

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-10-1874 (formerly M-09-1135)

In the case of

United Healthcare/
Secure Horizons

(Appellant)

Claim for

Medicare Advantage (MA)
(Part C)

(Enrollee)

(HIC Number)

United Healthcare/
Secure Horizons - AARP
Medicare Complete

(MA Organization (MAO)/MA
Plan)

(ALJ Appeal Number)

On June 24, 2010, the Administrative Law Judge (ALJ) issued a decision finding that the MA plan must cover the CyberKnife stereotactic radiotherapy for the enrollee's adenocarcinoma of the prostate. The ALJ's decision followed the Medicare Appeals Council's April 12, 2010 remand. On the MA plan's request for the Council's review, on February 24, 2011, the Council issued a proposed decision reversing the ALJ's June 24, 2010 decision.¹

The regulation codified at 42 C.F.R. § 422.608 states that "[t]he regulations under part 405 of this chapter regarding MAC [Medicare Appeals Council] review apply to matters addressed by this subpart to the extent that they are appropriate." The regulations "under part 405" include the appeal procedures found at 42 C.F.R. part 405, subpart I. With respect to Medicare "fee-for-service" appeals, the subpart I procedures pertain primarily to claims subject to the Medicare, Medicaid and SCHIP

¹ On October 22, 2009, we issued our initial proposed decision (M-09-1135) reversing the ALJ's initial (May 21, 2009) decision (1-408032191), in which the ALJ determined that the plan was required to cover the enrollee's CyberKnife procedure. After considering the enrollee's response to the proposed decision, on April 12, 2010, we remanded the case to the ALJ for further action. The ALJ then issued his second, June 24, 2010 decision (1-589076905). We will set forth the case history in more detail below.

Benefits Act of 2000 (BIPA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). 70 Fed. Reg. 11420, 11421-11426 (March 8, 2005). The Council has determined, until there is amendment of 42 C.F.R. part 422 or clarification by CMS, that it is "appropriate" to apply, with certain exceptions, the legal provisions and principles codified in 42 C.F.R. part 405, subpart I to this case.

We review the ALJ's decision *de novo*. 42 C.F.R. § 405.1108(a). We will limit our review to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c).

The Council reverses the ALJ's June 24, 2010 decision. The decision herein is the Council's final decision in this case.

COUNCIL'S EXHIBITS

The plan's August 27, 2010 request for review of the ALJ's June 24, 2010 decision is entered into the record as Exh. MAC-1.

On September 14, 2010, the enrollee's counsel requested an extension of time to respond to the plan's request for review, which is admitted as Exh. MAC-2.

On October 4, 2010, the plan representative wrote us recounting his August 31, 2010 telephone conversation with Ms. A. Kelly, Wisconsin Physicians Services (WPS) Insurance Corporation's Senior Coordinator for Product Development, concerning the WPS's December 2008 Communiqué discussing the coverage of stereotactic body radiation therapy (SBRT),² and Local Coverage Determination (LCD) L26109, *LCD for Stereotactic Body Radiation Therapy*. The plan's October 4, 2010 letter and attachments, which the plan provided to the enrollee's counsel, are admitted as Exh. MAC-3.

By letter dated October 5, 2010, we granted the enrollee an extension of time to respond to the proposed decision. The Council's letter and the enrollee's October 22, 2010 response are admitted as Exh. MAC-4.

The first page of LCD L28366, reflecting a revision of the LCD effective "07/16/2008" (discussed below), is admitted as Exh. MAC-5.

² The primary reason for our remand was to further develop the record on the relevance of the Communiqué on the coverage issues in this case.

The enrollee's February 28, 2011 letter to the Council, and our response, in which we granted an extension of time to respond to our February 24, 2011 proposed decision, are admitted as Exh. MAC-6. The enrollee's April 11, 2011 submittal, including attachments, is admitted as Exh. MAC-7.³

BACKGROUND

This case has a protracted history. Two ALJ decisions favorable to the enrollee, two Council decisions (proposed reversals), and a Council remand were issued. The enrollee's arguments have changed over the course this case. The discussion of the parties' arguments and the case history, as set forth in our proposed reversals and our remand order, is incorporated herein by reference.

