*2006 U.S. Dist. LEXIS 93802, **

Jerry **Whitley,** as Personal Representative of the Estate of Carol **Whitley,** Plaintiff, v. **Carolina Care Plan,** Inc., Defendant.

C/A NO. 3:06-257-CMC

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF SOUTH CAROLINA, COLUMBIA DIVISION

2006 U.S. Dist. LEXIS 93802

December 27, 2006, Decided

CORE TERMS: grievance, destination, hutt, notice, transplant, experimental, therapy, rating, investigational, third-level, patient, implant, bridge, surgery, peer review, email, second-level, candidate, update, transplantation, memorandum, declaration, clinical, implanted, denial letter, first-level, notation, protocol, reviewer, implantation

COUNSEL: **[*1]** For Carol **Whitley,** Plaintiff: Mary Abby Edwards, LEAD ATTORNEY, McGougan Law Firm, N Myrtle Beach, SC; Rachel North-Coombes, LEAD ATTORNEY, Foster Law Firm, Greenville, SC; Robert Edward Hoskins, LEAD ATTORNEY, Foster and Foster, Greenville, SC.

For Jerry **Whitley,** as Personal Representative of the Estate of Carol **Whitley,** Estate of Carol **Whitley,** Plaintiff: Mary Abby Edwards, LEAD ATTORNEY, McGougan Law Firm, N Myrtle Beach, SC; Robert Edward Hoskins, LEAD ATTORNEY, Foster and Foster, Greenville, SC.

For **Carolina Care Plan** Inc, Defendant: Michael Brian Magargle, LEAD ATTORNEY, Constangy Brooks and Smith, Columbia, SC; Mitchell Myron Willoughby, Noah M Hicks, II, LEAD ATTORNEYS, Willoughby and Hoefer, Columbia, SC.

JUDGES: Cameron McGowan Currie, UNITED STATES DISTRICT JUDGE.

OPINION BY: Cameron McGowan Currie

OPINION: OPINION AND ORDER

Through this action, Plaintiff, Jerry **Whitley** ("Mr. **Whitley**" or "Plaintiff") seeks a determination that Defendant, **Carolina Care Plan,** Inc. ("Plan"), abused its discretion when it denied his deceased wife's claim for coverage of certain medical procedures. The matter is currently before the court on Mr. **Whitley's** motion to strike the declaration of **[*2]** the Plan's medical director, Edward D. Hutt, M.D. ("Dr. Hutt"), Dkt No. 26, as well as for a decision on the merits based on the parties' written submissions. *See* Dkt No. 9 (Joint Certification agreeing to resolution based on the joint stipulation and cross memoranda for judgment).

The parties filed cross-memoranda in support of judgment on September 29, 2006, and October 2, 2006. Dkt No 24 & 25. n1 Both filed responsive memoranda ("Replies") on October 10, 2006. Dkt No. 27 & 28. In addition, on October 3, 2006, Mr. **Whitley** filed a motion to strike the declaration of Dr. Hutt, which the Plan relied on in its memorandum in support of judgment. Dkt No. 26. The Plan filed an opposition to the motion to strike on

October 20, 2006. Dkt No. 29. Finally, Plaintiffs filed a notice of supplemental authority on October 23, 2006. Dkt No. 30.

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n1 The substantive memoranda rely on the extensive evidentiary record filed on August 29, 2006, as Dkt No. 14-17. This administrative record is sequentially numbered and is referred to herein with the prefix "AR" followed by page number(s) (*e.g.*, AR pp. 1-25).

- - - - - - - - - - - - - End Footnotes- - - - - - - - - - - - - - **[*3]**

For the reasons set forth below, the court strikes the affidavit of Dr. Hutt. The court further finds that the Plan abused its discretion in denying benefits. The court, therefore, finds that Plaintiff is entitled to judgment in his favor on the claim for benefits. The court will defer entry of judgment, and resolution of Plaintiff's request for attorneys' fees, to allow Plaintiff to address the Fourth Circuit's recent decision relating to the same. *See* ***Carolina Care Plan, Inc., v. McKenzie,*** Slip Op. No. 05-2060 (4th Cir. October 23, 2006). Briefing on this issue shall be as set forth at the conclusion of this order.

APPLICABLE LAW AND STANDARD OF REVIEW

It is undisputed that the benefits at issue are provided under an employee benefit plan governed by the Employee Retirement Income and Security Act, 29 U.S.C. § 1001 *et seq.* ("ERISA"). Mr. **Whitley's** claim for benefits is, therefore, pursued solely under 29 U.S.C. § 1132(a)(1)(B).

It is also undisputed that the Plan's benefits determination is subject to a modified abuse of discretion standard of review. *See, e.g.,* Dkt No. 25 at 5-6 (Plan's memorandum); *McKenzie,* **[*4]** Slip Op. at 5-7. Under the basic abuse of discretion standard of review, the court is required to uphold the administrator's decision if it is reasonable, even if the court would have come to a different conclusion had it considered the matter independently. *See Ellis v. Metropolitan Life Ins. Co.,* 126 F.3d 228, 232 (4th Cir. 1997). A decision is reasonable if it is "the result of a deliberate, principled reasoning process and if it is supported by substantial evidence." *Id.* at 232 (quoting *Brogan v. Holland,* 105 F.3d 158, 161 (4th Cir. 1997)).

The modified abuse of discretion standard of review applies when the decision-maker is operating under a conflict of interest, such as when a for-profit insurance company is both the funder and decision-maker. *See McKenzie,* Slip Op. at 5-7 (finding standard applicable even where relatively minor expense is involved). Under this standard, the court reduces the degree of deference to the extent necessary to neutralize any untoward influence resulting from the conflict of interest. *Id.,* Slip. Op. at 5.

Numerous factors are considered in "determining the reasonableness of a fiduciary's **[*5]** discretionary decision,." *Booth,* 201 F.3d at 342-43. These include:

> (1) the language of the plan; (2) the purposes and goals of the plan; (3) the adequacy of the materials considered to make the decision and the degree to which they support it; (4) whether the fiduciary's interpretation was consistent with other provisions in the plan and with earlier interpretations of the plan; (5) whether the decisionmaking process was reasoned and principled; (6) whether the decision was consistent with the procedural and substantive requirements of ERISA; (7) any external standard relevant to the exercise of discretion; and (8) the fiduciary's motives and any conflict of interest it may have.

Id. See also McKenzie, Slip Op. at 6-7 (quoting same).

As these criteria reveal, the plan language is the starting point. *Id.* ("[a]s with any interpretation of a contractual trust document, we begin by examining the language of the Plan"). This is because "ERISA demands adherence to the clear language of the employee benefit plan." *White v. Provident Life Accident Ins. Co.,* 114 F.3d 26, 28 (4th Cir. 1997). "When an ERISA plan vests discretion in **[*6]** an administrator who also insures the plan, reasonable exercise of that discretion requires that the administrator construe plan ambiguities against the party who drafted the plan." *McKenzie,* Slip Op. at 9.

MOTION TO STRIKE

The motion to strike relates to the sworn declaration of Dr. Hutt, who serves as the Plan's Medical Director. Hutt Decl. P 1. Dr. Hutt asserts that he is "familiar with the decision to deny the claim . . . .because [he] reviewed the claim at the time it was made." Hutt Decl. P 2. He then explains the Plan's reliance on the HAYES rating system n2 to deny Mr. **Whitley's** claim as experimental, investigational or unproven. Hutt Decl. P 3-5 & 9. He also provides his interpretation of the evidence and explains that the initial denial was based on his own application of the HAYES rating system to this interpretation. Hutt. Decl. at 6-7.

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n2 As discussed in the remainder of this order, the Plan has consistently relied on a rating from Winifred S. HAYES, Inc., as its basis for denying the claim as experimental, investigational or unproven. The particular report relied on was published in February 2003 and was obtained by the Plan in October 2004 from the HAYES website. The published report is referred to herein as the "HAYES Report." The rating in that report is referred to as the "HAYES Rating."

