notation: "(Called on 01/03/05) Monday . . . Send Letter – Recommended 'approval' as of yesterday." AR p. 437. Other notations refer to appointment of a representative from the hospital and deductible amounts.[29]

The Plan acknowledged receipt of the grievance by letter dated July 19, 2005. As before, this letter asserts that "individuals with no prior involvement in your case will make a decision on your grievance." AR p. 402.

August 2005. A Grievance Summary Sheet dated August 10, 2005 sets forth the information provided to the Grievance Committee and summarizes its decision. AR p. 392. The latter consists of the following handwritten note: "Unanimous vote to uphold the denial of benefits for the LVAD procedure /surgery as an exclusion of coverage per the COC Section 2, What's Not Covered – Exclusions, Experimental, Investigational, or Unproven Services."

The history of the claim provided on this form indicates that the first-level grievance was upheld as experimental/investigational but that a "peer reviewer overturned denial, stating LVAD was not experimental for destination therapy." A very short history of the patient's treatment is included, covering her transfer from MUSC to Duke for a transplant evaluation. This summary then states "on 10/11/04, member had placement of LVAD to bridge until member received heart transplant." However, it then states that the Plan was advised on October 13 that Mrs. Whitley "was not on the transplant list, that she was to have the LVAD for the remainder of her life." The summary then states: "HR nurse discussed w/ Dr. Hutt and ran HAYES report since LVAD was placed for destination

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[29] While no firm conclusion can be drawn from these notes, it appears possible that what Mr. Whitley recalls is a conversation with a Duke representative, who may have been reporting on their own conversation with the Plan on January 3, 2005. His recollection as stated in the letter, however, is more consistent with a conversation with a Plan representative. The failure of the Plan to address the identity of the other participant in the January 3, 2005 call makes either alternative a possibility.

instead of as a bridge. At time of service, HAYES rating of "C" for destination and "A for bridge to transplant and "B" as bridge to recovery."

The other materials provided, according to this sheet, included: (1) member/provider grievance letter; (2) customer/provider service notes; (3) reason for original determination; (4) authorization/notification notes; (5) certification of coverage; (6) claim/claim history; and (7) medical records. AR p. 392. Although there is a block for "other" there is no indication of any additional materials. What specific materials were provided is not apparent from these documents. Thus, it is unclear whether this grievance panel was provided with: the HAYES Report and Alert; the HAYES Update listing sixty-two more recent studies and articles; the URN-Review; or, most critically the Peer Review. There is certainly no evidence that they considered any of these materials even if they were provided.[30]

A "Special Notation" in what appears to be a computer record of this grievance states: "The committee requested Dr. Hutt, Medical Director and Belinda Cox, VP of Medical Affairs be present to address question regarding the HAYES Rating criteria. Due to their prior involvement in the case, they departed prior to the committee vote." AR p. 393. What information was provided by Dr. Hutt and Cox is not disclosed.

On August 15, 2005, the Plan wrote Mr. Whitley advising that his grievance had been denied as to all charges from October 9, 2004 forward.[31] AR p. 389. The one page letter is quite cursory, and relies only on the following denial reason: "the LVAD is considered experimental, investigational

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[30] The cursory denial letter does not even refer to the HAYES Rating. *See infra* p. 34.

[31] The period selected for denial (October 9 forward) is based on the date that Dr. Milano indicated his intent to place the LVAD "for destination therapy," not the date the surgery was performed: October 11, 2004. There is no suggestion that Mrs. Whitley would, but for the planned surgery, have been able to leave the hospital as of October 9, 2004.

or unproven, it is an exclusion of your policy and is therefore not a covered service." AR p. 389. As in the letter denying the first-level grievance, this letter quotes the Experimental Exclusion, but not the relevant defining terms. Notice is not mentioned as a denial reason.

The letter makes no reference to HAYES, the HAYES Report, or any other evidence of the status of LVAD therapy. There is, moreover, no reference to any distinction between "destination" and "bridge" usage of the LVAD. Indeed, the letter suggests that LVAD is experimental for all purposes.

The remainder of the letter advises Mr. Whitley of his right to seek copies of documents and criteria relied on by the Plan. It also advises him of his right to file a third-level grievance. AR p. 389 (signed by Dee Goodman, Grievance Coordinator).

August 19, 2005. Prior to receiving this denial, Mr. Whitley apparently mailed an August 19, 2005 letter stating that he has been granted additional time to "submit data in response to the July 19, 2005 letter regarding my grievance . . . ." AR p. 399. There is no evidence to suggest that this statement was untrue.

Mr. Whitley's letter refers to various enclosed documents, although they are not specifically listed. AR pp 399-401. He also states that the Plan booklet in effect at the time of Mrs. Whitley's surgery relied on Medicaid and Medicare Rating Criteria, not on HAYES. AR p. 400 (noting July 2005 modification of handbook to rely on HAYES).[32]

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[32] The actual change in the Plan documents appears to be reflected on AR p. 425-26 which adds to the Experimental Exclusion the statement that the status of a procedure would be determined "by the HAYES Rating criteria or other approved new technology and treatment criteria tool." AR p. 426. In addition, the following is added to the definitions, as an additional ground on which a treatment may be found to be experimental: "Rated with a C or lesser rating by the Hayes Rating System or other approved new technology and treatment criteria tool." AR p. 427.

It appears that several pages of the National Coverage Determinations Manual were included with the above letter. AR 405-09 (marked as "C1-C5"). This document, which addresses approval of procedures for Medicare purposes, indicates that LVADs were approved for destination purposes "for services performed on or after October 1, 2003." Pages printed out from the internet also discuss "HeartMate Destination Therapy by Thoratec." AR pp. 410-11 (this appears to be a promotional piece written by the manufacturer and consists mostly of anecdotal reports of success from participants in the REMATCH study). Similar pages discuss the HeartMate IP. AR pp. 412-13.

An abstract from a 2001 edition of the New England Journal of Medicine is also included which expressly addresses "Long-Term Use of a Left Ventricular Assist Device for End-Stage Heart Failure." AR pp. 415-16. This article discusses the REMATCH study which included 20 centers and 129 patients "with end-stage heart failure ineligible for cardiac transplantation" who were randomly selected to receive either a HeartMate LVAD or optimal medical therapy. Although the LVAD group had more adverse events, they reported a 52% survival rate at one year, versus 25% for the control group. At two years, the LVAD group had a 23% survival rate, versus 7% for the control group. Based on the above the "authors conclude[d] that the LVAD is an acceptable alternative therapy in advanced heart-failure patients ineligible for cardiac transplantation."

Another significant report which appears to have been included with this letter is a December 2002 report from the Columbia University Health Sciences journal "InVivo," which reported that the FDA had approved LVADs for "patients who are terminally ill but not eligible for a heart transplant because of age or other serious medical problems." AR pp. 417-418. This approval apparently was given in November 2002. *See* AR pp. 419-23 at 419 & 422 ("HeartMate Destination Therapy" report from Thoratec Corporation website reporting same).

Third-level Grievance

August 23, 2005 - October 28, 2005. A "Grievance Checklist" was completed in late August 2005, indicating that the above letter would be treated as a third-level grievance, rather than as a basis to reopen the second-level grievance. *See* AR 530 ("Grievance Checklist" completed by "Dee G" and referring to grievance received August 23, 2005).[33] A handwritten notation on the Grievance Checklist reads as follows "Jim– see me or call me when you get back to your desk about this."