Proposed Reversal of ALJ's May 21, 2009 Decision

In November 2008, the enrollee, then aged 72, was diagnosed with prostate cancer. In December 2008, he was offered several in-plan treatment options, including radiation treatment and intensity-modulated radiation therapy (IMRT). In late December 2008, he sought a second opinion from a specialist, P. LaNasa, M.D., Director of Radiation Oncology at The Center for Cancer and Blood Disorders, in ***, ***, on various treatment alternatives. Dr. LaNasa does not participate in the plan. Dr. LaNasa discussed several options, including radical prostatectomy, hormone therapy, radiotherapy with seed implantation, external beam radiation therapy, and the CyberKnife procedure, a non-invasive, image-guided surgery by which pencil beams of radiation are cross-fired within the tumor, sparing the surrounding tissue.

The enrollee sought plan pre-authorization for coverage of the CyberKnife procedure. In January 2009, Dr. LaNasa submitted a referral request for an office visit. The plan determined that a denial of the referral would be appropriate because, first,

³ We entered Exhs. MAC-1 and MAC-2 into the record when we issued our initial proposed decision, on October 22, 2009. Exh. MAC-1 was the plan's request for review of the ALJ's first decision; Exh. MAC-2 was the enrollee's exceptions. Following our April 12, 2010 remand, the ALJ marked all exhibits, numbered 1 through 22. Those exhibits included the plan's initial request for review, our October 22, 2009 reversal, and subsequent filings leading up to the ALJ's second, June 24, 2010 decision. Thus, we marked as Exhs. MAC-1 through MAC-7 those submittals we received after the ALJ's second decision, in connection with the plan's request for review of that decision.

Dr. LaNasa is not a member of the plan's contracted medical group and radiation oncology services are available within the group. Second, the plan determined that, because Medicare does not cover the procedure for prostate cancer, coverage would be denied even though the CyberKnife procedure is available through a plan network provider (Dr. S. Sorgen). The plan considered LCD L26109 (which lists Texas as a primary geographic jurisdiction). This LCD excludes from coverage consideration all indications other than those for cancers of the lung, liver, pancreas, and kidney, and spinal lesions, as not reasonable and necessary. The independent review entity (IRE), after consulting with a medical doctor, affirmed the plan's denial.

On May 21, 2009, the ALJ issued a hearing decision favorable to the enrollee. The ALJ found the enrollee's reasons for choosing the CyberKnife procedure valid, citing, *inter alia*, a low failure rate, low risk of urethral stricture, and a cost lower than that for the IMRT.

We then considered the plan's request for review and the enrollee's exceptions, and, on October 22, 2009, issued a proposed decision (M-09-1135) reversing the ALJ's May 21, 2009 decision.⁴ The enrollee responded with written argument and additional evidentiary submissions, contending that LCD L26109, as revised by a December 2008 contractor Communiqué, favored coverage of CyberKnife for prostate cancer effective July 16, 2008. The enrollee argued that the plan should be held bound by its position in its initial request for our review, and that LCD L26109 was applicable, notwithstanding the lack of specific evidence that the plan had elected to apply this LCD for its enrollees in Texas. The Communiqué indicated that ICD-9 code 185, "Malignant neoplasm of prostate," supports medical necessity of SBRT, but that coverage would be subject to certain limitations concerning the patient's performance on the Karnofsky Performance Scale and the ECOG Performance Status.

The Council's Remand

On April 12, 2010, we took an unusual action in vacating the ALJ's May 21, 2009 decision and remanding the case for further ALJ action, after issuing a proposed reversal. The primary reason for remanding (M-09-1135) was that the parties' dispute centered primarily on which LCD, if any, applied, inasmuch as

⁴ This case stemmed from the plan's denial of a referral to see Dr. LaNasa. While the case was pending review, the enrollee had the procedure, apparently between mid-July and early August 2009.

the record, at that point, did not include an explicit statement on the plan's election of an LCD on the CyberKnife procedure, but indicated that the plan relied upon LCD L26109 to deny the referral to see Dr. LaNasa. We interpreted LCD L26109 to exclude from coverage all indications other than for cancers of the lung, liver, pancreas, and kidney, and spinal lesions, as not reasonable and necessary. However, we recognized that the plan indicated that it follows the LCD in effect in the enrollee's home jurisdiction (Texas). ALJ Hearing CD (May 7, 2009 testimony of Dr. V. Reese, for the plan).