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In addition, Dr. Hutt addresses why he believes the two independent reviews obtained by the Plan (both favorable to coverage of the claim) should not result in a ruling in Mr. **Whitley's** favor. Dr. Hutt asserts that both reviews are irrelevant as they addressed only whether the treatment was "medically appropriate," not whether it fell within the Plan's Experimental Exclusion. This characterization of the two reports is incorrect as one of the two was obtained by the Plan for the sole and express purpose of addressing whether the service fell within the Experimental Exclusion. In concluding that the treatment at issue did not fall within this exclusion, this review (referred to in the remainder of the order as the "Peer Review") addressed each of the relevant Plan criteria. The other review was obtained as part of a transplant evaluation (referred to herein as the "URN-Review" or "URN Specialized Physician Review"). In concluding that Mrs. **Whitley** was not a good transplant candidate at the time of the review, the URN-Reviewer also addressed some of the criteria relevant to application of the Plan's Experimental Exclusion.

Thus, neither report was limited to the question of "medical **[*8]** appropriateness" of the treatment and both bear directly on the Experimental Exclusion. Dr. Hutt does not otherwise address these independent reviews on their merits. Dr. Hutt's attempt to discount these reports would, therefore, bear little weight even if his declaration was considered. n3

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n3 The Plan asserts in its opening memorandum that, in reaching "his" decision to deny benefits, "Dr. Hutt reviewed and especially relied on" thirteen specifically listed excerpts from a URN-Specialized Physician Review and abstracts culled from a HAYES research update (discussed *infra* as "HAYES Update"). Dkt 25 at 13-15. Dr. Hutt's declaration contains no statements which would support either assertion. Hutt does not, in fact, even refer to the HAYES research update or the abstracts contained therein. His only reference to the URN-Specialized Physician Review is the cursory discounting of it as discussed above.

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In any case, nothing in Dr. Hutt's declaration explains what information was provided to and considered by the **[*9]** third-level grievance panel. This is the body which rendered the Plan's final decision. While there is strong evidence that this body, as well as the panel before it, may have deferred unduly to Dr. Hutt's opinion, it remains that: (1) it is the decision of the final grievance panel which is actually at issue; and (2) nothing in Dr. Hutt's declaration aids the court in understanding what information that panel considered. n4

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n4 As discussed in the remainder of this order, it is clear that Dr. Hutt made the decision to deny the first-level appeal and had direct input as to the second. As to the third-level appeal, the evidence of his input is less direct. Nonetheless, his opinion as to the controlling nature of the HAYES Rating was provided to the third-level grievance panel in a manner which likely had a strong, if not determinative, influence on the outcome of the final appeal.

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Dr. Hutt's declaration is dated October 2, 2006. The final denial letter was written, and the record closed, almost a year earlier on **[*10]** October 28, 2005. Thus, Dr. Hutt's declaration clearly is not part of the record relied on by the Plan in making its benefit decision. Rather, it seeks to explain that decision with information not contained in the record.

There is no suggestion that the Plan advised Mr. **Whitley** of its intent to rely on such a declaration before it was filed with the Plan's memorandum in support of judgment. Indeed, all evidence is to the contrary as evidenced by the parties' July 26, 2006 Joint Certification which provided the following assurances:

> a. The parties certify that they conferred on July 25, 2006 with respect to the matters contained in the Specialized Case Management Order.
>
> b. There are currently no issues raised by the Joint Stipulation on which the parties are not in agreement.
>
> *c. No parties object to the procedure for disposition of the action proposed by the Joint Stipulation.*
>
> *d. The parties confirm that they exchanged all documents on which any party intends to rely for resolution of the action.*

Dkt No. 9 (Joint Certification -- emphasis added). The procedure to which the parties indicated agreement is set forth, in part, below:

> 5. If **[*11]** the matter is not resolved by mediation, the parties shall, within sixty (60) days after the conference addressed in Paragraph 2 above, file cross-memoranda in support of judgment with respect to all benefits claims governed by ERISA. The Joint Stipulation shall be filed at the same time. Each party shall have five (5) days thereafter to file an optional reply. These memoranda should follow the form of Local Rule 7.05. *All references in memoranda shall be to the consecutively-numbered page of the attachments to the Joint Stipulation.* In its discretion, the court may order a hearing. Unless so ordered, the court will decide the ERISA benefits issues upon the record before it without a hearing. Motions for summary judgment need not be filed. *Any party objecting to the court disposing of the case on the Joint Stipulation must file an objection with or prior to the filing of the joint certification required by Paragraph 2 of this order.*

Dkt No. 7 (original emphasis deleted -- above emphasis added).

The parties, thereafter, filed their joint stipulation (with attached administrative record) on August 29, 2006. Dkt No. 14-17. This extensive record does not include Dr. Hutt's **[*12]** declaration which, as noted above, was not prepared until over a month after the administrative record was compiled and exchanged and long after the Plan's final denial of Plaintiff's claim. Thus, Dr. Hutt's declaration is clearly not part of the administrative record to which the parties agreed to limit their reliance in their July 2006 joint certification.

As suggested above, the critical difficulty with consideration of Dr. Hutt's declaration is that it is not a part of the administrative record. While supplementation of the record might, in some instances, be appropriate, it would only be appropriate if proper notice was given of the intent to rely on the additional evidence. Under the procedures of this court, that notice should have been given prior to the filing of the Joint Certification which occurred on July 26, 2006.

Had the Plan provided notice of its intent to rely on testimony of Dr. Hutt, the court would first have determined whether to allow that testimony. If the court determined that such testimony should be allowed, it would likely have allowed Plaintiff to depose Dr. Hutt as to his full role in the decision-making process. That deposition might, in turn, have **[*13]** led to the deposition of other Plan representatives to test the veracity of Dr. Hutt's testimony.

To the extent any of these depositions related to communications with third parties, the court would, upon request, have considered whether to allow Plaintiffs to designate opposing witnesses to address the same communications. Likewise, to the extent the testimony was in the nature of expert witness testimony (the reasonableness of relying on the HAYES Rating), a counter-expert would most likely have been allowed. In addition, the usual expert witness disclosure requirements would have applied.

None of the decisions detailed above was ever made because the Plan gave no notice of its intent to rely on Dr. Hutt's testimony until his declaration was filed with Defendant's memorandum in support of judgment. n5 Under these circumstances, it would be decidedly unfair to allow the Plan to rely on Dr. Hutt's declaration.

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n5 In opposing to the motion to strike, the Plan refers to several cases which have allowed expansion of the record under relatively unusual circumstances. Nothing in the Plan's memorandum, however, supports allowing such expansion *when not timely sought.* Under the procedures applied in this district, that would be no later than upon the filing of the joint stipulation.

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For all of the reasons set forth above, the court grants Mr. **Whitley's** motion to strike Dr. Hutt's declaration.

DECISION OF THE COURT ON SUBSTANTIVE CLAIMS

After examining the administrative record, joint stipulation, and parties' memoranda, the court enters the following Findings of Fact and Conclusions of Law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure. To the extent that any findings of fact represent conclusions of law, or vice-versa, they shall be so regarded.

FINDINGS OF FACT

OVERVIEW

The claims at issue in this action involve implantation of a left ventricle assist device (LVAD). This implantation was performed at Duke University Medical Center ("Duke") on October 11, 2004, and resulted in charges in the amount of $ 369,775.75.

The patient, Carol **Whitley** ("Mrs. **Whitley**" or "member"), is now deceased. n6 The claim is, therefore, pursued on behalf of Mrs. **Whitley's** estate by the estate's personal representative, Jerry **Whitley** ("Mr. **Whitley**").

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n6 The Plan uses the term "member," rather than the ERISA terms "participant" or "beneficiary" to refer to Mrs. **Whitley** and to other individuals covered under its policies The court will use the same terminology in this order.