On the day after this form was prepared, Barbara Excell sent an email to James Zupon (addressing him as "Jim") which states:

> Just wanted to *provide the following information to you from Dr. Hutt on the Carol Whitley case as second level is the next step.* CCP did not authorize the LVAD. CCP was informed of and authorized a complicated CABG by Duke that MUSC was hesitant to perform and CCP authorized a consult/evaluation for the potential transplant. Duke performed a right heart prophylactic CABG and a LVAD that CCP did not authorize or even know about until after the procedure. *CCP did not and do[es] not use FDA or Medicare guidelines for authorization and CCP has a track record of using Hayes for several years.* CCP has sent the updated Hayes criteria on LVADs to Mr. Whitley per his request. Please let me know if you have any questions.

AR p. 675 (emphasis added).[34]

On September 20, 2005, the Plan wrote to the Whitleys and their counsel, indicating the date and time of the grievance hearing (October 25, 2005 at 1:00 p.m.). AR p. 535. No evidence is provided as to whether the Whitleys attended the hearing.

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[33] There is no indication that the Plan questioned Mr. Whitley's claim that he had been granted additional time to provide support for his second-level appeal. Neither is there any evidence that Mr. Whitley's claim was untrue.

[34] The reference to second-level is incorrect. As noted above, the Plan elected to treat Mr. Whitley's August 19, 2005 letter as invocation of his rights to a third-level grievance.

An October 21, 2005 memorandum from Dee Goodman to Karen Phillips, Teresa [Brooks], and Patricia Ortiz, provides detailed pre-hearing information.[35] AR pp. 539-40 (these three individuals appear to constitute the panel, although only two of them signed the hearing summary discussed below). This memorandum explains that the LVAD claim was denied at the first-level grievance because "Dr. Hutt reviewed and determined that services were experimental/investigation based on a HAYES rating of 'C.'" It also states that a second-level grievance was upheld, but gives no further reason or grounds. The first paragraph then concludes: "This is an issue of benefits. The panel should focus on this issue and this issue alone." Notably, there is no mention of notice as a denial reason.

The memorandum then explains the duties of the panel "to listen and fully understand the reasons for the hearing, and then make a fair and proper decision." It also states that the decision is to be "independent of all previous decisions." Nonetheless, Goodman (who had been involved in earlier stages of review) states that she will act as "moderator/facilitator," "will make introductions and guide the discussion," and will "prepare the required written response."

An attached summary briefly describes Mrs. Whitley's treatment history, beginning with her hospitalization at MUSC and transfer to Duke for possible transplant. AR p. 540. This summary states that the Plan received a call on October 13, 2004 indicating that the LVAD had been placed for destination therapy which prompted "HR [to run] a HAYES report since the LVAD was placed for destination *rather than as a bridge for transplant as originally planned.*" AR p. 540 (emphasis added). Because this revealed a "HAYES rating of 'C,' the *LVAD for destination was considered*

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[35] The record does not appear to contain any similar detailed memorandum for either of the earlier grievances. Neither is there any indication that the Whitleys were invited to attend and be heard at the second-level grievance, although Dr. Hutt and another Plan representative were asked to provide oral explanations of the Plan's position.

experimental/investigational." *Id.* (emphasis added).

The summary discloses that the November 3, 2004 URN-Specialized Physician Review concluded that continuing Mrs. Whitley on "LVAD destination therapy [was] is the most prudent [plan at that time]," acknowledging that with weight loss and control of her diabetes, she might become a transplant candidate. It then states that Dr. Hutt advised Duke's representative that the services would not be covered as experimental on the following day.

As to the earlier grievances, the summary acknowledges that because the Plan originally logged the matter in as a "medical grievance," it was forwarded for peer review, with that reviewer finding the LVAD not to be investigational. The summary then discounts this review as follows: "However, it was later determined that the grievance was a benefit issue and not a medical issue." AR p. 540. The results of the various grievances were summarized as follows:

- the Plan's decision on the provider's first-level grievance was upheld by the Grievance Coordinator based on the HAYES rating of "C" indicating the procedure was experimental/investigational;
- the member's first-level grievance was upheld on the same basis;
- the member's second-level grievance was upheld because the procedure was experimental/investigational or unproven (no basis stated).

See AR p. 540 (paraphrased above). As in the earlier sections of this memorandum, this listing contains no mention of a notice-based denial reason.

There appear to have been three exhibits attached to the memorandum.[36] Two are duplicates of the same letter: the Plan's October 19, 2004 letter to Dr. Milano (initial denial letter relying solely

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[36] All three follow the memorandum in the record and are preceded by exhibit cover pages.

on Experimental Exclusion). The third is a copy of the Plan's December 28, 2004 letter to Mr. Whitley acknowledging receipt of his first-level grievance. This copy bears Mr. Whitley's handwritten notations regarding a call made in early January 2005 (before denial of the first-level grievance).

It is not clear from the record whether any additional documents were provided to the panel which made the final decision.[37] What inferences might be drawn from the physical arrangement of the administrative record suggest that, at most, only a handful of documents supporting the Whitleys' position might have been provided to the panel and that those were not drawn to the panel's attention in any meaningful way.[38] The physical arrangement of the record also suggests that the grievance panel may not have had the critical HAYES documents.[39]

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[37] No index or records custodian affidavit is provided from which the court might discern what pages were provided to this grievance panel. As noted above, only a few pages are marked in a way which suggests they were provided as exhibits.

[38] One must search the record for over 100 pages before finding any documents which state or support the Whitley's position. What supportive documents do appear in subsequent pages of the record include: (1) Mr. Whitley's July 15, 2005 grievance letter (AR pp. 658-67); (2) Duke's November 22, 2004 letter challenging the denial and explaining what notice and approval was given (AR pp. 671-72); a faxed copy of the peer review determination adverse to the plan (AR pp. 676-79); Mr. Whitley's December 22, 2004 letter (AR pp. 680-82); Duke's faxed "To Whom It May Concern" letter and attached records requesting provisional approval for a heart transplant (AR pp. 699-717); and an incomplete inclusion of the pages which were apparently provided as attachments to Mr. Whitley's August 19, 2005 letter (AR pp. 733-750).

[39] None of the relevant HAYES documents (HAYES Report, HAYES Alert, and HAYES Update) appear at *any* point following the memorandum to the grievance panel. The HAYES Report contains the rating on which the Plan relied in denying the claim but also reveals that the Report was nineteen to twenty months old at the time of Mrs. Whitley's surgery. The HAYES Update casts doubt on the continued validity of the HAYES Report, given the extensive listing of more recent articles and warning that the results of the search would result in HAYES reexamination of the status of the procedure.

While a copy of the Peer Review report does appear in the subsequent pages of the administrative record, the court is unable to determine whether it was provided to the third-level grievance panel. *See* AR pp. 676-79 (Peer Review appearing over 100 pages after summary to panel). Further, to the extent this document was drawn to the panel's attention, it was in explaining why the Peer Review report should be disregarded (for the curious reason that the Plan obtained this report based on a mistaken treatment of the grievance as a medical rather than a benefits issue).[40]

As noted above, the memorandum to the panel does mention the URN-Specialized Physician Review. As with the Peer Review, this mention was in the context of discounting the Review's relevance. Unlike the Peer Review, this document does not appear in subsequent pages of the record, suggesting that it may not have been made available for them to draw their own conclusions.

The record also contains a Grievance Hearing Summary Sheet[41] (presumably provided to the third-level grievance panel). This summary restates the grievance issue in a manner similar to the way the issue was stated in the August (second-level) Summary Sheet, although it is modified to indicate that two prior grievances were upheld (both based on the Experimental Exclusion and HAYES rating of "C"). AR p. 536. The summary then explains:

> The Peer Reviewer determined that the LVAD was not experimental. However, it was later determined that the grievance was a benefit issue and not medical. HR

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[40] The distinction between a medical and a benefits issue is not explained. It would not, however, appear to a medical necessity determination as the peer reviewer was expressly asked to address whether the placement of the LVAD for destination therapy would fall within the Plan's Experimental Exclusion. In any case, no explanation is offered for why the distinction would justify ignoring a peer review obtained by and on behalf of the Plan itself.