We rejected the enrollee's argument that the Communiqué issued by WPS was, in effect, a revision of LCD L26109, even though the LCD itself did not evidence expanded coverage of SBRT for prostate cancer. We did, however, determine that clarification was needed on the apparent discrepancy between the Communiqué and LCD L26109 on whether the LCD was revised to include coverage of SBRT for prostate cancer. Accordingly, we directed the ALJ to order the plan to have its Medical Director state what its CyberKnife coverage policy for prostate cancer is and which LCD the plan elected to apply for its Texas enrollees. We also directed the ALJ to have the IRE provide written documentation on the relevant LCDs and any LCD revision histories in light of the apparent discrepancy between the Communiqué and LCD L26109.

Developments on Remand; ALJ's Second Decision

The plan's Medical Director submitted a written statement regarding the coverage policy for CyberKnife/SBRT for prostate cancer, indicating that the plan had elected to apply LCD L26109. The IRE submitted a position paper. After a supplemental hearing on May 13, 2010, the ALJ issued a June 24, 2010 decision favorable to the enrollee. The ALJ found that the plan had uniformly applied LCD L26109 in the enrollee's geographic region, and, because this LCD was applied, the Communiqué-based "revision" of the LCD also must be applied to cover the enrollee's CyberKnife surgery.

Council's Second (February 24, 2011) Proposed Reversal

The plan again requested our review, and the enrollee raised exceptions. On February 24, 2011, we issued a proposed decision reversing the ALJ's June 24, 2010 decision. The enrollee filed additional argument and evidence, which included print-outs of

electronic mail exchanges between the enrollee's counsel and Dr. K. Bussan, the Medical Director of WPS Medicare. Exh. MAC-7.⁵

DISCUSSION

After thoroughly reviewing the record, considering the parties' arguments, and weighing the evidence for and against coverage, we conclude that the preponderance of the evidence of record warrants a decision for the plan. We set forth our reasons below.

As of February 2011, when we issued our second proposed reversal, neither party disputed the applicability of LCD L26109 to this case. The more specific point of dispute between the parties was the scope of coverage of SBRT/CyberKnife under LCD L26109, and whether this LCD was revised to include the use of SBRT for prostate cancer.

The regulations provide that an MA organization offering an MA plan must provide enrollees with "basic benefits," which are all items and services covered by Medicare Part A and Part B available to beneficiaries residing in the plan's service area. 42 C.F.R. § 422.101(a). While ALJs and the Council are not bound by LCDs, they must accord LCDs substantial deference if they are applicable to a particular case. 42 C.F.R. §§ 405.1062(a), (b). A plan must comply with national coverage determinations, LCDs, and general coverage guidelines included in original Medicare manuals and instructions. 42 C.F.R. § 422.101(b). If a plan covers geographic areas encompassing more than one local coverage policy, it may apply to plan enrollees in all areas the policy that is the most beneficial to the enrollees. Alternatively, a plan offering an MA regional plan, to the extent it elects to do so, must uniformly apply all of the LCDs that apply in the selected local coverage policy area in that MA region to all parts of the same MA region. *Id.*

In light of an indication that the plan applied LCD L26109 to the enrollee's case, the inquiry for the ALJ was whether LCD L26109 covered the CyberKnife procedure for the enrollee. The ALJ found that it did, but this was error because, as we noted in our two proposed reversals and remand order, nowhere within the four corners of LCD L26109 itself is there any indication

⁵ As Dr. Bussan explained, "[i]n 2006, WPS Medicare purchased the FI [fiscal intermediary] contract from Mutual of Omaha." Exh. MAC-7, attachment 3, page 10.

that the CyberKnife or SBRT is covered for prostate cancer. The ALJ apparently recognized that, but did not explain why he did not then defer to its plain language, which provides that the *only* covered indications are spinal lesions, lung cancer, liver cancer, pancreatic cancer, and renal cell carcinoma. The application of LCD L26109 to this case allows for only one conclusion - that prostate cancer is not a covered indication.