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The final denial was based on two related grounds, both of which are advanced as denial reasons in this action. First, the Plan maintained that "LVAD *for destination therapy* was considered by [the HAYES rating system] to be experimental at the time of the service." The Plan, therefore, denied coverage under a plan exclusion for experimental, investigational, or unproven services ("Experimental Exclusion"). AR p. 3 (emphasis added). Second, the Plan maintained that it was not informed of the intent to implant an LVAD *for destination therapy* until after the procedure was completed. The Plan concedes, however, that it had approved other significant heart treatment, apparently including high-risk bypass surgery and preparation for a possible heart transplant. AR p. 3 (December 14, 2005 letter from Plan summarizing reasons for denial-emphasis added). n7

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n7 The Plan has consistently relied on the Experimental Exclusion in its various denials. Its

reliance on the alleged lack of notice has been sporadic.

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The purpose of the implant ("for destination therapy") was critical to the denial. n8 This is because use for other purposes (*e.g.*, "as bridge to transplant") would not have been considered experimental, investigational, or unproven under the HAYES Report on which the Plan relied. *See supra* n. 2 and *infra* at 19 (explaining HAYES Report).

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n8 The term "destination therapy" refers to implantation of the LVAD as a permanent treatment which, according to the literature, may extend life by several years before a new implant is needed. "Bridge to transplant," by contrast, refers to implantation only pending an intended heart transplant. The line between the two goals of treatment is not, however, always clear. This is because a patient who is not a transplant candidate due to correctable or controllable conditions (*e.g.*, obesity and diabetes), may become a transplant candidate after implantation of the LVAD.

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The HAYES Report on which the Plan relied was published in February 2003, nineteen to twenty **[*17]** months before Mrs. **Whitley's** surgery. At some point between Mrs. **Whitley's** surgery and December 14, 2005, a period of seventeen months, the published HAYES Rating was changed. *See* AR p. 3 (December 14, 2005 letter from Plan representative conceding that, as of that date, "LVAD for destination therapy is no longer considered experimental or investigational by Hayes"). Neither party has provided the court with the date of that change. The record is also silent as to what studies or other evidence was considered by HAYES when it ultimately did change the relevant rating.

RELEVANT PLAN TERMS

1. Notice Term. The Plan provides as follows regarding notification for services received from Network Providers such as Duke. n9

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n9 It is undisputed that Duke is a network provider. Thus, if denial rested solely on a failure of notification, the real parties in interest might be Duke and the Plan, rather than Mr. **Whitley** and the Plan, because Duke would be precluded from charging Mrs. **Whitley** or her estate for the service. The denial, however, rested on dual grounds. In any case, the Plan does not challenge Mr. **Whitley's** standing as the real party-in-interest.

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Notification Requirements

> 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.

After noting the member's duty to provide notice before receiving certain health services from non-Network Providers, the Plan document encourages confirmation that "services from non-Network Providers" are covered "because in some instances, certain procedures may not meet the definition of a Covered Health Service and are therefore excluded" or may fall within an exclusion such as the "Experimental, Investigational or Unproven Services exclusion." *Id.*

2. Coverage of Transplant Services n10

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n10 The transplant provisions are relevant because Mrs. **Whitley** was transferred to Duke because she was under consideration for a heart transplant. *See* AR p. 27 (October 4, 2004 letter to MUSC). Her initial care at Duke was, therefore, reviewed under the provisions applicable to transplant candidates.

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The Plan document provides that it covers "Transplantation Services" as follows:

> Covered Health Services for the following organ and tissue transplants when ordered by a Network Physician. Transplantation services must be received at a Designated Facility. Benefits are available for the transplants listed below when the transplant meets the definition of a Covered Health Service, and is not an Experimental, Investigational or Unproven Service:
>
> . . .
>
> . Heart transplants.
>
> . . .
>
> **Notify Us**
>
> We have specific guidelines regarding Benefits for transplant services. Contact us at the telephone number on your ID card for information about these guidelines. You and your Network Physician must notify us as soon as the possibility of a transplant arises (and before the time a pre-transplantation evaluation is performed at a transplant center). If you do not notify us, and if the transplantation services are not performed at the Designated Facility, you will be responsible for paying all charges, and no Benefits will be paid.

AR p. 890.

3. Exclusion for Experimental, Investigational or Unproven Services n11

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n11 For ease of reference, the court refers to this exclusion as the "Experimental Exclusion."

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The policy excludes coverage for:

> Experimental, Investigational or Unproven Services Health services and associated expenses for Experimental, Investigational or Unproven Services, treatments, devices and pharmacological regimens except for health services which are otherwise Experimental, Investigational or Unproven that are deemed to be, in our judgment, Covered Health Services under (Section 1: What's Covered - - Benefits). The fact that an Experimental, Investigational or Unproven Service, treatment, device or pharmacological regimen is the only available treatment for a particular condition will not result in Benefits if the procedure is considered to be Experimental, Investigational or Unproven in the treatment of that particular condition.

AR p. 893. The two Plan definitions discussed below govern the scope of this exclusion.

4. Relevant Definitions

> "Covered Health Service(s) -- those health services provided for the purpose of preventing, diagnosing or treating a Sickness, Injury or their symptoms.
>
> . . .
>
> A Covered Health Service must meet each of the following criteria:
>
> . It is supported by national medical standards of practice. **[*21]**
>
> . It is consistent with conclusions of prevailing medical research that demonstrate that the health service has a beneficial effect on health outcomes and are based on trials that meet either the following designs:
>
> - Well-conducted randomized controlled trials. (Two or more treatments are compared to each other, and the patient is not allowed to choose which treatment is received).
>
> - Well-conducted cohort studies. (Patients who receive study treatment are compared to a group of patients who receive standard therapy. The comparison group must be nearly identical to the study treatment group.)

. It is a cost-effective method and yields a similar or better outcome to other available alternatives.

. It is a health care service or supply described in (Section 1: What's Covered - - Benefits) as a Covered Health Service, which is not excluded under (Section 2: What's Not Covered - - Exclusions).

Decisions about whether to cover new technologies, procedures and treatments will be consistent with conclusions of prevailing medical research, based on well-conducted randomized trials or cohort studies, as described.

AR p. 922.

"Experimental, **[*22]** Investigational or Unproven Services--medical, surgical, . . . or other health care services, technologies, supplies, treatments, procedures, drug therapies or devices that, *at the time we make a determination regarding coverage* in a particular case, are determined to be any of the following:

. Not approved by the U.S. Food and Drug Administration (FDA) to be lawfully marketed for the proposed use and not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use.

. Subject to review and approval by any institutional review board for the proposed use.

. 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, regardless of whether the trial is actually subject to FDA oversight.

. A service that does not meet the definition of a Covered Health Service. If you have a life-threatening Sickness or condition (one which is likely to cause death within one year of the request for treatment) we may, in our discretion, determine that an Experimental, Investigational or Unproven Service meets **[*23]** the definition of a Covered Health Service for that Sickness or condition. For this to take place, we must determine that the procedure or treatment is promising, but unproven, and the service uses a specific research protocol that meets standards equivalent to those defined by the National Institutes of Health.

AR p. 924 (underlining in original, italics added).

Summary of the Administrative Record.

October 4, 2004. Mrs. **Whitley** was initially admitted to the Medical University of South Carolina (MUSC). On October 4, 2004, MUSC requested approval from the Plan to perform a heart transplant. AR p. 145. The Plan promptly notified MUSC that it would not provide

coverage for the requested transplant because MUSC was not a network provider. The Plan indicated, however, that the services could be performed by Duke, as it was a "network provider under the transplant benefit through United Resource Networks" (URN). AR p. 27 (October 4, 2004 letter to MUSC). n12

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n12 In later letters, the Plan indicates that Mrs. **Whitley** was transferred from MUSC to Duke because MUSC was unable or unwilling to perform a high risk coronary artery bypass graft ("CABG"). *See* AR p. 3 (January 14, 2005, letter from Plan acknowledging approval of a CABG to be performed at Duke). A CABG is not, however, mentioned in the October 4, 2004 correspondence. An October 7, 2004 record from Duke does, however, mention an intent to explore "possible revascularization." AR p. 153.