[41] This summary is in addition to the more detailed memorandum discussed above. As noted above, a similar short summary sheet was prepared for the second-level grievance. There is no indication whether Mr. Whitley was provided with a copy of the memorandum prepared for the third- level grievance or the summary sheets prepared for both the second and third-level grievances.

> notes indicate that member had transplant evaluation done and was to receive LVAD as bridge. However, HR was later notified that the LVAD was for destination; that she would have the LVAD for the remainder of her life. HAYES report rating was "C" for destination and "A for bridge to transplant and "B" for bridge to recovery.

AR p. 536. In addition to the type of materials listed previously, this form indicates that "other" materials are also provided. As noted above, however, it is impossible to discern from the record what materials were provided to or reviewed by this or the earlier grievance panel.

According to notes written on the summary sheet, the Panel voted to disallow the claim based on both a failure of notice and the Experimental Exclusion: "Prior auth was requested for CABG, not LVAD. LVAD is considered experimental for use as a permanent destination therapy. Therefore is an exclusion of certificate. Cert does not cover experimental/investigational." AR p. 536.

On October 26, 2005. Teresa Brooks (a member of the third-level grievance panel) emailed James Zupon, with copies to the other two panel members (Karen Phillips and Patricia Ortiz), stating that the hearing was conducted at 1:00 p.m. on October 25, 2005, and that the hearing committee met the following day to discuss the case. Brooks states that they "reviewed all documents provided and took into consideration the discussion at the hearing" and then voted to deny the claim based on: (1) a lack of prior authorization for the LVAD (stating that the records mention only CABG); and (2) evidence that LVAD was solely for destination. As to the latter, she states: "Since the LVAD was for destination, HAYES indicates a 'C Rating' which states experimental. According to the CCP certificate . . . this is an exclusion to the member's benefit." AR p. 538.[42]

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[42] This email and the above quoted notes do not distinguish between *notice* of LVAD for bridge and *notice* of LVAD for destination purposes. Rather, the assumption seems to be that there is no evidence that LVAD was approved for any purpose and that the only approval was for CABG. The notes provided to the third-level grievance panel, however, suggest that LVAD *was* approved as a bridge to transplant. Moreover, the denial of the second-level grievance did not rest on a lack of notice.

On October 28, 2005, Dee Goodman, on behalf of the Plan, wrote Mr. Whitley advising him of the Plan's denial of his "third-level grievance." She states:

> Our Hearing Review Panel has carefully reviewed your grievance and all supporting documentation and has determined that we correctly processed your claims in accordance with your Certificate of Coverage.
>
> The Panel's decision was based on the following:
>
> Carolina Care Plan utilizes the HAYES rating system and HAYES rated the LVAD experimental/investigational for use as a permanent destination therapy. Since the LVAD was considered experimental, investigational or unproven on the date of Ms. Whitley's surgery, the Panel determined it is an exclusion of the member's Certificate of Co[verage] and is therefore not a covered service.

AR p. 532. The letter then quotes the exclusion for Experimental, Investigational or Unproven Services. The letter also states that the "*notification protocol* was not followed" as the Plan's records do not reflect notice of Duke's plan to implant an LVAD until after the procedure was completed. AR p. 533 (emphasis added). The letter then states that the decision completed all levels of the grievance process. AR p. 533.

Post-grievance Communications.

December 2005. On December 7, 2005, Mr. Whitley had a conversation with James Zupon, the Plan's Manager of Compliance, Complaints and Grievances, relating to Mrs. Whitley's claims for treatment at Duke. *See* AR p. 3 (Zupon's December 14, 2005 letter discussing call and responding to inquiries raised). In response to Mr. Whitley's request that the Plan "[e]xplain the protocol that wasn't followed that lead to the denial of benefits," Zupon explains that the difficulty was "the procedure that was performed, rather than a disregarded protocol." AR p. 3.[43] Zupon

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[43] The only "protocol" listed in the denial letter was the "notification protocol." *See supra* p. 42 (quoted AR p. 533).

further explains that "the LVAD for destination therapy *was considered by HAYES* to be experimental at the time of service." *Id.* (emphasis added). He then asserts that the Plan was not aware before the surgery that Duke intended to place an LVAD *for destination therapy purposes and, had it been so informed, would have advised Duke that the service would not be covered.* [44]

As to the possible need for a future replacement of the LVAD implant, Zupon states: "As you are aware, the LVAD for destination therapy is currently no longer considered experimental or investigational by HAYES." AR p. 3. Nothing in this letter indicates *when* HAYES made the change or on what materials it relied in changing its published opinion. No other evidence has been presented as to when this change occurred or on what information the change was based.

CONCLUSIONS OF LAW

Based on the evidentiary record as summarized above, the court reaches the following conclusions of law.

A. NOTICE

1. The Plan failed to timely assert and later abandoned lack of notice as a basis for denial of the claim.

ERISA requires every employee benefit plan to:

> (1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and (2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair hearing by the appropriate named fiduciary of the decision denying the claim.

29 U.S.C. § 1133 (1988).

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[44] Thus, to the extent notice is mentioned, it is only in explaining that Duke would have been advised that the LVAD would be treated as experimental if the Plan had known of its intended use. There is no suggestion in this letter that the Plan was not advised of the intent to implant an LVAD for any purpose or of lack of notice as a grounds for denial of the claim.

Corresponding regulatory provisions, likewise, require that notices of benefit denials provide "the specific reason or reasons for the adverse determination" as well as "[r]eference to the specific plan provisions on which the determination is based." 29 C.F.R. § 2560.503-1(g)(1)(i) & (ii). ERISA regulations also require every employee benefit plan to "establish and maintain a procedure" which affords "a reasonable opportunity to appeal an adverse benefit determination to an appropriate named fiduciary of the plan, and under which there will be a full and fair review of a claim and adverse benefit determination." 29 C.F.R. § 2560.503-1(h)(1).

As the Fourth Circuit has recognized,

> These procedural guidelines are at the foundation of ERISA. Congress intended that ERISA provide plan administrators and participants the opportunity and freedom to resolve internal disputes without necessarily having to resort to the expense and delay of the courts. . . . Given this goal, Congress assured plan participants of procedural fairness, by mandating that plan administrators provide a "full and fair review" of the claims and the specific reasons for claim denials. In the words of the Third Circuit, "'full and fair review' must be construed not only to allow a pension plan's trustees to operate claims procedures without the formality or limitations of adversarial proceedings but also to protect a plan participant from arbitrary or unprincipled decision-making."

Weaver v. Phoenix Home Life Mut. Ins. Co., 990 F.2d 154, 157 (4th Cir. 1993) (quoting *Grossmuller v. International Union, United Auto., Aerospace and Agric. Implement Workers of Am.*, 715 F.2d 853, 857 (3d Cir. 1983)).

Numerous communications between the Plan and Mrs. Whitley or Duke precede the denial of the first grievance. At least three of these communications expressly address denial of the claim. All three refer only to the Experimental Exclusion.