The ALJ also erred in finding that a contractor's newsletter or bulletin, specifically, WPS's December 2008 Communiqué, revised LCD L26109 to favor coverage. The ALJ's June 24, 2010 decision concluded that, because the plan applied LCD L26109, and the Communiqué effectively revised this LCD to include prostate cancer as a covered indication for SBRT, the plan must therefore cover the enrollee's CyberKnife procedure.

The Council remanded this case on April 12, 2010, precisely because LCD L26109 did not contemplate coverage of SBRT for prostate cancer, but the Communiqué suggested that the LCD was revised to allow coverage, effective July 16, 2008. See Exhs. 15 at 72-74; 22 at 13. A contractor's Communiqué is not equivalent to an LCD. Had we agreed with the enrollee's proposition, we would not have remanded this case for clarification on the scope of LCD L26109.

As we alluded to earlier, the enrollee's position has shifted over time. Before we issued the February 24, 2011 reversal, the gravamen of the enrollee's argument was that the WPS Communiqué itself was a revision of LCD L26109. See Exh. MAC-4. The enrollee referenced a copy of LCD L26109, noting that it is

"Updated on 2/11/2009", with a revision effective date of 11-05-07 and a revision ending date of 04-18-10 . . . The explanation as to how this version of the LCD failed to include the WPS, December 2008, part A Communiqué Language modifying the SBRT [Cyber/knife] policy for prostate cancer may be found within the LCD. Page 13 of the LCD reveals this version of L26109 was "**Last Reviewed on Date 09/21/08**". The plain and simple meaning of these words is: The "Updated on 02/11/2009" version of L26109 relied on the 09-21-08 review of 'SBRT for primary prostate cancer' policy. As a result, the "Updated on 02/11/2009" version of L26109 was published without the policy change published in the December 2008 Communiqué.

Although the applicable version of L26109 could have been published with greater precision, that does not change the analysis regarding the later date of the WPS, December, 2008, part A, Communiqué versus the earlier date of the "Last Reviewed on Date 09/21/08" version of the LCD. In addition, because WPS functioned as the FI to 48 States, WPS published a part A Communiqué every month in order to give notice as to changes in WPS policy. And WPS had been publishing Part A Communiqués every month for more than five years when this dispute arose.

Succinctly stated, **the December 2008 Communiqué trumps the "last reviewed on 09-21-08" version of the L26109 LCD. . . .**

Exh. MAC-4 at 2 (emphasis in original).

The LCD L26109 in effect when the referral was denied, and when the enrollee had the CyberKnife procedure, did not include prostate cancer as a covered indication. The entry dated February 11, 2009, under the LCD's revision history section, indicates that, effective November 7, 2007, WPS assumed the Mutual of Omaha Part A FI (fiscal intermediary) business and that the LCD was being modified retroactively to reflect the business name change. It also expressly states, "No other changes were made, and the LCD content has not changed." Under the subheading "Reasons for Change" below, on the same page, there is a date "09/21/2008" as the "Last Reviewed On Date." See Exh. 18 at 23. Therefore, if the December 2008 Communiqué actually was intended to revise LCD L26109's substantive coverage "content," then that change should be reflected within the four corners of the LCD, but it is not. Nor does the LCD refer to the December 2008 Communiqué, or identify "Related Documents" to indicate that another document was being incorporated into the LCD to reflect a coverage change. The plain language of the LCD states that only certain indications are covered; prostate cancer is not among them.