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Mrs. **Whitley** was, therefore, transferred to Duke for evaluation and treatment. It is undisputed that the Plan gave approval for the transfer to Duke and for Duke to perform a transplant evaluation and some other heart related treatment, though precisely what was approved is in dispute. *See, e.g.,* AR p. 3 (December 14, 2005 letter from Plan summarizing history of claim and stating that the "Plan approved the CABG to be done at Duke because of the complexity of the specific case and we were informed it could not be performed at MUSC"); AR p. 9 (October 12, 2004 computer entry indicating Mrs. **Whitley** received a "two vessel CABG yesterday, and placement of LVAD . . . to bridge the pt until she gets a heart transplant"); AR p. 222 (October 13, 2004 computer entry expressing concern as to purpose for which LVAD was implanted--discussed *infra*).

October 7-13, 2004. Mrs. **Whitley** was transferred to Duke on October 6, 2004. AR p. 216. By October 9, 2006, the transplant cardiologist reviewing her case, Carmelo A. Milano, M.D. ("Dr. Milano"), had determined that Mrs. **Whitley** was not a good transplant candidate, at least not at that time. AR pp. 7-8 (October 9, 2004 report by Dr. **[*25]** Milano finding Mrs. **Whitley** to be a "poor candidate for revascularization" and a "suboptimal candidate for cardiac transplantation"). This determination was based on Mrs. **Whitley's** obesity and diabetes with neuropathy. Dr. Milano, therefore, suggested implantation of a "destination left ventricle assist device" as the best treatment option. *Id.* Dr. Milano noted, nonetheless, that Mrs. **Whitley** could become a transplant candidate if she modified her weight. AR p. 8.

Plan's records of communications, October 6-13, 2004. The following undated record made by Lisa Hardin, RN, a representative of the Plan, appears to have been made around the time of Mrs. **Whitley's** admission to Duke.

> This 57 year old female was transferred from MUSC via ambulance to Duke University Medical Center. She had a cath at MUSC which showed three vessels 100% occluded and the only functioning vessel is the ramus. *At MUSC they wanted to transplant her,* but MUSC is not a center for excellence and they cannot do a transplant. She is on the heart pump at this time. *MUSC could not do the "high risk CABG" being contemplated.* They [missing words] . . .nd heparin. Trying to wean ballon pump, **[*26]** cardiac surgery. I spoke to Dr. Hutt at length about this and he said that this should be paid in network because the service could not be offered at MUSC. I have asked to have faxed clinicals sent to me in the am. *I spoke with Julia at Duke and I told her that if this case came down to transplant that it would go under her transplant benefit.* She verbalized an understanding.

AR p. 211-13 (print outs of the screens in the record appear to be partial print outs which, when reconciled, still leave some gaps). n13

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n13 Lisa Hardin ("Hardin"), is a nurse reviewer who appears to have been the primary individual in charge of handling this claim. Her entries also frequently bear the initials "lh/rn."

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Another screen, which includes a date of October 6, 2004, indicates receipt of faxed clinicals from Duke. This entry, also by Lisa Hardin, gives the following information: "57 year old s/p inferior STEMI with cardiogenic shock. Other [history] includes DM. She was transferred here from MUSC. She has transplant **[*27]** evaluation done 10/06/2004. See evaluation case." AR. p. 214.

Other screens appear to be a continuation or modification of this screen, and include additional detailed clinical information, AR pp. 217-19. These screens reveal that the Plan was informed that the patient was 100% occluded in three vessels, and that Duke would "discuss *possible* revascularization" and, "in the meantime, will have transplant meet the patient." *Id.* (emphasis added). This screen then states:

> *Poor coronary targets.* If IABP comes out, would do cardiac MRI for viability. *Transplant workup in progress.* On admission this mbr was in cardiogenic shock. Notified Paula of receipt of clinicals and day auth through 10/11/2004. Requested an update at this time. *Dr. Hutt aware of this situation and agrees.*

AR p. 217-19 (emphasis added). n14

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n14 The section of the administrative record in which these records appear also contains duplicates of the screens referenced in the Plan's December 2005 letter (discussed *infra*). That letter, however, refers only to the October 7 and 12 computer entries. *See* AR p. 215 (identical to AR p. 6); AR p. 220 (identical to AR p. 9). Other similar screens in this section of the record, also not mentioned in or attached to the January 2005 letter, are discussed in the remainder of the text (relating to dates October 13-21).

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The computer entry dated October 7, 2004, states:

> Additional clinicals received an[d] reviewed. *Pt was evaluated by cardiac surgery and they have decided to proceed with a CABG on Monday.* Centro 1 line placed today for venous access. Requested an update on Tues[day] post CABG to let me know how the pt is doing.

AR p. 6 (signed "lh/rn"-- emphasis added).

The next entry is dated October 12, 2004, the day after the surgery. This entry states:

> Clinical update received from Carolyn at Duke . . . . Pt underwent a two vessel CABG yesterday, and *placement of LVAD. . . . The left ventricular assistance device is placed to bridge the pt until she gets a heart transplant.*

AR p. 9 (signed "lh/rn").

The next computer entry reflects a phone conversation between Hardin and a Duke representative on October 13, 2004. This entry reads as follows: "Call received from Carolyn at Duke and she said that this *mbr is NOT on the transplant list. She is to have the LVAD for the remainder of her life.* I notified Michelle Griffin at URN and Hetal Joshi, CCS." AR p. 221 (emphasis added). n15

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n15 This computer entry is generally consistent with an October 13, 2004 notation on Mrs. **Whitley's** chart which indicates that a representative of Duke spoke with the Plan's transplant insurance case manager on that date, advising the case manager that a destination LVAD had been performed after determining that Mrs. **Whitley** was not a candidate for transplant at that time. Nonetheless, the Duke notes indicate an intent to reconsider if weight and diabetes were later controlled. AR p. 164. The latter point is, however, missing from Hardin's report of the communication.

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In a notation made several hours later, Hardin wrote: "I have discussed this case at length with Dr. Hutt since I have been notified of this mbrs *LVAD for destination.*" AR p. 222. She then wrote: "Additional comments: *We ran a Hayes report (at the request of Dr. Hutt) since the LVAD was placed for destination rather than as a bridge to transplant as we originally thought.* According to Hayes, LVAD to destination is a [text ends abruptly -- no other page completes]." AR p. 222 (emphasis added). n16

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n16 The Plan apparently obtained the same HAYES Report twice, on October 13 and 14, 2004. *See* AR pp. 304-06 (dated 10/13/04) & AR pp. 17-18 (dated 10/14/04).

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Duke Evidence Regarding October 6-11 Communications. In a November 22, 2004 letter, Duke representative Joseph W. Robbins states that he and one other Duke representative had numerous conversations with Lisa Hardin between October 6, 2006 and October 11, 2006, in which the placement of an LVAD was approved. AR 180-81 (discussed below by date **[*30]** of letter). He further states that he was told by the Plan representative

to do whatever was necessary to save the patient's life.

October 14-18, 2004. In a letter dated October 14, 2004, Dr. Hutt wrote to Dr. Milano asking that Mrs. **Whitley's** "entire medical record inclusive of preoperative, intraoperative and post operative notes and transplant evaluation" be sent to him by facsimile "no later than" the following day. AR p. 166. The Plan again obtained a copy of the HAYES Report on October 14, 2004 (HAYES Report discussed *infra*). Duke forwarded the records as requested. n17

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n17 An October 15, 2006 computer entry by Hardin states:

> Faxed clinicals were received from Michelle Griffin, our URN coordinator as Duke thought that she was the case manager for this case. She forwarded them to me. I gave them to Dr. Hutt. He still does not have the transplant evaluation and operative reports. I sent a letter on behalf of Dr. Hutt requesting the records so he can make a benefit decision.