The first such communication was a teleconference between the Plan and Duke on October 15, 2004. The Plan's notations regarding this teleconference indicate that Duke was advised that the claim might be denied based on the Experimental Exclusion. AR p. 224 & 227. The next two

communications are in the form of denial letters. The earlier letter is dated October 19, 2004, and was directed to both Duke and Mrs. Whitley. AR p. 28. This letter refers only to the Experimental Exclusion as a basis for denial. The Plan repeated this basis for denial of coverage of the LVAD on November 4, 2004, when it advised Duke that it would not approve a heart transplant. AR p. 29-30. As with the prior call and letters, this letter makes no mention of a concern as to the adequacy of notice.

The only pre-grievance document which suggests any concern as to notice is Hardin's October 13, 2004 computer entry. This entry refers only to a concern that the Plan was not advised of Duke's intent to implant the LVAD *for destination therapy*. There is, however, no evidence that Hardin or any other Plan representative communicated these concerns to Duke or the Whitleys until after the first-level grievance was concluded.

The January 18-19, 2005 email string in which Dr. Hutt recommended denial of the first-level grievance, likewise, fails to mention any concern as to the adequacy of notice. Indeed, Dr. Hutt recommended only that the claim be "*sen[t] out denied as experimental*," and that the plan "handle any other re-review on the appeals side if it comes to that." AR p. 43 (Hutt email dated January 19, 2005–emphasis added). Donald Pifer, Vice President of Network Management, forwarded Dr. Hutt's comment on to Renee Bouye who responded that she would notify Dee Goodman "to *send out the denial based on the COC we don't cover experimental investigational or unproven* and the Hayes rating was a C or D." AR p. 42 (emphasis added).

This string was forwarded to Goodman at 11:39 a.m. on January 19, 2005. There are no intervening documents or other evidence which would explain why and on whose authority Goodman included lack of notice as a reason for denying this grievance. Nonetheless, the letter suggests that the source was Dr. Hutt: "Our Medical Director reviewed your medical records and

determined that we did not receive notification from you or the hospital requesting services for the Left Ventricular Assistance Device ('LVAD')." AR pp. 25-26. Moreover, this letter suggests a complete lack of notice of an intent to implant an LVAD, rather than relying on the change in purpose between bridge and destination therapy. In any case, this letter, which denied the first-level grievance, constitutes the first notice from the Plan to the Whitleys or Duke that the claim might be denied for lack of notice.

The claim proceeded to a second-level grievance. That grievance was also denied, but only on the basis of the Experimental Exclusion. Lack of notice is not mentioned in the denial letter. AR p.389. Thus, the Plan abandoned lack of notice as a denial reason by not including it in its denial of the second-level grievance.

The letter denying the second-level grievance appears to have crossed in the mail with Mr. Whitley's letter indicating that he had been granted an extension of time to provide materials in support of his second-level grievance. AR pp. 399. The Plan treated this as an invocation of the third-level grievance procedure, rather than as a reason to reopen the second-level grievance.

Presumably recognizing that lack of notice had been abandoned as a denial reason , the Plan instructed the third-level grievance panel: "This is an issue of benefits. The panel should focus on this issue and this issue alone." AR p. 539-40. Thus, the third-level grievance panel was not asked to address the issue of notice.[45]

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[45] The summary provided to the third-level grievance panel also stated: "HR notes indicate that member had transplant evaluation done and *was to receive LVAD as bridge*. However, HR was later notified that the *LVAD was for destination*; that she was to have the LVAD for the remainder of her life." AR p. 536 (Grievance Hearing Summary Sheet– emphasis added). This statement suggests that the Plan was aware that Duke intended to implant an LVAD, but was unaware of the particular purpose for which the LVAD was to be implanted (bridge versus destination). Thus, the statement appears to be included to explain why the Plan did not forewarn Duke that the Plan would

Despite this directive and without any notice to the Whitleys of its intent to consider notice, the Plan again relied on lack of notice in denying the third-level grievance. As in the letter denying the first-level grievance, the third-level grievance denial letter asserts that the Plan had no notice of *any* intent to implant an LVAD. AR p. 532-33 ("Our records also indicate that [the] Plan's notification protocol was not followed as our records show *we were first notified of the LVAD on October 12, 2004, which is post-surgery.*").[46]

After receiving the denial letter from the third-level grievance panel, Mr. Whitley called James Zupon to discuss the matter further. Zupon responded in a letter dated December 14, 2005 in which he repeats the inquiry and provides a response as follows:

> **Explain the protocol that wasn't followed that lead to the denial of benefits?** It was the procedure that was performed, rather than a disregarded protocol that lead to the denial of benefits. As indicated in our grievance response letters, the LVAD for destination therapy was considered by HAYES to be experimental at the time of the service.

AR p. 3. The reference to a "protocol" clearly refers to the third-level grievance panel's reference to the "Plan's notification protocol." AR p. 533 (letter denying third-level grievance, quoted above). Thus, Zupon's disavowal of reliance on a protocol failure indicates a renewed abandonment of this

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deny coverage, under the Experimental Exclusion, if the purpose of the LVAD implant was for destination therapy.

[46] The third-level grievance panel's conclusion that the Plan received *no notice* of an intent to implant an LVAD *for any purpose* is inconsistent with any *evidence* which has been disclosed as having been given to the panel. *E.g.* AR p. 536 (quoted in preceding footnote). It would, however, be consistent with the *unsupported characterizations of the record* found in the email Barbara Excell forwarded to James Zupon upon receipt of the third-level grievance. This email stated: "CCP did not authorize the LVAD. CCP was informed of and authorized a complicated CABG . . . . Duke performed a right heart prophylactic CABG and a LVAD that CCP did not authorize or even know about until after the procedure."). Thus, the third-level grievance panel may have relied on erroneous information provided in Excell's email..

denial reason. What other discussion of notice appears in his letter suggests only that, had the Plan had complete information from Duke prior to the surgery, it could have forewarned Duke that the service would not be covered. It does not suggest that the Plan is relying on notice as an independent denial reason.[47]

Despite Zupon's apparent abandonment of notice as a denial reason, the Plan persists in relying on notice as a denial reason. Specifically, the Plan maintains that it did not receive notice of Duke's intent to implant an LVAD *for any purpose* prior to the date of the surgery. *See, e.g.,* Dkt No. 25, p. 2.

Based on the above sequence of events, the court concludes that notice was not timely raised as a denial reason, was subsequently abandoned, and cannot be relied on in this action. Critically, the facts underlying the notice-based denial were known to the Plan no later than October 13, 2004. No explanation is offered for the delay in raising this denial reason. Neither is there any explanation for the decision to again rely on this denial reason in denying the third-level grievance after not having mentioned it as a denial reason in its letter denying the second-level grievance. By relying on a previously abandoned denial reason in the denial of the final grievance, the Plan deprived Mrs. Whitley of her statutory and regulatory rights to a full and fair review. Finally, the court finds notice was again waived and abandoned as a denial reason in James Zupon's post-grievance letter to Mr. Whitley which disavowed reliance on any "protocol" failure.

As a general rule, late raised denial reasons are remedied by remanding the claim for a full

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[47] In this regard, the letter states: "The notes also indicate the decision to do an LVAD for destination rather than the planned CABG was not made until Saturday, October 9, 2004 [citing Dr. Milano's notes]. [The Plan] was not notified of the decision to perform the LVAD for destination until Tuesday October 12, 2004 . . . one day after the surgery. *Had we been notified of the request for an LVAD prior to this, we could have informed you and Duke it would not be covered.*" AR p. 3 (emphasis added).

and fair review. *Weaver,* 990 F.2d. at 159. This rule may, however, be modified in extraordinary circumstances. *See id.* For example, in *Weaver*, the court found the circumstances to justify entry of judgment in favor of plaintiff where the plan "admitted that it [did] not know the standards by which the decision . . . was made [by the third party administrator] and . . . produced no evidence that it even remotely considered any specific reasons in denying the claim." *Id.*

The undersigned concludes that the present case presents the type of extraordinary circumstances which justify precluding the Plan from relying on a late-raised denial reason. These extraordinary circumstances include: (1) the Plan's delay in raising lack of notice as a denial reason *despite full knowledge of the relevant facts* prior to the first denial; (2) the Plan's abandonment of notice as a denial reason by failing to rely on lack of notice in denying the second-level grievance; (3) the Plan's failure to otherwise advise the Whitleys of its intent to rely on lack of notice during the third-level grievance; and (4) the Plan's disavowal of reliance on a "protocol" failure in Zupon's post-grievance letters.

