the two authors do not alter this conclusion. ALJ Decision at 10-11. The complainants evidently thought that the contractor was misusing the authors' work to demonstrate the ineffectiveness of IV Ig for treating secondary immunodeficiency in adult HIV+ patients. A review of the LCD record makes clear that the contractor was instead undertaking a survey of the literature on IV Ig use for immunodeficiencies to identify those uses which were documented as effective. Neither author's study provides evidence to affirmatively support the use sought by complainants here. Each author opined that IV Ig may be useful or appropriate for some adults with immunodeficiency secondary to HIV with recurrent bacterial infections. Neither, however, cited any definitive literature to support that position. While they mentioned the Kiehl study (addressed elsewhere) or proposed extrapolation from studies in children, they never indicated that HIV+ adult use of IV Ig represented the consensus standard of medical care. On the contrary, the bulk of the record before the ALJ supports the opposite conclusion, i.e., that the consensus standard of care is that IV Ig is rarely if ever indicated for use in recurrent infections in HIV+ adults.

[11] As the ALJ noted, the contractor indicated that it was prepared to consider on an individual basis coverage of IV Ig for a small subset of adult HIV+ patients with recurrent infections who also show marked hypogammaglobulinemia. ALJ Decision at 8, and citation therein. This flexibility is not reflected at this point on the face of the LCD, and the ALJ therefore properly focused his review on whether the record supporting the LCD provision as written was complete and adequate to support its validity.

hypogammaglobulinemia or recurrent bacterial infections). See Complainants' Br. at 13 and Complainants' Ex. K. Since only reasonable and necessary treatments are covered by Medicare, the contractor could reasonably require affirmative evidence of effectiveness to include this use of IV Ig therapy among those for which coverage is provided by the LCD.

Additional complexity arises from the undisputed fact that treatments for HIV+ patients have evolved dramatically over the last twelve years with the advent and refinement of highly-active antiretroviral therapy (HAART) since 1995. Complainants note that many prior studies considered IV Ig in terms of treating HIV infection itself rather than controlling recurrent sino-pulmonary infections secondary to HIV. They further argue that HAART itself, while efficacious for HIV infection, has not been shown to control recurrent secondary infections, or at any rate to boost antibody response to pneumococcal vaccine.[12] Complainants' Br. at 21-24. The ALJ rejected these contentions on the grounds that the absence of studies supporting the effectiveness of IV Ig for sino-pulmonary or other bacterial infections in HIV+ adults supports rather than undercuts the LCD and that two studies submitted by complainants themselves actually provide support for the effectiveness of HAART in improving immune response to pneumococcal antigens in HIV+ patients. ALJ Decision at 9, n.7. and 10. If anything, the change in the standard of care for HIV-infected adults to include some form of HAART suggests a need for specific study of whether IV Ig offers any additional benefit to HIV+ patients who experience recurrent bacterial infections. The answer to this question may well differ from the results of older studies of whether HIV+ adults prior to HAART obtained any benefit from IV Ig. Complainants have identified no significant scientific basis to presume that the answer to the question would favor their position when the appropriate studies have not been found in the literature.

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[12] Complainants also assert that the contractor's audits of their treating physician were based on the mistaken idea that the physician was using IV Ig as a specific treatment for HIV infection whereas the therapy was actually used solely to treat secondary immunodeficiency and resulting recurrent infections (which merely happened to arise from HIV infection). Complainants' Br. at 15. The issues before the ALJ, and before us, are not related to any audits of the treating physician but rather relate solely to whether the record is complete and adequate to support the challenged LCD provision.

Complainants do point to their own physician's (apparently unpublished) retrospective analysis of medical records of 75 patients with CD4 lymphocyte counts below 500 cells/cu mm to determine whether anti-retroviral therapy increased their response to pneumococcal vaccination. Complainants' Br. at 24-27. He concludes that his data do not "support the premise that secondary humoral immunodeficiency in patients with HIV infection can be reversed by simply treating HIV itself." Id. at 26. Whatever validity this small retrospective and non-peer-reviewed analysis may have in regard to that conclusion, the study does nothing to answer the relevant question of whether the addition of IV Ig treatment does effectively treat recurrent bacterial sino-pulmonary infections in HIV+ adults receiving current state-of-the-art anti-retroviral care.