AR p. 223. Duke apparently resent the records to the Plan via facsimile on October 18, 2006. *See* AR pp. 167-74 (records sent via facsimile).

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On October 15, 2004, Hardin had a conversation with a Duke representative. Hardin reports the conversation as follows:

> Call received from Carolyn case manager at Duke. We are still awaiting the clinicals to be faxed in. Still in ICU [condition and current treatment described]. Anticipate being in unit for the weekend. *Left Carolyn a message that I cannot authorize any more days until Dr. Hutt receive[s] the clinicals and decides if this is experimental or investigational.*

AR p. 224 (emphasis added). This appears to be the first notice to Duke of the Plan's position that the treatment was experimental. No concern as to the adequacy of Duke's prior notice is mentioned.

Hardin's next computer entry is on October 18, 2004, and reflects that she received a call "from Carolyn the case manager [at Duke] as well as the LVAD coordinator wanting to know the benefit decision and that they were quite anxious to find out an answer to the case." AR p. 227-29. Hardin later returned the call (apparently speaking to another individual "Laura") to advise that the records were available and "that the medical director was to review them today." This individual asked "what criteria **[*32]** Dr. Hutt was going by that determined this an 'investigational/experimental' procedure as [M]edicare pays for it." Hardin states:

> I told her Hayes as criteria, and she wanted a copy of it to review. I faxed her the criteria and a reply was received that the fax did go thru. *I called Dr. Hutt back today at 4:55 p.m. and he said he still had not yet had time to review the notes I scanned to him. Will check with him again first thing in the am to see what his*

answer is.

AR pp. 228-29 (emphasis added).

October 19, 2004. On October 19, 2004, the Plan denied coverage based its conclusion that the use of the LVAD for destination therapy was experimental or investigational under the terms of the Plan. AR p. 28 (October 19, 2004 letter signed for Dr. Hutt by L. Hardin, RN). In this denial letter, directed to Dr. Milano, the Plan quotes the exclusion for "Experimental, Investigational, or Unproven Services" then states:

> The use of the LVAD began on October 11, 2004, which is a non-covered service. Therefore, we will not be covering any service beyond this date. I have included a copy of the information we used to make this decision. If you should have any **[*33]** questions you may contact me at [phone number provided].

AR p. 28 (the referenced attachments are not included at this point in the record but apparently consisted of copies of the HAYES Report for LVAD discussed below).

The Plan's October 19, 2004 denial letter does not suggest any concern regarding lack of notice. It does, on the other hand, explain that the patient can file a grievance challenging the denial. n18

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n18 The record contains numerous copies of this letter. One appears immediately following a facsimile cover sheet to Dr. Milano from Lisa Hardin which indicates that four additional pages are attached. AR pp. 302. The pages which follow suggest that Dr. Milano was provided with the HAYES Report on which the Plan relied then and relies now, including a November 2001 "HAYES Alert" which describes as "promising" a then-recent "REMATCH" study reported in the New England Journal of Medicine, 2001. AR pp. 304-06.

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HAYES Report. The Plan has consistently relied solely on the rating found **[*34]** in the HAYES Report from Winifred S. HAYES, Inc., as its basis for denying the claim under the Experimental Exclusion. The particular report relied on reflects a publication date of February 2003, and was obtained by the Plan on October 13 and 14, 2004. This specific report is referred to herein as the HAYES Report. The rating of LVAD provided in that report is referred to as the HAYES Rating.

The HAYES Report gives the LVAD an A rating for "use as a bridge to cardiac transplantation," and a B rating for "use as a bridge to recovery" for patients meeting certain specific criteria (the "bridge to recovery" criteria are inapplicable to Mrs. **Whitley).** As to use as a "permanent destination therapy," the HAYES Report provides a C rating and includes the following explanation:

> C -- For LVAD use as permanent destination therapy for patients with end-stage CHF who are not eligible for transplantation and in whom no return of cardiac function is anticipated. This Rating is based on early but promising findings and

> reflects the limited treatment options available for these patients.

AR p. 17. This Report explains that a "C" rating indicates "Investigational and/or experimental. **[*35]** The data on this procedure are promising but inconclusive regarding safety and/or efficacy. There is no clear medical consensus regarding its safety and/or efficacy." AR p. 18.

October 20, 2004. On October 20, 2004, the Plan obtained an online search update relating to the LVAD rating through the HAYES Inc. website ("HAYES Update"). AR pp. 122-143 (repeated at AR 484-505). The search covered the period January 2004 though October 2004, and retrieved sixty-two articles for which abstracts covering twenty-five pages were provided. AR p. 122-43 (although the cover page indicates there are 25 pages, only 22 are included in the record). The abstracts are described as covering "retrospective studies, case reports, small and large patient group case series and review articles." AR p. 484. Under "Anticipated Impact," this document states: "The search findings *will trigger a review* of the existing HAYES Medical Technology Directory Report." *Id.* (emphasis added).

Despite the significant number of abstracts revealed, and the warning that the search would lead to a review of the then-current rating, there is no indication that the Plan ever considered the content of this Update. **[*36]** For example, there is no mention of the HAYES Update in any letter or internal record, other than Hardin's notation that she was forwarding the HAYES Update to Hutt. AR p. 346. Neither are there any marks on the printout of the HAYES Update which would suggest that any of the numerous abstracts were reviewed. There is no other evidence which would suggest that Dr. Hutt, or any other decision-maker at the Plan, ever reviewed or considered the HAYES Update. n19 Further, there is no evidence that these materials were provided to either the second or third-level grievance panels.

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n19 The Plan argues that Dr. Hutt considered and relied on selected abstracts within the HAYES Update in concluding that LVAD for destination therapy remained experimental at the time of Mrs. **Whitley's** surgery. This claim is wholly without evidentiary support, with or without consideration of Dr. Hutt's disallowed declaration. *See supra* n. 3 (noting that Update is not mentioned in Dr. Hutt's declaration).

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There are also two records of **[*37]** phone conversations from October 20 and 21, 2004. While both relate to the Plan's intent to deny coverage under the Experimental Exclusion, neither refers to the Hayes Update.

The earlier record indicates that Carolyn from Duke called Hardin with a patient update on October 20, 2004. After providing the update, Carolyn asked "if she still needed to call in updates if the case is not covered." AR p. 230 (the screen appears to cut off the final portions of the notes). The same record indicates that Hardin "left a message for Dr. Hutt to let me know if any of the MD's at Duke had called him today." *Id.*

The phone record from October 21, 2004, also written by Hardin, states:

> I spoke with Dr. Hutt and he stated that he spoke with Dr. Milano on a peer to peer review. He states that Dr. Milano was quoting an article from 2001 n20 and

> Dr. Hutt states the latest is from 2003 in which Hayes still calls destination therapy a "C" rating, which [is] experimental and investigational. I notified Carolyn UR nurse that the md's talked and that the decision remains as non covered from CCP. . . .

AR p. 231 (the screen appears to cut off the final portions of Hardin's notes).

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n20 The HAYES Alert which the Plan obtained contemporaneously with the HAYES Report refers to a 2001 article published in the New England Journal of Medicine. That article addressed the "REMATCH" study and appears to be the article referenced in this discussion.