Finally, the court finds that denial for lack of notice is unfounded for reasons discussed in the remainder of this order. Therefore, remand for reconsideration of this denial reason would be futile.

2. Duke complied with the Plan's notice requirements.

Because Duke is a Network Provider, the following provision of the Plan document controls notice:

> We require notification before you receive certain Covered Health Services. In general, Network providers are responsible for notifying us before they provide these services to you. Your Provider cannot bill you for these services if they fail to notify Us.

AR pp. 874-75 (also indicating, specifically as to non-network providers, that notice provides an

opportunity for the Plan to advise if the service is excluded from coverage). While it is possible that some greater detail as to the required notice is provided in whatever agreement controls the Plan-Network Provider relationship, no such agreement has been provided to the court or referenced by the parties. Thus, the only "notice" requirement is the very generic requirement quoted above.

It is undisputed that Duke gave notice of and received approval to perform heart surgery on Mrs. Whitley and to evaluate her for a possible heart transplant. The precise scope of the authorized surgery is less clear, largely because the Plan has been inconsistent in stating what was approved. Nonetheless, Plan documents created before surgery require the conclusion that the Plan approved, at the least, high-risk CABG. AR p. 6 (Hardin's October 7, 2004 computer entry indicating Duke had decided to "proceed with a CABG on Monday").

Plan documents created shortly after surgery also support the conclusion that the Plan gave prior approval for implantation of an LVAD. Indeed, the only "notice" concerns expressed in the contemporaneous records relate to the precise purpose for which the LVAD was to be implanted. *See* AR p. 9 (Hardin's October 12, 2004 computer entry indicating that LVAD was placed as bridge to transplant, and stating no concerns as to notice or approval); AR pp. 221-22 (Hardin's October 13, 2004 computer entries expressing surprise and concern that the LVAD was implanted *as destination therapy*, rather than as a bridge to transplant); AR 537 (third-level Grievance Hearing Summary Sheet acknowledging that HR knew member "was to receive LVAD." Thus, there is no evidence to support denial on the basis stated by the third-level grievance panel, which relied on the unsupported assumption that the Plan had received no notice at all of an intent to implant an LVAD.

The court's review of the extensive record suggests only one document on which the third-level grievance panel might have rested such a conclusion. That document is Barbara Excell's email

to James Zupon which claimed that the Plan had received *no notice* of Duke's intent to implant an LVAD. AR p. 675. There is no evidentiary support for this assertion.[48]

Moreover, the summary which was provided to the grievance panel acknowledged that the Plan received notice of Duke's intent to implant an LVAD. AR p. 537 (asserting, nonetheless, that the Plan was only aware of an intent to implant the LVAD as a bridge to transplant). The divergence between the statements in the two records and the panel's ultimate determination that the Plan received no notice of the intent to an implant an LVAD suggest that Excell's email with its inaccurate statements (and reference to Dr. Hutt's views) may have been provided to and relied on by the panel.

Documents cited by the Plan in support of denial for lack of notice do not support its position. Indeed, the documents cited by the Plan are not even evidence of what notice the Plan received.[49] Nowhere does the Plan adequately address the clear inference from Hardin's computer entries: that the Plan did receive notice of an intent to implant an LVAD and the only concern related to a possible change in the purpose of the implant. Thus, there is no evidence to support the Plan's position that it received *no notice* at all of the intent to implant an LVAD.

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[48] There is no evidence that Excell would have first-hand knowledge of the relevant events. The primary (if not sole) Plan representative with such knowledge is Hardin. What evidence exists of Hardin's knowledge suggests concerns only regarding a change in the purpose for which the LVAD was to be implanted.

[49] The documents cited by the Plan in support of its claim that it received no notice of Duke's intent to implant an LVAD consist of the letter written by Zupon in December 2005 (AR p. 3) and the October 9, 2004 report of Dr. Milano addressing the decision to implant an LVAD for destination therapy (AR pp. 7-8). *See* Dkt No. 25 at 2 (citing AR pp. 3 & 7-8). Neither constitutes evidence of what notice was provided to the Plan. The December 2005 letter is merely a summary provided by James Zupon, who would have no direct knowledge of what notice the Plan received. Similarly, Dr. Milano's notes do not evidence what notice was provided to the Plan, only what decisions he made and communicated to the Whitleys.

The court would also find in Plaintiff's favor if the notice-based denial reason was construed more narrowly, as being based on a change in the *particular purpose* for which the LVAD was implanted. While the existence of such a concern is supported by Hardin's contemporaneous notes, there is no evidence which would support either a finding that Duke represented that the LVAD would *only* be implanted as a bridge-to-transplant or that the Plan imposed such a limitation on the approval which was given to implant an LVAD for some purpose.

The most direct evidence of pre-surgery notice is contained in the letter from Duke dated November 22, 2004. This letter expressly states that the author personally received repeated pre-surgery approvals to implant the LVAD from the Plan (generally from Hardin), as well as a blanket approval to do whatever was necessary to save Mrs. Whitley's life. There are no documents in the record which directly contradict the statements in this letter.[50]

In short, while the Plan may have made assumptions as to the purpose for which the LVAD would be implanted, there is no evidence that the Plan advised Duke that any approval was limited based on the specific purpose of the implant or that Duke misled the Plan as to its intentions. Moreover, in light of the general acceptance of LVAD implantation for destination purposes (discussed *infra* Conclusions of Law § B), there was no reason for Duke to assume that the Plan might treat approval differently given the specific purpose.

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[50] The only notice-related Plan documents prepared by someone with first -hand knowledge are the computer entries made by Hardin prior to and soon after the surgery. While LVAD is not mentioned in any pre-surgery entry, Hardin's post-surgery statements suggest surprise only at the purpose for which the LVAD was implanted, not surprise that it was implanted at all. There are no records prepared by any individual with first-hand knowledge which directly challenge Duke's characterization of the pre-surgery communications between Duke's representatives and the Plan's representatives.

3. Purpose for which the LVAD was implanted.

The only close question relating to notice is the true purpose for which the LVAD was implanted. There is substantial evidence to support the conclusion that Duke referred to the placement as destination therapy in one of Mrs. Whitley's records. This same record supports the conclusion that Duke implanted the LVAD with the knowledge that a transplant might never be possible.

At the same time, all records indicate a hope and goal of improving Mrs. Whitley's condition sufficiently that she could become a transplant candidate. Thus, the true purpose of the implant was something of a hybrid between destination therapy and a bridge-to-transplant. Under these circumstances, there was no clear line between the two purposes for which an LVAD might be implanted and Mrs. Whitley's condition placed her in an area of shifting purpose.

The Plan was, at the least, on notice of the uncertainty as to purpose. This is because Mrs. Whitley was still subject to evaluation as a heart transplant candidate at the time the LVAD was implanted.[51] Obviously, if that evaluation came back negative, as it ultimately did, an LVAD installed as a bridge-to transplant would become destination therapy.