Complainants suggest that the ALJ failed to understand the ethical issues concerning the use of placebos in clinical trials, which complainants contend might preclude the performance of such definitive studies. Complainants' Br. at 18. This misunderstanding, according to complainants, resulted in the ALJ wrongly judging IV Ig ineffective for the use at issue based on the lack of placebo-controlled trials. Id. The ethical concerns revolve around whether a proven treatment exists of which the placebo groups is deprived and whether valid alternative study designs exist which avoid any added risk of harm to a placebo group. Complainants' Br. at 17-21, and Atts. A, B, C and D.[13] Complainants' theory is that IV Ig has already shown such "outstanding treatment benefits" that any future study of its use

[13] The contractor objects to consideration of these attachments on the grounds that they were not offered before the ALJ and that the regulations limit Board review to the record before the ALJ. Contractor Br. at 27. As the contractor notes, the regulations contemplate a paper review by the Board of the LCD review record developed before the ALJ along with the parties' arguments on appeal. 42 C.F.R. § 426.476; see also 68 Fed. Reg. at 63,713. It is not clear that this expectation precludes consideration of the articles on the ethics of placebo-controlled trials proffered by complainants here as attachments to their appellate brief. Arguably, these publicly available articles do not purport to be new evidence as to the adequacy or completeness of the LCD record but rather to be background to the complainants' argument that the ALJ wrongly evaluated the absence of placebo-controlled studies as disproving effectiveness. We need not resolve this question, however, since our treatment of that argument in this decision would be the same without regard to the attached documents, which are therefore not material.

in HIV+ adults using a blinded placebo-controlled protocol would be unethical, making requiring such a study unreasonable. Complainants' Br. at 17. Complainants argue that the absence of high-quality studies to support IV Ig use in HIV+ adults with recurrent infections is due to this ethical constraint in light of the demonstrated effectiveness of IV Ig.

Complainants rely for this theory mainly on the Kiehl study having been stopped by the local ethics board because the treatment was "so effective that continued administration of placebo to some subjects of the study was unethical." Complainants Br. at 17, referencing Complainants' Ex. Q (Kiehl study). The Kiehl study was conducted between 1991 and 1994, prior to the availability of HAART. Patients were excluded from the study if they received any antiretroviral drugs besides zidovudine or if they received continuous prophylactic treatment with microbials (with certain exceptions). Thus, the comparison being made was between patients (with or without zidovudine) receiving either IV Ig or no prophylactic treatment for recurring infections. In that context, once the IV Ig treatment showed any significant benefit over the absence of treatment, patients could not ethically be continued on a regime omitting a beneficial treatment merely to provide a control group.

The situation in which a study of IV Ig would be attempted today raises the different question of whether comparison of patients treated with standard of care (HAART with anti-microbial therapy, according to the contractor)[14] could now ethically be compared with HAART plus IV Ig therapy to determine what, if any, added value IV Ig might bring to infection control in HIV+ adults or some subset of such patients. In such studies, neither patient group might arguably be receiving less than the proven standard of care. Certainly, no prior study identified in the record establishes that the use of IV Ig in such circumstances is the standard of care.

Questions have also been raised in the literature about "structural flaws" in the design and implementation of the Kiehl study (e.g., an "open" or non-blinded study with a large percentage of participants excluded from the data analysis). Contractor's Br. at 31, and exhibits cited therein.[15] In

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[14] See Contractor's Br. at 31, and exhibits cited therein.

[15] Complainants also relied below on a letter from Williams, et al., to Vox Sang, discussing a pilot study of six

(continued...)

addition, as the ALJ noted, the Kiehl study authors themselves conclude with a recommendation for "a double-blinded, placebo-controlled study to substantiate the role of IV immune globulin treatment of HIV-infected adults." ALJ Decision at 13. Thus, the authors evidently did not believe that the stopping of their study precluded further design of an ethical study of this question.