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October 26, 2004. On October 26, 2004, various Duke physicians wrote a letter "To Whom It May Concern," with the express purpose of "document[ing] the medical necessity for the transplant procedure." AR pp. 309-10. This letter provides a detailed description of Mrs. **Whitley's** current condition and prior treatments, but acknowledges that she would only be a transplant candidate "when her weight can be modified." The letter is signed by one nurse and two doctors, including Dr. Milano. AR. p. 310. The letter, plus numerous attachments related to Mrs. **Whitley's** medical condition, were transmitted by facsimile on October 28, 2004 to the Plan (attention Lisa Hardin). AR pp. 308-28. n21

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n21 By the time this letter was written, Duke was aware that the Plan had denied coverage because the LVAD was placed for destination therapy rather than as a bridge to transplant. Thus, the statements in and purpose of this letter might be viewed with some skepticism. On the other hand, the statements within the letter are wholly consistent with all medical records: that the LVAD was implanted with knowledge that it might ultimately be solely for destination purposes, but with the hope that Mrs. **Whitley** might reduce her weight and become a transplant candidate. *See, e.g.,* AR p. 106 (minutes relating to an October 13, 2004 meeting which included Dr. Milano and other Duke representatives and which states, as to Mrs. **Whitley** "Not a [transplant] candidate at this time; . . . would reconsider [transplant] if pt reaches WT goal of 155 lbs.").

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November 3, 2004. On November 3, 2004, the Plan received, via facsimile, a Specialized Physician Review prepared on behalf of the United Resource Network ("URN"). This Review addresses, expressly, whether Mrs. **Whitley** is a suitable transplant candidate. This extensive report ("URN-Review") contains the following headings: I. Clinical Summary; II. Disease Treatment Statement; III. Literature Review; IV. Alternatives; and V. Community Standard. The last three sections address the propriety of use of the LVAD as destination therapy as an alternative to a heart transplant. AR pp. 88-91.

The URN-Review was prepared by a physician who specialized in cardiac transplantation. The following discussion is of particular relevance:

> The patient is now 2 1/2 weeks after implantation of a HeartMate XVE Left Ventricular Assist Device for destination therapy. *This is a FDA approved and Medicare reimbursed procedure following the landmark REMATCH Trial (published in the New England Journal of Medicine) which evaluated destination therapy left ventricular assist device treatment versus medical therapy for end stage heart failure.*
>
> In patients [who] present as [Mrs. **Whitley**] did with **[*40]** refractory heart failure, non graftable coronary artery disease and inability to wean from inotropes and intraaortic ballon pump, *appropriate therapy does include consideration for long term implantable [LVAD] therapy.* However, once this is accomplished, the patient has a two to three year life expectancy on the device pending untoward complications. This time can be used in selective individuals to optimize their clinical status for transplantation. The longer she remains on the HeartMate device without untoward clinical events, the better condition she would be in for eventual cardiac transplantation . . . . At the present time, in light of her BMI, and the recent insertion of Heartmate, there does not appear to be a medical indication to list her for transplantation.

AR p. 90 (emphasis added). Under a section titled "Literature Review," this reviewer states:

> The REMATCH Study clearly has documented that the mechanical support is superior to medical therapy in patients suffering from end stage heart failure. Extrapolation of this data to the acute setting is still in its infancy, although . . . the decision to proceed with destination therapy at an early time **[*41]** in this patient appears to be medically warranted.

AR p. 91.

Under "Alternatives," the reviewer states: At the present time, this reviewer feels that continuing the patient's original plan of LVAD destination therapy is the most prudent one." He recognizes, nonetheless, that transplantation could be reconsidered if Mrs. **Whitley** is able to achieve "full physical rehabilitation and . . . minimize her weight issues and optimally control her diabetes." AR p. 91.

The reviewer also addresses community practice in his geographic area (Washington, DC). In this regard, he states: clinical studies would be consistent with the placement of the HeartMate [LVAD] acutely in this setting. However, decisions regarding options of cardiac transplantation would be deferred until better management of her weight and diabetes could be obtained." *Id.*

November 4, 2004. On November 4, 2004, the Plan again wrote Dr. Milano, indicating that the question of the propriety of the LVAD implant and transplant candidacy had been referred to Dr. Babos, Medical Director from URN (United Resource Network), who, in turn, requested a third party review by an outside medical specialist reviewer. **[*42]** *See* AR p. 29-30 (letter to Dr. Milano from Dr. Hutt, signed on his behalf by Hardin); URN-Review (discussed above). The Plan states that the reviewer agreed that transplantation was not appropriate *at the present time.* It also concedes that the reviewer concluded "*that continuing the patient's original plan of LVAD destination therapy is the most prudent one*" and noted that, with

weight loss and control of her diabetes, the patient might become a transplant candidate. AR p. 29 (quoting reviewer, emphasis added). *See also* AR 331-32 (additional copy of letter to Dr. Milano from Dr. Hutt).

The Plan relied on this URN-Review in concluding that it would not cover any transplantation services. It also restated, in the same letter, that it would not cover the LVAD for destination therapy based on the Experimental Exclusion. As to this exclusion, the Plan expressly stated that it relied on the HAYES rating system. *Id.* The Plan did not discuss the significant support for coverage of the LVAD as destination therapy found in the URN-Review.

As with the Plan's earlier denial letter, this letter makes no reference to any concern regarding notice. Neither is there any reference **[*43]** to notice in Dr. Hutt's email directing that the denial letter be written. n22 The letter was copied to Mrs. **Whitley.**

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n22 At 10:45 on November 4, 2005, Dr. Hutt emailed Hardin directing her to write the above letter. This email states:

> The answer to placing her on the transplant list is NO.
> The decision to use the LVAD for destination in the setting of this acute MI with heart failure is not supported by the literature or any current, past, or future proposed clinical trials and is therefore experimental and investigational. Her therapy at Duke is not a CCP covered benefit. Lisa, write up such a denial letter and send it to all relevant parties.

AR p. 333 (emphasis added).

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November 22, 2004. On November 22, 2004, Joseph W. Robbins wrote the Plan on behalf of Duke. AR pp. 180-81 (listing department as Transplant Financial Services). The letter states that its purpose "is to formally appeal the denial . . .for the insertion of a left ventricular assistance device into Carol **Whitley** for the **[*44]** treatment of end-stage heart disease." Robbins states as follows regarding his earlier communications with the Plan:

> On October 6, 2004[,] the Transplant Financial Coordinators at Duke verified the insurance coverage with **Carolina Care Plan** and got case management involved. The Transplant Financial Coordinator, Julia B. Holden and I were both *told by the case manager, Lisa Hardin, that basically anything we needed to do to save the patient was approved. According to Lisa she consulted with the Medical Director to confirm any services required to save the patient were approved.* A left ventricular assistance device and transplant evaluation were mentioned specifically. It was further *confirmed by Lisa that an LVAD and transplant evaluation were approved at that time.* We were also told that a transplant network, United Resource Network, had to be accessed.
>
> *I confirmed again on Friday 10/8/04 that the LVAD and transplant evaluation were approved.* On Saturday 10/9/04, Dr. Milano saw the patient and concluded that the patient needed to lose weight before proceeding with transplant. He also concluded that the [LVAD] was needed as soon as possible. He refers to **[*45]**

> the LVAD as a "destination vad" and then goes on to say that if the patient modified her weight, she could become a transplant candidate. I confirmed again on Monday 10/11/04 that the LVAD and transplant evaluation were approved. On that day, Dr. Milano inserted the LVAD.

AR pp. 180-81 (emphasis added--continuing to discuss patient's progress toward and possible eventual transplant candidacy, and related "bridge to transplant" nature of the procedure).

December 1, 2004. On December 1, 2004, the Plan wrote to Joseph Robbins at Duke acknowledging receipt of a grievance. The letter indicates a response will be provided within thirty days of the Plan's November 29, 2004 receipt of the grievance and further assured Robbins that: "Individuals with no prior involvement in your case will make a decision on your grievance." AR p. 385.

December 10-28, 2004 -- Peer Review. On or about December 10, 2004, the Plan referred the question of whether LVAD for destination should be treated as experimental to a third party peer reviewer ("Peer Reviewer"). In his December 22, 2004 response, the Peer Reviewer, a cardiologist, notes that the Plan documents exclude coverage for "experimental, **[*46]** investigation or unproven" services, but responds "No" to the following inquiry:

> 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?