4. Conclusion as to Notice

Both for procedural and factual reasons, the court finds that the Plan abused its discretion when it relied on lack of notice as a reason to deny the first and third-level grievances. The

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[51] This was the very purpose of the URN-Review which was still in the process of being completed at the time of Mrs. Whitley's surgery. The URN-Reviewer concluded that, while she was not then a good transplant candidate, placement of an LVAD might enable Mrs. Whitley to improve her condition sufficiently to change that conclusion. The URN-Reviewer, therefore, concluded that implantation of an LVAD was the most appropriate treatment option for Mrs. Whitley unless and until her condition changed.

procedural reasons include: (1) failure to timely raise lack of notice as a denial reason; (2) abandonment of lack of notice as a denial reason in the denial of the second-level grievance; and (3) consideration of lack of notice as a denial reason at the third-level grievance stage without prior notice of the intent to do so. In addition, the court finds that the Plan waived lack of notice as a denial reason after conclusion of the grievance process when it advised Mr. Whitley that it was not relying on any "protocol" failure.

The court also finds that the Plan abused its discretion in denying the claim on this ground because it lacks substantial evidence to support a finding of lack of notice. This is, in part, because the Plan documents do not contain language which would require any more precise notice than was clearly given: notice of an intent to implant an LVAD for treatment of a failing heart. Moreover, there is no substantial evidence to support the conclusion that the Plan was advised that Duke would only implant the LVAD for bridge-to-transplant purposes or that the Plan advised Duke that the approval to implant the device was so limited. Finally, the Plan has failed to present evidence to contradict the statements contained in Duke's letter indicating that blanket approval was given to do whatever was necessary to save Mrs. Whitley's life.

The above decisions have been made applying a modified abuse of discretion standard of review. The court would, however, reach the same conclusion were it to apply the unmodified abuse of discretion standard of review.

B. Experimental Exclusion.

Reading the relevant definitions ("Covered Health Services" and "Experimental, Investigational or Unproven Services") together yields six independent criteria.[52] All of these

[52] Each definition includes four criteria. After elimination of overlapping criteria, however, only six total criteria remain.

criteria, summarized below, must be satisfied for a service not to be excluded under the Experimental Exclusion:

1. meet national medical standards of practice;

2. be consistent with conclusions of prevailing medical research that demonstrate that the health service has a beneficial effect on health outcomes based on either well-conducted randomized controlled trials or well-conducted cohort studies;

3. be a cost-effective method that yields a similar or better outcome to other available alternatives;

4. be approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use and be identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use;

5. not be subject to review and approval by any institutional review board for the proposed use; and

6. not be the subject of an ongoing clinical trial that meets the definition of a Phase 1, 2, or 3 clinical trial set forth in the FDA regulations.

See supra p. 11-12 (quoting relevant definitions in full); AR p. 922 & 924 (definitions in Plan documents).

In arguing that implantation of an LVAD for destination purposes fell within the Experimental Exclusion in October 2004, the Plan relies solely on the second criteria listed above which requires that the service be "consistent with conclusions of prevailing medical research ...."

See Dkt No. 25 at 2-3 & 7-9.[53] Thus, the Plan concedes, *sub silentio,* that the other five criteria are satisfied.

In support of its argument that the second criterion was not satisfied at the time of Mrs. Whitley's surgery (in October 2004), the Plan relies exclusively on the HAYES Rating (published in February 2003).[54] For the reasons set forth below, the court finds that the Plan abused its discretion in relying solely on the HAYES Rating to the exclusion of all other evidence of whether LVAD for destination therapy was "consistent with conclusions of prevailing medical research." The court further concludes that proper consideration of all evidence available to the Plan at the time of its final decision compels the conclusion that the service was not excluded under the Plan's Experimental Exclusion.

As in regard to notice, the court reaches this conclusion applying a modified abuse of discretion standard of review. The court would, however, reach the same conclusion under the more deferential, unmodified abuse of discretion standard of review.

1. The Plan's sole reliance on HAYES was not consistent with Plan Documents.

The Plan has consistently relied solely on the HAYES Rating published in February 2003 in denying coverage for Mrs. Whitley's October 2004 surgery. This reliance is demonstrated, *inter*

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[53] Although the Plan purports to rely on this single Plan criteria, it cites two cases addressing a variety of judicially crafted criteria for determining when a service is experimental. Dkt No. 25 at 8. The two cited cases list seven overlapping criteria, none of which support the Plan's denial of Mr. Whitley's claim as discussed in the remainder of this order. In any event, there is no need to resort to judicially crafted criteria when the Plan documents provide a detailed definition.

[54] The definition of experimental services refers to the status of the service "at the time [the Plan] make[s] a determination regarding coverage . . . ." This would suggest that the proper time frame for testing the status of the service was in October 2005, when the third-level grievance panel issued its decision. Nonetheless, for present purpose the court will assume that the relevant date is the date the service was provided.

alia, by Excell's email to Zupon relating to the third-level grievance in which she states: "Just wanted to provide the following information to you from Dr. Hutt on the Carol Whitley case . . . . CCP did not and do[es] not use FDA or Medicare guidelines for authorization and CCP has a track record of using Hayes for several years." AR p. 675. The summary provided the third-level grievance panel, likewise, advised them that the first-level grievance was denied because "Dr Hutt reviewed [the claim] and determined that services were experimental investigational based on a HAYES rating of 'C.'" AR p. 539-40. The same reason is given to this panel for the Plan's initial denial and denial of the second-level grievance. AR p. 536.[55]

Not surprisingly, the third-level grievance panel relied on the HAYES Rating in its letter denying the final grievance. AR p. 532. Zupon, likewise, acknowledged the Plan's reliance on the HAYES Rating in his post-grievance letter explaining the Plan's actions. AR p 3.

Nothing in the record suggests that the Plan ever considered any other evidence of the medical community's acceptance of LVAD for destination therapy as shown by the prevailing medical research and reports. This is despite the fact that such evidence was available to (and in most instances had been obtained by) the Plan itself.[56]

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[55] The third-level grievance panel was told, flatly, that the "HAYES report rating was "C" for destination and "A" for bridge to transplant." AR p. 537. It does not appear that this grievance panel was: (1) told of the date of publication of the HAYES rating on which the Plan relied; (2) provided with a copy of the HAYES Report from which they might determine the date; (3) informed of the existence of the HAYES Update; (4) provided with the URN-Review; or (5) provided with other documentation which suggested the HAYES Rating was out-of-date. It is also unclear whether the panel was provided with a copy of the Peer Review which expressly challenged the Plan's reliance on the outdated HAYES Report.

[56] Other evidence in the record which the Plan could have considered includes the HAYES Update which the Plan obtained in October 2004 and the two outside reviews by experts in the relevant field which were also obtained by the Plan. In addition, Plaintiff provided the Plan with

The Plan does not even appear to have considered evidence which it obtained from HAYES which suggested the need to update the February 2003 HAYES Report. For example, there is no evidence that anyone on behalf of the Plan ever reviewed the HAYES Update which Hardin obtained on October 20, 2004. Similarly, while the Plan obtained the opinions of two outside experts, its only discussion of those opinions consists of explaining why they should not be or were not considered. No document suggests that Dr. Hutt or any grievance review panel ever considered the substance of either the Peer Review or URN-Review. Other documents (*e.g.*, documents evidencing FDA and Medicare approvals) are mentioned only by Plan representatives in the context of explaining that the Plan does not consider such evidence. *See* Excell email to Zupon. AR p. 675.