Moreover, as we stated in our last proposed reversal, the enrollee's argument (in Exh. MAC-4) to the effect that the February 11, 2009 version of L26109 "relied on the 09-21-08 review of 'SBRT for primary prostate cancer' policy," thus, effectively publishing the policy change in the December 2008 Communiqué without expressly including a discussion of the substantive policy change within the LCD itself strains credulity. We do not believe that a contractor would intend to

effectuate a *substantive* coverage change adding another covered indication in such a vague, indirect manner. We also rejected the enrollee's argument that it is illogical to believe that WPS revised its SBRT policy in a piecemeal fashion, and that a reasonable explanation is that the contractor intended to revise all LCDs concerning coverage of the SBRT for all jurisdictions by issuing the December 2008 Communiqué. The enrollee attempts to cover all of the bases with such an argument, but the argument is just not persuasive. It bears repeating that the very words in LCD L26109's revision history indicate the opposite, i.e., no change was made to the LCD's *content*. And we find no other indicia of any such substantive change within the four corners of the LCD.

Now, the enrollee states that LCD L26109 does not apply to this case. Exh. MAC-7 at 1. Apparently, he does so mainly because he now accepts, as he must, that the LCD was not revised to include prostate cancer as a covered indication and, thus, does not favor his position.⁶ Following our February 24, 2011 proposed reversal, the enrollee's counsel obtained information from Dr. Bussan, the Medical Director of WPS Medicare, that the *December 2008 Communiqué suggesting that LCD L26109 was revised to include prostate cancer as a covered indication was issued in error*. Exh. MAC-7, attachment 3.⁷ Dr. Bussan informed the

⁶ But, the enrollee's counsel simultaneously states, inconsistently, in the same filing: "Even if published as a 'mistake', the December 2008 WPS Communiqué modified L26109 to allow SBRT for prostate cancer." Exh. MAC-7 at 2. The LCD was not so modified.

⁷ The enrollee's submittal (Exh. MAC-7) includes evidence of communication between only the enrollee's counsel and Dr. Bussan that did not occur in the presence of both parties. It includes hearsay statements. See Fed. R. Evid. 801(c). This case is not a lawsuit to which the Secretary of Health and Human Services is a party; nor is it before a federal court organized and appointed under Article III of the U.S. Constitution. The parties herein are not bound to comply with the Federal Rules of Evidence or the Federal Rules of Civil Procedure.

We comment, however, that the plan did not object to the enrollee's submittal (Exh. MAC-7) on any grounds. Moreover, before the Council issued the February 24, 2011 reversal, the plan submitted to us an October 4, 2010 letter discussing the communication between the plan's appeals analyst and Ms. A. Kelly, Senior Coordinator for Product Development at WPS. See Exh. MAC-3. The enrollee's counsel did not object to the plan's October 4, 2010 submittal on hearsay or other grounds, but responded with another filing pointing out the purported "inaccuracies" in the plan's October 4, 2010 letter. Exh. MAC-4. Counsel also went on to ask for, and we granted, additional time to contact WPS Medicare on his own, in an effort to obtain additional information that could favor the enrollee's position. The parties each have had the benefit of full review of the other party's submittals.

enrollee's counsel that the following text, quoted verbatim, would be placed on the publications page of WPS Medicare's website (see Exh. MAC-7, attachment 3, page 6-7):

LEGACY A DECEMBER 2008 COMMUNIQUE ERROR

It has been brought to our attention that the December 2008 *Communique* contained an error. The article "Coverage - Revised Policies" Stereotactic Body Radiation Therapy (SBRT)" incorrectly stated that ICD-9 Codes that Support Medical Necessity 185 Malignant neoplasm of prostate was added to the policy as a covered indication. This was incorrect. ICD-9 code 185 Malignant neoplasm of prostate is not a covered indication and has never been a covered indication for Legacy A. The LCDs on our web site and on the CMS Coverage Database were both correct and did not include ICD-9 185 Malignant neoplasm of prostate at that time or currently. We regret this error and any inconvenience it may have caused.

Exh. MAC-7, attachment 3, page 7.