We need not, and do not, reach any independent final conclusion about the ethics of possible future study designs that might yield strong evidence about the effectiveness of IV Ig therapy for the present purpose. Nor do we make an independent evaluation of the standard of care for HIV+ adults with recurrent infection. Our review, instead, evaluates whether the contractor could reasonably have reached the conclusions it did concerning both questions. Based on the LCD record, the contractor reasonably concluded that the absence of any high-quality study supporting IV Ig therapy in HIV+ adults with recurring bacterial infections reflected a general recognition of HAART and antimicrobial therapy as the standard of care for such patients rather than a consensus that this use of IV Ig was so well-supported as to make such studies unethical. The contractor thus reasonably concluded that no definitive studies of the kind described in the first category of evidence in Section 13.7.1 of the PIM supported coverage of IV Ig therapy for secondary immunodeficiency in HIV+ adults. Nothing presented in the record before the ALJ makes that conclusion unreasonable.[16]

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[15](...continued)
HIV+ adults with recurrent infection for whom some benefit was reported. Complainant's Response to LCD Record, Att. A. The conclusion again was a call for further studies, "preferably of randomised placebo-controlled cross-over design," in order to "determine the place of this therapy in the management of the HIV-infected patient with recurrent bacterial infections." Id. at 2; see also ALJ Decision at 12.

[16] As far as the second-level evidence of general medical acceptance, the PIM instructed the contractor to look to sources of published research, medical consensus, and expert opinion. The contractor included in the LCD various sources of such scientific opinion. As noted above, for example, consensus reports on off-label uses of IV Ig do not provide support for the use sought by complainants. Such consensus reports outweigh the occasional anecdotal report or the experience of a few physicians such as the complainants' physician.

We conclude that the ALJ committed no material error in determining that the record was complete and adequate to support the validity of the LCD provision at issue.

3. The ALJ did not err in concluding that complainants' objections to other provisions in the LCD were outside the scope of his review because complainants did not show they were aggrieved parties as to those provisions.

On appeal, complainants point to numerous objections which they raised to specific requirements in the LCD for documenting and monitoring recurrent infections and for treatment modalities. Notice of appeal at 27. They argue that the ALJ "completely ignored" these objections which they described as providing independent bases to find the LCD invalid. Id. For example, they assert that the requirement for repeated infections, many confirmed by culture growth or radiography, is inappropriate for sinusitis which is difficult and/or expensive to demonstrate by culture or radiographic testing. Id. at 27-28. Complainants raised concerns about lack of clarity of dosage guidelines, the utility of the criteria for tracking progress on therapy, the value of weaning attempts, and the lack of specificity in requirements for monitoring the underlying abnormality. Id. at 28-34.

The ALJ did not address the merits of any of these objections, but he did not ignore them. All of these objections go to the conditions of coverage for treatment of those patients who are covered for IV Ig treatment under the LCD. None of the complainants is covered for IV Ig treatment under the LCD since none of them suffers from primary humoral immunodeficiency or secondary humoral immunodeficiency incident to childhood HIV infection or chronic lymphocytic leukemia. In order to have standing as an "aggrieved party" under the regulations, a complainant must be a Medicare beneficiary (or beneficiary's estate) who "is in need of coverage for a service that is denied based on an applicable LCD . . . ." 42 C.F.R. § 426.110. Only an aggrieved party is permitted to initiate review of an LCD or provisions of an LCD. 42 C.F.R. § 426.320(a). The LCD provision under which coverage for IV Ig services were denied to these complainants is the bar on coverage for secondary immunodeficiencies (with the noted exceptions). The ALJ was therefore correct in concluding that none of the complainants had shown standing to object to those provisions of the LCD that were inapplicable to them. See ALJ Decision at 13-14.

4. The ALJ could properly apply the reasonableness test to evaluate the LCD record without resolving the dispute about the LCDs of other contractors on IV Ig usage.