AR p. 32 (dated December 22, 2004). He also answers "Yes" to the following question: "Based on all information reviewed does the member have benefits for a Left Ventricular Assistance Device?"

In support of the above conclusions, the Peer Reviewer states that the HeartMate LVAD procedure in question did not meet any of the four criteria listed [in the Handbook] for non-coverage." AR p. 33. He addresses each of 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. **[*47]**
>
> * 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 Peer Reviewer also discusses the "results of the REMATCH study published in the NEJM in 2001": which he stated "clearly document the survival benefits of destination LVAD support over medical therapy in patients suffering from end stage heart failure." AR p. 33.

After applying these standards to Mrs. **Whitley's** situation, the Peer Reviewer states "LVAD support and ultimate permanent or 'destination' therapy is currently being done in similar patients with FDA-approved devices and justified by data such as presented in the REMATCH study."

The Peer Reviewer criticizes the Plan's reliance on HAYES as follows:

> The [Plan] has based its determination . . . on the Hayes rating system. . . . This ["C" rating] of LVAD therapy 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 **[*48]** 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.

In explaining his ultimate conclusion that the LVAD should be covered, the Peer Reviewer states that this particular use of LVAD was approved by the FDA and covered by Medicare. He also notes that, although the LVAD was designated as destination therapy in the medical records, Mrs. **Whitley's** use of the LVAD might well allow her to improve sufficiently to be a good transplant candidate. AR p. 34. This report is dated December 22, 2004, and was apparently faxed to the Plan on December 28, 2004. n23

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n23 The REMATCH study relied on by the Peer Reviewer was, apparently, considered by HAYES prior to publication of its February 2003 Report. *See supra* n. 20 (discussing HAYES Alert discussion of 2001 REMATCH study). The HAYES Report could not, however, have considered reports of clinical experience or other studies or events post-dating publication of its February 2003 Report and preceding Mrs. **Whitley's** October 2004 surgery. As revealed by the HAYES Update, there wre sixty-two abstracts of such studies and reports in the first ten months of 2004 alone. Among the critical events post-dating the February 2003 HAYES Report is broadened FDA approval. As to FDA approval, the "HAYES Alert" states: "*The three LVAD systems currently cleared for market by the [FDA] are indicated for long-term use only as a bridge to transplantation.*" AR p. 65 (emphasis added). The above-quoted peer review as well as the URN-Review discussed earlier in this order, by contrast, address a more recent and broader FDA approval covering, *inter alia,* use of the LVAD for destination therapy.

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First-level Grievance

December 22-29, 2004--On December 22, 2004, Mr. **Whitley** wrote to Dr. Hutt summarizing the events leading to Mrs. **Whitley's** transfer to Duke and her medical care there. AR pp. 22-24. In this letter, Mr. **Whitley** asserts that he understood that a transplant was still under consideration when the LVAD was placed, but would be dependent on Mrs.

Whitley losing thirty pounds. Mr. **Whitley** questions the HAYES Rating and notes that Duke was the developer of the LVAD and that Duke, along with FDA, Medicare and Medicaid as well as other insurers do not deem the LVAD investigational or experimental. He asks that the letter be treated as notice of a formal appeal. AR p. 24.

The Plan acknowledged receipt of Mr. **Whitley's** grievance by letter dated December 28, 2004, promising a response within thirty days. The letter advises Mr. **Whitley** that he (on his wife's behalf) may submit additional written materials in support of the grievance and that his wife may have a representative appointed to assist in presenting the grievance. The letter further assures him "*that individuals with no prior involvement in your case will make a decision on your grievance.*" AR p. **[*50]** 175 (emphasis added). This letter is signed by Valerie Keller of the Compliance Department.

On December 29, 2004, Dee Goodman, the Plan's Grievance Coordinator, wrote to Robbins at Duke advising him that Duke's grievance, received on November 29, 2004, remained in the review process. This letter states that a decision would be issued by January 12, 2005. AR p. 191.

January 3-14, 2005.

Plan records indicate a phone call was either made or received on January 3, 2005, relating to the Peer Review. The full notation reads as follows: "I adv per d. goodman peer reviewer has recommended approval . . . but this needs to be reviewed by dr. hutt and to pls give it til jan 12." It is not clear if the person on the other end of this call was Mr. **Whitley** or a Duke representative. The next two calls listed, however, are calls from a Duke representative on January 18 and 19 to check on the status of the claim. These are followed by a call from the Plan to Duke on January 20 advising that the denial would be upheld. n24

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n24 AR p. 199 (January 18 notation stating: " prov called back to check on status of grievance. Adv I will contact Grievance department and give him a call back."); AR p. 199 (January 19 notation stating: "prov joe r . . .cal[l]ed back to speak to someone in grievance. supervisor Kim B took the call and advised the prov that she will have renee bouye call him back."); AR p. 199 (January 20 notation stating: "called prov back after speaking with renee in compliance. rec'd [voice mail] left msg indicating the denial was upheld based on the procedure being experimental and not approved by the FDA. advised that a formal letter will be forthcoming detailing the decision. advised that renee will be available to answer any additional questions he should have. left my contact number.").

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Mr. **Whitley** maintains that he called the Plan on January 14, 2005, to inquire regarding appointment of a representative. He asserts that he was told that the Plan had recommended that the disputed claim be paid and that he did not need to provide any further support for his claim. *See* AR p. 429 (Mr. **Whitley's** July 15, 2005 letter to Plan--discussed *infra*).

The record also contains a handwritten notation on a copy of the Plan's December 28, 2004 letter which appears to be notes of such a call made by Mr. **Whitley** during January 2005. n25 The Plan has no contemporaneous records of a call from Mr. **Whitley,** unless it is the January 3, 2005 call referenced above.

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n25 As discussed below (addressing July 2005 appeal letter), the notation refers to a January 3, 2005 call. This suggests either that Mr. **Whitley** may be referring to a conversation with someone else who had called the Plan on January 3, 2005 (possibly a Duke representative), or that the notation refers to his own call on January 3, 2005.

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January 19, 2005. [*52] The Plan denied Mr. **Whitley** and Duke's first-level grievances on January 19, 2005. This denial relies on both the lack of notice and the experimental exclusion. AR p. 25-26. The letter is signed by Dee Goodman, Grievance Coordinator.

As regards the Experimental Exclusion, the denial letter first quotes the Plan exclusion language (though not the controlling definitions), then states that the Plan "rel[ies] on the HAYES rating system" which had given the LVAD a C rating. AR p. 25. Neither the URN-Review nor the Peer Review are mentioned.

As to lack of notice, and this is the Plan's first reliance on that ground, the Plan asserts that the "Medical Director reviewed your medical records and determined that we did not receive notification from you or the hospital requesting services for the [LVAD]." AR 25. The letter does not, however, address the November 22, 2004 letter from Robbins (written on behalf of Duke) in which he detailed repeated conversations with Hardin and asserted that the Plan, through Hardin, provided an essentially "blanket" approval for whatever needed to be done to save the patient's life. Neither is there any record which suggests what evidence the Medical Director **[*53]** (Dr. Hutt) relied on in deciding, if he did so decide, that Robbins was untruthful in his letter as it related to notice.