As noted above, the Plan document in effect at the relevant time sets forth six criteria to be considered in deciding whether a treatment falls under the Experimental Exclusion (summarized above). None of these criteria refer to HAYES or any other published rating. The Plan's exclusive reliance on the HAYES Rating is, therefore, inconsistent with the written requirements of the Plan *unless* the HAYES Rating can be deemed the equivalent of one of the Plan's listed requirements.

The Plan effectively argues for such a determination by relying on the HAYES Rating as determinative of whether the treatment at issue is "consistent with the conclusions of prevailing medical research that demonstrate that the health service has a beneficial effect on health outcomes that are based on trials that meet either [of two specified] designs." Dkt 25 at 3 (Plan's memorandum). The two designs specified in the Plan are "well-conducted randomized controlled trials," and "well-conducted cohort studies." *Id.* (quoting definition).

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evidence relating to FDA and Medicare approval of LVAD as destination therapy.

Certainly, the HAYES rating is not, itself, either a "well-conducted randomized controlled trial" or a "well-conducted cohort study." Rather, HAYES is a third-party service which apparently takes such trials and studies, as well as other evidence, into consideration in reaching its rating decisions. Whether HAYES considered such trials and studies, how it did so, and the weight given to which trials and studies is not, however, revealed by the limited documents provided to the court.[57]

As in *Weaver*, therefore, it appears the Plan has relied on standards established not by the Plan but by a third party. *See Weaver*, 990 F.2d at 159 (discussed *supra* Conclusions of Law §A.1.). While there is evidence that HAYES considers some of the same criteria as the Plan, it is far from clear that the HAYES Rating considers all of the same criteria and in the same way. Thus, it cannot fairly be said that the HAYES Rating is the equivalent of any one of the Plan's criteria or all of them.

Even if the criteria on which HAYES relied in establishing its rating were wholly consistent with the criteria listed in Plan documents, the Plan's absolute reliance on the HAYES Rating would constitute an abrogation of the Plan's fiduciary responsibility. This is because reliance on a rating (or other decision) solely under the control of a third party prevents Plan participants from any meaningful opportunity to present evidence and seek a fair review of any rating with which they disagree.[58]

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[57] The printout of the HAYES Rating explains that the HAYES Rating system "reflects the strength of the evidence regarding efficacy and safety of a medical technology, its impact on health outcomes, indications for use, patient selection criteria, medical consensus, and comparison to alternative technologies." AR p. 66. What specific "evidence" is considered and how it is evaluated or weighed is not revealed.

[58] There is, for instance, no suggestion that Plan participants are able to seek review of the HAYES Rating by HAYES, much less that HAYES would conduct such a review under standards similar to those imposed on ERISA fiduciaries.

Finally, and perhaps most critically, the HAYES Rating on which the Plan relied was published in February 2003. Thus, even if it was reasonable for the Plan to rely on the Hayes Rating as one source of evidence as to whether the above-quoted Plan criterion was satisfied, it was not reasonable for the Plan to rely on this February 2003 rating as the sole evidence of the status of a treatment in October 2004.

2. Even if the Plan language as amended in July 2005 applied, it would not support denial of the claim.

The Plan was amended, effective July 2005, to refer to HAYES "criteria" in the Experimental Exclusion and to the HAYES Rating in related definitions. Obviously, such a *post-hoc* amendment would not control a decision relating to services provided in October 2004.

Even if applicable, the amendment would not support denial of the claim. First, the reference to HAYES "criteria" would only incorporate whatever criteria HAYES considers in issuing its ratings. As noted above, these criteria are not available to the court except to the extent they are generally referenced on the published rating pages found in the record. *See supra* n. 57.

The reference to the HAYES "Rating" in the definitions comes closer to supporting the Plan's position. However, the undersigned concludes that, even under this language, the Plan has an obligation to insure that the rating it relies on is up-to-date and to provide Plan participants an opportunity to challenge the accuracy of the rating through an appeal to someone serving in a fiduciary capacity. To do otherwise would be an abuse of discretion.

In the present case, the HAYES Report relied on was nineteen to twenty months old at the time of Mrs. Whitley's surgery. During those months, significant developments had occurred relating to acceptance of LVAD for destination purposes. These developments included the

extension of Medicare coverage to implantation of LVADs for destination therapy which was changed effective October 1, 2003, a year before Mrs. Whitley's surgery.[59]

In addition, numerous studies had been completed and reports of them published during this period as disclosed by the abstracts listed in the HAYES Update covering the period January 1, 2004, through October 20, 2004.[60] This Update advised the user that the "summary is based only on the published abstracts [and] *any coverage decisions or changes in policy should be based on review and analysis of complete study reports*." AR p. 484 (emphasis added). It further advised that: "Changes in HAYES Ratings™ will be made only after the HAYES Medical Technology Directory™ report has been reviewed and updated." *Id.* (emphasis added). Despite these caveats, there is no evidence that the Plan ever considered the contents of the abstracts or the underlying articles.

Absent evidence to the contrary, and none is offered, HAYES' subsequent change of its Rating may reasonably be presumed to have been based, at least in part, on materials contained in the Update obtained in October 2004. The court will, therefore, assume that HAYES itself

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[59] Given the date of this approval (October 2003), it could not have been considered in the February 2003 HAYES Report. It would, however, appear to be the type of information which HAYES would otherwise have considered. *See* AR p. 17 (HAYES Report stating that the HAYES rating system "reflects the strength of the evidence regarding efficacy and safety of a medical technology, its impact on health outcomes, indications for use, patient criteria, medical consensus and comparison to alternative technologies."); *Id.* (stating that "Medical devices with an A rating have FDA approval, but not necessarily for a specific clinical application."); AR p. 18 (defining "B" rating to include drugs and devices "approved by the FDA for other applications or indications. It may be endorsed in a limited/restrictive context by a federal agency or a scientific organization for the application under consideration.").

[60] Even this extensive listing would not be complete as it does not include materials published from February 2003 through December 31, 2003.

considered the various articles abstracted in the Update to support a change in rating.[61]

3. The Plan failed or refused to consider substantial, unbiased evidence that LVAD for destination was not experimental as defined in the Plan and that the HAYES Rating was out of date.

As noted above, the HAYES Rating on which the Plan relied was published nineteen to twenty months prior to Mrs. Whitley's surgery. This alone suggests the need to update the HAYES Rating.

The Plan took the first step in that direction by obtaining the HAYES Update. There is, however, no evidence that any Plan representative ever read the Update which provided abstracts of sixty-two articles and studies or obtained and considered any of the abstracted articles. Notably, the HAYES Update itself advised the Plan that such review was necessary.

Neither did the Plan heed the notice on the HAYES Update that such an extensive listing of articles would lead to a new review of the status of LVAD for destination therapy. Thus, with notice of possible concerns with the February 2003 HAYES Rating *as stated by HAYES itself*, the Plan failed to consider information available from the same service which might lead to a different Rating.

The Plan also failed or refused to consider evidence from other sources, most critically the recommendations of the Peer Review and the URN-Review. Both reviews were prepared by experts in the relevant medical field and at the Plan's request. Both also support the conclusion that implantation of an LVAD for destination therapy did not fall within the Plan's Experimental Exclusion as of the date of Mrs. Whitley's surgery.

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[61] The record does not reveal when the HAYES rating changed. It is, however, clear that the change occurred sometime before Zupon's December 7, 2005 letter was written. It also appears likely that the change was triggered, in part, by the HAYES Update obtained by the Plan on October 20, 2004, given that the printout of this Update expressly states: "The search findings will trigger a review of the existing HAYES Medical Technology Directory Report." AR p. 484.