Complainants argue that "the frequency with which the therapy is accepted and utilized by other health care providers" is a "key" index of whether the therapy should be considered reasonable and necessary. Notice of appeal at 34. For that reason, complainants contend that the ALJ could not decide whether IV Ig was reasonable and necessary therapy for the clinical conditions at issue without determining whether or not the therapy was treated in the present contractor's LCD in a manner inconsistent with the 67 other contractors' LCDs on the subject. Id.

Complainant's notice of appeal cites no authority for the proposition that comparing other contractors' LCD provisions to the one at issue is "key" to determining whether the contested provision is valid under the reasonableness test. The preamble to the regulations expressly instructed the ALJ (and the Board) not to 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." 68 Fed. Reg. at 63,704.

The ALJ did discuss the competing assessments of the 67 LCDs in some detail. ALJ Decision at 14. He noted that complainants did not identify a single LCD that would provide coverage for their clinical conditions, but rather offered the general conclusion that "the overwhelming majority . . . allow use of immune globulin for immunodeficiency states which cannot be accurately classified as a primary immunodeficiency and are therefore classified as secondary regardless of the originating cause of the immune deficiency." Id. at 14-15, citing Complaint at 26. He further noted that the contractor asserted that, of the currently effective LCDs, only five allow coverage of IV Ig for use in adult HIV, while five bar all coverage for HIV, and 39 limit coverage in the case of HIV to patients under the age of 13. Id. at 14, citing BABS Response at 21-23. While it might have some relevance to the reasonableness of a contractor's findings and conclusions if all or the vast majority of comparable LCD provisions were based on the opposite conclusion, the preamble clearly contemplates that inconsistency among contractors may occur. In such instances, the preamble notes that more than one approach by various contractors may meet the reasonableness standard. 68 Fed. Reg. at 63,704.

We find no material error in the ALJ's conclusion that he need not parse through dozens of other LCDs to try to resolve the conflicting descriptions offered by the parties, given that complainants never pointed to even one LCD that expressly provided coverage for IV Ig therapy for recurrent infections with secondary immunodeficiency related to HIV infection in adults.

5. The ALJ properly concluded that the contractor's compliance with the PIM in promulgating the LCD was not relevant to the issue before him.

We have already discussed the role of the PIM in analyzing the evidentiary standards to be considered in evaluating the reasonableness of the contractor's findings and conclusions in support of the LCD. The complainants on appeal except to another aspect of the ALJ Decision under the rubric of contending that the contractor did not follow proper procedure in promulgating the LCD. Complainants' Br. at 35-43. The essence of the exception is that the ALJ erred in finding irrelevant their contentions that the contractor was motivated by hostility toward their physician in promulgating the LCD provision at issue. The ALJ rejected these arguments on the ground that they were irrelevant to the question of whether the LCD meets the reasonableness standard. ALJ Decision at 15.

The PIM provision on which complainants rely appears in section 13.1.3, which discusses what is considered an LCD. The concluding paragraph reads as follows:

> Contractors shall ensure that LCDs present an objective and positive statement and do not malign any segment of the medical community. LCDs do not address any fraud and contractors should not use terms such as "fraud" and "fraudulent" in their LCDs. For example, the following sentence would be inappropriate in an LCD. "If, on postpay review this carrier finds that XYZ procedure was billed to Medicare after the effective date of this LCD, it will consider that billing fraudulent." This sentence would be more accurate and less inflammatory if the word "fraudulent" were replaced with the phrase "not reasonable and necessary."

Focusing on the instruction not to "malign" any provider, the complainants assert that the LCD was issued as the "product of a longstanding effort by BC of Kansas to malign Dr. Nemechek and his practice" rather than being "the result of legitimate factors." Complainants' Br. at 35. Complainants then recite the

history of the contractor's audits and repayment efforts resulting from the contractor's expressed concerns about unusually high utilization. Id. at 36-37. They contend that the provider's high usage resulted from his specialized urban practice. Further, they point to the reversal of the contractor's repayment claims against Dr. Nemechek by a hearing officer. Id. at 39 and Complainants' Ex. X. They assert that the revision of the LCD to bar these services was particularly egregious because it followed the hearing officer's conclusion that the services were reasonable and necessary. Id.