Dr. Bussan's multiple statements distinguishing between a contractor's newsletter, bulletin, or similar type of publication, such as a Communiqué, and an LCD, is notable. Dr. Bussan stated that the "official source for CMS contractor's coverage of services is the Local Coverage Determination published on the CMS Coverage database." He added that "CMS does not require contractors to publish LCD changes in their newsletters. CMS does require the LCD to be placed on the contractor's website and the CMS Coverage Database." He also indicated that contractor bulletins and newsletters are "references," but not definitive, "official" sources of coverage information. Exh. MAC-7, attachment 3. Consistent with the discussion in our February 24, 2011 proposed reversal, we conclude that the December 2008 WPS Communiqué is not equivalent to an LCD, nor is it a revision of LCD L26109 or any other LCD addressed at various times throughout this appeal. The Communiqué is not coverage authority. It is not a basis to allow the ALJ's decision to stand.

The plan's submittal, received before the enrollee obtained clarification from Dr. Bussan, tends to weigh against the enrollee's position. The plan's representative stated that Ms. Kelly, the Senior Coordinator for Product Development at WPS, explained -

that the December 2008 WPS Communiqué was meant to amend the [LCD] L28366 for Part B coverage but not Part A and only for the J5 region [multiple states, but not Texas]. She advised that the L26109 was not amended and that . . . legacy coverage was not affected by this 2008 December Communiqué. . . . LCD L26109 . . . was in effect . . . during the dates of service at issue in 2009. . . . She advised that the . . . [WPS] Medical Director . . . would have to address this miscommunication and clarify the errors . . . in the . . . Communiqué.

Exh. MAC-3 at 1-2.⁸ Dr. Bussan addressed this "miscommunication" and clarified the "error." Exh. MAC-7, attachment 3.

We now turn to the enrollee's remaining arguments. As noted earlier (see note 6 *supra*), the enrollee argues that, despite Dr. K.B.'s clarification, the Council should find that the "SBRT coverage" was "modified" through the erroneous issuance of the Communiqué, a mistake yet to be rectified.⁹ Counsel argues that we should find such a "coverage modification will remain in effect until WPS publishes the correction." Exh. MAC-7 at 1-3. Counsel is overreaching. We have made it abundantly clear herein, and in our remand and last proposed reversal, that the Communiqué is not "official" coverage authority; it did not revise LCD L26109; and it is not an LCD. As unfortunate as the erroneous publication of the Communiqué is, the erroneous publication and that the WPS website still does not reflect acknowledgement of the error are not a basis to allow the ALJ's legally erroneous decision to stand.

⁸ However, Ms. Kelly's explanation (Exh. MAC-3) that the Communiqué was actually intended to revise *another* LCD, L28366 (primary geographic jurisdiction is Wisconsin) seems consistent with the "07/16/2008" revision effective date contained in LCD L28366, and appears to comport with the effective date indicated in the Communiqué. LCD L28366 shows a revision consistent with the Communiqué. Thus, based on this and Dr. Bussan's explanation, the Council can only conclude that, if the contractor intended to revise LCD L26109, to reflect the content of the Communiqué, it would have done so within LCD L26109. We have included the first page of LCD L28366, reflecting a revision effective "07/16/2008," in the record as Exh. MAC-5.

⁹ Counsel indicates that, despite the assurance that the "mistake" in issuing the Communiqué would be publicly acknowledged on the contractor's website, the contractor has yet to "publicly correct" the error. Exh. MAC-7 at 3. The Council has not been able to find evidence of issuance of a correction on the contractor's website.

The enrollee seems to be asking the Council to consider the contractor's "mistake" in publishing the Communiqué to reach a decision and suggests that the enrollee could very well have relied specifically on the contents of the Communiqué to mean that coverage is available for the CyberKnife/SBRT for prostate cancer. See Exh. MAC-7 at 2-3. Counsel states: "Providers/enrollees absolutely are allowed to rely on policies published in Medicare Bulletins." *Id.* at 3.

It is certainly conceivable that Medicare beneficiaries could rely to their detriment on unclear or erroneous information on a contractor's or insurer's website. It also is conceivable that such individuals could misinterpret or disregard, or selectively consider, otherwise accurate website information for a variety of reasons. But, counsel does not argue that the enrollee in fact relied specifically on the December 2008 Communiqué to "self-direct" his prostate cancer treatment, and the record does not indicate as much.