In his report, the Peer Reviewer addressed a series of Plan-drafted inquiries directly related to application of the Plan's Experimental Exclusion. These included the following query: "Based on all information reviewed, including the Hayes Rating and the definition of experimental investigational or unproven services outlined in the member's Benefit Handbook, would placement of the Left Ventricular Assistance Device for 'destination therapy' be considered an investigational and/or experimental device?" The Peer Reviewer answered this inquiry: "No." *See supra* p. 26 (discussing AR pp. 33). He also answered "Yes" to the following question: "Based on all information reviewed does the member have benefits for a Left Ventricular Assistance Device?" *Id.*

The Peer Reviewer expressly found that the "HeartMate LVAD procedure in question did not meet any of the four criteria listed [in the Handbook] for non-coverage." He addressed these criteria as follows:

> * FDA Approval - LVAD placement is approved by the FDA for all applications from acute failure to wean from bypass after heart surgery, to bridge to transplantation, to destination therapy.
>
> * IRB approval needed . . . The procedure did not require review or approved informed consent by The Duke Institutional Review Board.
>
> * The procedure was not part of an ongoing clinical trial.
>
> * The procedure is not listed as a non-covered service in the benefit handbook.

AR p. 33.

The reviewer also criticized the Plan's reliance on HAYES, noting that the HAYES rating on which the Plan relied:

> was published about two years ago (February 2003) and does not take into account the large clinical experience in LVAD support which has occurred to date. (Annals of Thoracic Surgery. 2004, April; 1321-7 and Surgical Clinics of North America 2004. Feb; 91-123.) This improved durability of LVAD systems as well as

> decreased incidence of complications would justify a higher rating than C for current applications of this technology.

AR p. 33.

The Plan has provided no reasonable explanation for its rejection of the Peer Reviewer's thorough and well-supported opinion which relied, in part, on specifically referenced studies published since February 2003 (the publication date of the HAYES Rating). There is, in any case, no discussion in the third-level grievance panel's decision which would suggest that it considered and rejected the opinion of the Peer Reviewer on its merits. It is not even clear that the actual Peer Review was provided to the grievance panel. Instead, it appears that the panel was, effectively, directed to disregard the substance of the Peer Review because the Plan had obtained the opinion unnecessarily. *See* AR p. 537 (advising panel that the "Peer Reviewer determined that the LVAD was not experimental. However, it was later determined that the grievance was a benefit issue and not medical.").

The Plan also elected to disregard the views of the URN-Reviewer. While the report of the URN-Reviewer was not directed expressly to the status of LVAD implantation for destination therapy, his comments do address relevant Plan criteria and support the conclusion that LVAD for destination therapy would not be excluded under the Plan's Experimental Exclusion. *See supra* at 23-24 (discussing URN-Review).

Additional documentation provided by Mr. Whitley, most notably the change in the Medicare coverage stance as of one year before Mrs. Whitley's surgery, was also dismissed by the Plan as irrelevant. *See* AR p. 675 (Excell email to Zupon, quoted *supra*). The court disagrees. While not determinative, evidence of Medicare coverage is certainly relevant to whether the service "meet[s]

national medical standards of practice" and satisfies various other Plan criteria. Likewise, FDA approval of use of a device for a particular purpose is relevant under the express terms of the Plan.[62] *See supra* p.55 (fourth criterion). Indeed, HAYES would appear to consider both in its evaluations. *See supra* n. 57 & 59.

4. Substantial evidence compels the conclusion that LVAD for destination therapy was not experimental in October 2004.

The Peer Review and URN-Review were both prepared by specialists in the relevant field. Both address the standing of LVAD for destination therapy in the context of criteria found in the controlling Plan document. Neither finds any Plan criteria which would support the conclusion that the treatment is experimental as that term is defined in the Plan. Other documents submitted by Mr. Whitley, including those relating to FDA approval and Medicare coverage, likewise support a finding that the treatment was, in October 2004, not experimental as defined by the Plan documents when used for destination therapy.

The Plan, by contrast, relies solely on an outdated HAYES Rating. It does not address the relevant criteria as set out in the Plan or explain why the opinions of either the Peer Reviewer or URN Reviewer should be rejected. Under these circumstances, the court finds that the Plan lacks substantial evidence to support denial of the claim based on the Experimental Exclusion.

5. The Plan's decision-making process was neither reasoned nor principled.

The Plan's refusal to consider any evidence other than the HAYES Report is, itself, strong evidence that the Plan's decision-making process was neither reasoned nor principled. In addition, the particular procedures followed demonstrate that Mr. Whitley was never given a fair and unbiased

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[62] Mr. Whitley also provided information regarding the change in FDA approval.

review at any stage of the Plan's grievance process. Indeed, it appears that the original decision-maker, Dr. Hutt, influenced the entire process, either directly or through reports written by others, thus precluding any unbiased review.

For example, it is beyond doubt that Hutt directed the denial of the first-level grievance. He also provided his opinion though oral statements to the second-level grievance panel. In addition, the written materials provided to both the second and third-level grievance panels strongly encouraged them to treat the HAYES Report as controlling when, in fact, its application and currency were central issues.

The third-level grievance panel's reliance on lack of notice as a denial reason also suggests that they were provided with a copy of Excell's email to Zupon. In addition to providing incorrect information as to notice, this email interjects Dr. Hutt's opinion by stating: "Just wanted to provide the following information to you *from Dr. Hutt* on the Carol Whitley case as second [sic] level is the next step." The email then advises Zupon that "CCP did not and do[es] not use FDA or Medicare guidelines for authorization and CCP has a track record of using Hayes for several years."

There is no evidence that either of the latter two panels was asked to consider the Plan's criteria and information which supported Mr. Whitley's position, including the two external reviews obtained by the Plan. The latter were mentioned only in discounting them as irrelevant or as having been improperly obtained. Finally, there is no evidence that the latter two grievance panels were provided with information which reflected on the continued validity of the published HAYES Rating, including the HAYES Update.[63] These errors demonstrate that the Plan failed to provide a

[63] In addition to the above errors, the court notes that the Plan has failed to maintain the record in a way which would allow the court to determine what evidence was provided to and considered by the third-level grievance panel. This has left the court to draw inferences based on

full and fair review.

6. Conclusion as to Experimental Exclusion.

The Plan lacked substantial evidence to support its conclusion that LVAD for destination therapy fell within the Experimental Exclusion at the time of Mrs. Whitley's surgery. The Plan's decision and decision-making process ignored Plan language and precluded the Whitleys from obtaining a full, fair and unbiased review. The court, therefore, finds that the Plan abused its discretion both in its ultimate decision and in the process used to reach that decision.

CONCLUSION

For the reasons set forth above, the court grants the motion to strike the affidavit of Dr. Hutt, and finds Plaintiff is entitled to judgment in his favor on the substantive claim. The court defers entry of final judgment to allow briefing on the issue of the proper amount of damages[64] and to allow Plaintiff to submit his application for attorneys' fees. Briefing on the latter should address the effect of *McKenzie*. Plaintiff shall file his application for fees and support as to the proper amount of damages no later than January 14, 2007. The normal time frames for briefing of motions shall apply.

IT IS SO ORDERED.

s/ Cameron McGowan Currie
CAMERON MCGOWAN CURRIE
UNITED STATES DISTRICT JUDGE

Columbia, South Carolina
December 27, 2006

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the arrangement of the record and the minimal discussion found in the panel's notes and emails. Those inferences suggest that the panel did not receive or consider the evidence favorable to Plaintiff, or even the evidence on which the Plan itself relied. As noted in the text, the latter, particularly the HAYES Report and Update, contained information which should have put the panel on notice of the need to consider the more recent information.

[64] The court has been provided with the total amount of the medical charges. It is not, however, clear whether that amount should be reduced to account for co-payments or deductibles.