Careful reading of the full context of the injunction not to malign a segment of the medical community in an LCD makes evident that the guidance goes to using non-inflammatory language in setting out the provisions of the LCD. Nothing suggests that a contractor may not adopt a non-coverage LCD provision if its enforcement would have a heavier impact on some providers than on others. The language of the LCD at issue here was entirely neutral and contained no implication that provision of IV Ig for the clinical condition at issue was fraudulent as opposed to simply not reasonable and necessary (and therefore not covered by Medicare).

As for the hearing officer's decision, its conclusion was based on the absence of any specific bar to IV Ig treatment for immunoglobulin deficiencies in HIV+ patients. Complainants' Ex. X, at 3. The hearing officer specifically noted that the contractor later revised the LCD to include a specific bar, and opined as follows:

> This policy specifically addresses the issue of patients infected with HIV and when the treatment will be covered for such cases. However, this was not in effect at the time Dr. Nemechek provided this care. The IVIG treatment provided for these patients was within the scope of coverage applicable at the time for IVIG, and the original payments for these billings should stand as appropriate.

Id. The hearing officer thus made no general finding that the services must be considered reasonable and necessary but rather concluded that the services complied with the applicable contractor policy defining coverage at the time of service delivery. We therefore disagree that there was anything egregious about the contractor's conduct in revising its LCD.

Complainants further assert that the contractor here behaved abusively because contractors ––

> are permitted to revise an LCD **only** on condition that (1) a validated widespread problem demonstrates a widespread risk to the Medicaid trust funds [sic]; (2) a LCD is needed to assure beneficiary access to care; (3) a contractor has assumed the LCD development workload of another contractor and is undertaking an initiative to create uniform LCD's across its jurisdiction; or (4) frequent denials are issued following routine or complex review or frequent denials are anticipated.

Complainants' Br. at 40 (emphasis in original), citing PIM § 13.4B.

Complainants have again misrepresented the PIM provision which they cite and ignored the PIM provision which is on point. The provision cited by complainants is entitled "Contractors MAY Develop New/Revised LCD" and prefaces the list of the four situations with the statement that "[c]ontractors have the option to develop LCDs when any of the following occur." PIM § 13.4B (emphasis in original). On the other hand, section 13.4A, entitled "Contractors Shall Develop New/Revised LCDs" provides that "[c]ontractors shall develop LCDs when they have identified a service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review." PIM § 13.4A (emphasis in original). Plainly, the LCD revision here falls under the latter provision in which contractors are instructed that they "shall" issue LCDs.

Finally, complainants allege that the "real motive" and "true purpose and intent" for the LCD revision is exposed in an internal contractor memorandum which they obtained. Complainants' Br. at 42-43. The brief memorandum states that the code for injection immune globulin is "aberrant over threshold" for family practice specialty in Kansas City and that usage increased 125% from the prior year. The next paragraph states that ––

> Dr. Murti [of the contractor] is in the process of rewriting the Immune Globulin policy and we will nab that as the corrective action. I would preliminarily like to suggest looking at at least one provider Nemecheck [provider number omitted] as he is driving the aberrancy . . .

Complainants' Ex. BB. While the term "nab" casts a less than professional light on the memorandum, the context does not

establish anything more than that the contractor's decision to look at revising the LCD was driven, at least in part, by utilization concerns. Complainants have not shown that the specific provision which resulted failed to meet the reasonableness test in light of the scientific and clinical evidence of record discussed above. The ALJ correctly found that the latter was the only issue before him. ALJ Decision at 15.

Conclusion

For the reasons explained above, we uphold the ALJ Decision in its entirety.

/s/
Judith A. Ballard

/s/
Donald F. Garrett

/s/
Leslie A. Sussan
Presiding Board Member