On the contrary, the record indicates that the enrollee ably pursued this appeal, *pro se*, through the issuance of the ALJ's initial (May 21, 2009) decision, after canvassing various local coverage policies among various jurisdictions, meeting with multiple specialists, and considering literature on prostate cancer treatment options. Reference ALJ hearing CD (April 16, 2009). Only after the plan requested our review of the ALJ's first decision did the enrollee secure the assistance of counsel, who offered the Communiqué as evidence of a favorable coverage policy in connection with the enrollee's response to the Council's first proposed reversal. See Exh. 15. However, ultimately, it matters not whether the enrollee did or did not actually rely on the Communiqué. The enrollee and his counsel should be aware that ALJs and the Council are not empowered to sit in equity.¹⁰

And, more to the point, in this Medicare Part C case, by virtue of the enrollee's and the MA plan's relationship, their respective rights and obligations are outlined in the Evidence of Coverage. Counsel's citation of section 1879 of the Social

¹⁰ Counsel goes on to state that "[i]t now seems apparent Secure Horizons went 'forum shopping' for the LCD that would be the most restrictive in regard to SBRT for prostate cancer." Exh. MAC-7 at 5. We are not inclined to agree and this argument does not sway the Council toward the enrollee's position. Counsel also states "[i]t also seems apparent Secure Horizons had no idea as to the existence of the December 2008 WPS Legacy, Part A Communiqué." *Id.* That could be true. But, at this point, whether or not the plan knew of its existence is immaterial.

Security Act in the enrollee's request for equitable relief (see Exh. MAC-7 at 5) is misplaced in this case.¹¹

The enrollee also asks that the Council consider granting, in the alternative, relief in the form of another remand for a third ALJ hearing, with a specific instruction that *another* LCD, L26835 (contractor, TrailBlazer Health Enterprises, LLC), should be applied. Exh. MAC-7 at 5. Counsel's argument in this regard seems to be rooted in his position that LCD L26109, the "WPS Legacy LCD", is a Part A LCD; in contrast, LCD L26835 is a "Part B LCD." Counsel argues that the CyberKnife procedure the enrollee had was performed on an outpatient basis and the radiation delivery codes for the procedure were "Part B codes". He goes on to state that the IMRT recommended by the plan's radiation oncologists also would have been administered on an outpatient basis and would have been billable as Part B codes. He also states that the hospitals affiliated with the outpatient radiation therapy centers used by the plan doctors were not contracted with WPS and the facility at which the enrollee had the CyberKnife procedure was not contracted with WPS. Exh. MAC-7 at 3-4. Therefore, counsel argues, the WPS Legacy Part A LCD, L26109, "has no place" in "this Part B dispute." Exh. MAC-7 at 3.¹²

These arguments are somewhat inconsistent with the argument elsewhere in Exh. MAC-7 that LCD L26109 was actually "modified" with the "mistaken" publication of the WPS Communiqué, and that the Council should consider the contractor's still-uncorrected error in this regard to determine that the "coverage modification will remain in effect until WPS publishes the correction." Exh. MAC-7 at 3. But, putting that aside, these arguments concerning the Part A/Part B distinction are

¹¹ Counsel wrote Dr. Bussan: "It would be very helpful if you were to respond with a statement to the effect that the enrollee should not be held financially liable for the payment of the SBRT . . . I think the [Council] would be attentive to the admission of error on the part of WPS, accompanied by a request to find in favor of the enrollee in this one instance . . ." Dr. Bussan stated: "That decision is up to the [Council], not me" and "As I am sure you know, mistakes happen." Exh. MAC-7, attachment 3, page 1. The contractor's "admission" of error is no basis for upholding the ALJ's decision.

¹² We presume that counsel's arguments in this regard were, to some extent, influenced by Dr. Bussan's statement that "WPS Legacy A LCDs only apply to WPS Legacy A facilities. WPS Legacy A facilities were formerly the Mutual of Omaha facilities before WPS purchased their Medicare line of business. The Medicare contractor for the state of Texas is Trailblazer." Exh. MAC-7, attachment 3, page 3.

inapposite and unavailing. The bottom line is that LCD L26109 does not include prostate cancer as a covered indication.

The enrollee may have wanted to draw such a distinction to bolster the next argument that the "Texas Trailblazer LCD on SBRT, L26835, is the correct LCD to apply" because this LCD does recognize the use of SBRT for prostate cancer, subject to certain limitations. Exh. MAC-7 at 4. However, in our initial proposed reversal, we discussed multiple LCDs, including LCD L26835, in some detail largely because the enrollee himself offered, in August 2009, a lengthy opposition, broad in scope, in response to the plan's initial request for review.¹³ That opposition included a discussion of LCD L26835. See Exh. 11 at 51. It is evident that, at that time, counsel was aware that LCD L26835 did not favor coverage for the enrollee's case because he argued that the ALJ did not actually err in his initial decision because he appropriately "deferred" (or at least considered) LCD L26835, but nonetheless found in favor of the enrollee. *Id.*; see ALJ's initial decision, page 7.

LCD L26835 provides that lesions of the prostate are not covered for "primary definitive SBRT as literature does not support an outcome advantage over other conventional radiation modalities, *but may be appropriate for SBRT in the setting of recurrence after conventional radiation modalities.*" See LCD, Exh. 21 at 20 (*italics added*). Thus, LCD L26835 limits the use of SBRT/CyberKnife for prostate cancer for specific situations not presented in this case. As we explained in our two proposed reversals, the facts of this case do not indicate that the enrollee's November 2008 prostate cancer diagnosis that prompted

¹³ This is one of several reasons why the Council's prior proposed reversals included a comprehensive discussion of the overarching coverage issues. The plan complains that this case appears to have evolved from an initial denial of a request to see an out-of-plan provider to a larger dispute concerning coverage for the non-covered CyberKnife procedure the enrollee "self-directed" despite the plan's denial. Exh. MAC-1. The Council appreciates the plan's comment. However, the plan is reminded that the ALJ's initial decision was broad in scope in ordering the plan to cover the procedure, and the plan's request for review of that decision addressed to some extent the medical necessity of the procedure itself and the applicable coverage authorities. See Exh. 10. We appreciate that the plan might have seen the need to comprehensively address its various disputes with the ALJ's initial decision. While we will not address herein all of the reasons why we decided to comprehensively address the coverage issues, the plan should be aware that one concern for the Council is the full consideration of both parties' contentions. If, as was the case here, the Council is inclined to reverse ALJ action favorable to one party, then the Council's decision should fully address that party's contentions.

the request for plan approval was due to the recurrence of previously diagnosed prostate cancer, or that the enrollee had undergone conventional radiation modalities for prostate cancer. The Council sees no reason for another remand to address the applicability of this LCD, as the enrollee requests in Exh. MAC-7 at 5, because we addressed this issue previously and have done so again herein.

For similar reasons, we will not remand this case again for another ALJ hearing to allow the enrollee further "opportunity to provide [the] outcome advantages of primary definitive SBRT over other conventional radiation modalities" for the treatment of prostate cancer. Exh. MAC-7 at 4-5. The enrollee has had ample opportunity to do so. He availed himself of that opportunity. We previously addressed the enrollee's arguments in this regard in our initial proposed reversal. Moreover, in light of our determination as to LCD L26835, we do not see what purpose a showing of SBRT's outcome advantages over other conventional radiation modalities would serve at this point.

Finally, we note that the plan contends, and we agree now, as we did in our proposed reversals, that the CyberKnife treatment for prostate cancer was not a plan-covered benefit when the plan denied the request, or during the time period when the enrollee had the procedure (apparently from July 16, 2009 through August 3, 2009, according to the plan). We agree that the enrollee was "locked in" to the plan's providers concerning his prostate cancer treatment options, but chose to proceed with the CyberKnife procedure at his own expense. Equally important, as we explained in some detail in our proposed reversals, the enrollee has not shown that network providers who offered treatment alternatives were unavailable or inadequate to meet his needs. The enrollee was, therefore, "locked in" to the plan's network providers. 42 C.F.R. § 422.112(a).

The Council hereby reverses the ALJ's June 24, 2010 decision.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

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

Date: August 19, 2011