What evidence is available as to Dr. Hutt's reasoning for the denial is found in an email string and suggests that he did not even consider the notice issue. *See* AR pp. 42-44. Moreover, this evidence suggests that Dr. Hutt made only a cursory decision to affirm the denial based predominantly on a desire to move the process to the next level, rather than to consider the merits of the grievance *Id.* (responding to inquiries as to how to handle the grievance:"*Let's send it out denied as experimental and handle any other re-review on the appeals side if it comes to that.*"). n26

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n26 This exchange was apparently prompted by a January 18, 2005 inquiry from the provider as to the status of the grievance. After confirming that this was "the LVAD case," Renee Bouye wrote Donald Pifer, Vice President of Network Management stating that "In our meeting, Dr. Hutt said he wanted to send this back out. I asked him about it the other day and he said he wanted to send it back out but I have heard nothing else. Do we really need to send this back out or can we just respond as a benefit issue?" Noting that the denial was based on the HAYES rating and an experimental exclusion, she notes "We are days away from missing our TAT by a month. Please advise." Pifer forwarded the email to Dr. Hutt asking "what do you suggest?" *Dr. Hutt replied: "Let's send it out denied as experimental and handle any other re-review on the appeals side if it comes to that."* AR p. 43 (emphasis added-quoted in text of order). The exchange between Pifer and Bouye which follows agrees to "handle this as a benefit" issue and states that the Grievance Coordinator will be told to deny as experimental and based on the HAYES rating of "C or D." *No mention of a notice concern appears anywhere in these email exchanges.*

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This email string also discloses that Dr. Hutt was, effectively, the sole decision-maker on this grievance. As he was the initial decision-maker, this is obviously contrary to assurances the Plan gave Mr. **Whitley** and Duke (Robbins) in its letters acknowledging receipt of their grievances. In short, Dr. Hutt affirmed his own earlier decision, based solely on the summary HAYES Report Hardin obtained on October 13 and 14, 2004. In doing so, he disregarded the information and opinions offered by the URN-Review and Peer Review.

The denial letter advises Mr. **Whitley** of the right to receive copies of criteria and documentation relied on by the Plan. n27 It also advises him of the member's right to file a second-level grievance. AR p. 25-26.

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n27 From the record, it appears that the Plan may have attached its two letters to Dr. Milano as well as the October 4, 2004 letter to MUSC. AR pp. 27-30. There is, however, no indication that either the URN-Review or Peer Review were provided.

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Second-level Grievance

[*55] July 2005. On July 15, 2005, Mr. **Whitley** filed a second-level grievance. AR pp. 428-31. In this detailed letter, Mr. **Whitley** states that after he received the Plan's December 28, 2004 letter:

> I called **Carolina Care Plan** on January 14, 2005, and requested information regarding the appointment of a representative and the procedure for submission of additional data . . . . I was told that **Carolina Care Plan** had recommended payment for my wife's treatment related to the LVAD. I was also told that **Carolina Care Plan** was waiting on additional materials sent from Duke . . . and as soon as that occurred, I would be notified in writing of the . . . Plan's decision, which I understood would be approved coverage for the LVAD procedure and all related medical costs.
>
> I also asked a **Carolina Care Plan** representative if I was wasting time and energy submitting additional data relating to the LVAD. The . . . representative again assured me that the LVAD procedure was covered and that **Carolina Care Plan** did not require additional information regrading the LVAD. . . . I relied on these assurances and did not submit additional data because the representative told me . . . that the procedure **[*56]** had been approved . . . .

AR p. 429. Mr. **Whitley** then describes his subsequent receipt of the January 19, 2005 denial letter and his understanding of pre-surgery communications between Duke and the Plan. n28

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n28 Mr. **Whitley's** understanding of these communications would, of course, be second-hand information.

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Three exhibits appear to have been attached to this letter. AR pp. 432-37. Among the attachments was a copy of the Plan's December 28, 2004 letter which bears the following handwritten 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. n29

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n29 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.

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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 **[*58]** 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 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. n30

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n30 The cursory denial letter does not even refer to the HAYES Rating. *See infra* p. 34.

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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. n31 AR p. 389. The one page letter is quite cursory, and relies only on the following denial reason: "the LVAD is considered experimental, investigational 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.

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n31 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.

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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). **[*61]** n32

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n32 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.

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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 **[*62]** 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 **[*63]** "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). n33 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."

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n33 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.

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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). n34

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n34 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.

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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.

An October 21, 2005 memorandum from Dee Goodman to Karen Phillips, Teresa [Brooks], and Patricia Ortiz, provides detailed pre-hearing information. n35 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.

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n35 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.

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

The summary discloses that the November 3, 2004 URN-Specialized Physician Review concluded that **[*67]** 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 **[*68]** (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. n36 Two are duplicates of the same letter: the Plan's October 19, 2004 letter to Dr. Milano (initial denial letter relying solely 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).

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n36 All three follow the memorandum in the record and are preceded by exhibit cover pages.

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It is not clear from the record whether any additional documents were provided to the panel which made the final decision. n37 What inferences might be drawn from the physical arrangement of the administrative record suggest that, at most, only a handful of **[*69]** 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. n38 The physical arrangement of the record also suggests that the grievance panel may not have had the critical HAYES documents. n39

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n37 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.

n38 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). **[*70]**

n39 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.

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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 **[*71]** grievance as a medical rather than a benefits issue). n40

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n40 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.

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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 n41 (presumably provided to the third-level grievance panel). This summary restates **[*72]** 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 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.

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n41 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.

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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 **[*74]** to the member's benefit." AR p. 538. n42

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n42 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.

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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 **[*75]** 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 **[*76]** 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. n43 Zupon 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.* n44

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n43 The only "protocol" listed in the denial letter was the "notification protocol." *See supra* p. 42 (quoted AR p. 533).

n44 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.

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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 **[*78]** of the decision denying the claim.

29 U.S.C. § 1133 (1988).

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, **[*79]** 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 **[*80]** 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,* **[*81]** " 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 **[*82]** 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. n45

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n45 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 deny coverage, under the Experimental Exclusion, if the purpose of the LVAD implant was for destination therapy.

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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.*"). n46

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n46 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..

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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 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 **[*85]** as an independent denial reason. n47

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n47 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).

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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 **[*86]** 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 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 **[*87]** 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 **[*88]** 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 **[*89]** 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 **[*90]** 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. n48

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n48 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.

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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 **[*91]** 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. n49 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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n49 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.**

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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. n50

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n50 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.

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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.

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 **[*94]** 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. n51 Obviously, if that evaluation came back negative, as it ultimately did, an LVAD installed as a bridge-to transplant would become destination therapy.

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n51 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.

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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 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 **[*96]** 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. n52 All of these 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 **[*97]** 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).

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n52 Each definition includes four criteria. After elimination of overlapping criteria, however, only six total criteria remain.

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In arguing that implantation of an LVAD for destination purposes fell within the Experimental Exclusion **[*98]** 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. n53 Thus, the Plan concedes, *sub silentio,* that the other five criteria are satisfied.

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n53 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.

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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). n54 For the reasons set **[*99]** 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.

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n54 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.

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As in regard to notice, the court reaches this conclusion applying a modified abuse of discretion standard of review. **[*100]** 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 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. n55

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n55 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.

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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. n56

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n56 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 evidence relating to FDA and Medicare approval of LVAD as destination therapy.

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The Plan does not even appear to have considered evidence which **[*102]** 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 **[*103]** 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).

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. n57

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n57 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.

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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. n58

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n58 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.

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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 **[*106]** "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. n59

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n59 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.").

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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. n60 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<TM> will be made only after the HAYES Medical Technology Directory<TM> 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.

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n60 Even this extensive listing would not be complete as it does not include materials published from February 2003 through December 31, 2003.

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Absent evidence to the contrary, and none is offered, HAYES' subsequent change of its Rating may reasonably **[*108]** 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 considered the various articles abstracted in the Update to support a change in rating. n61

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n61 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.

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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. **[*109]** **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 **[*110]** Exclusion as of the date of Mrs. **Whitley's** surgery.

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 **[*111]** 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 **[*112]** 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* **[*113]** 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. n62 *See supra* p.55 (fourth criterion). Indeed, HAYES would appear to consider both in its evaluations. *See supra* n. 57 & 59.

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n62 Mr. **Whitley** also provided information regarding the change in FDA approval.

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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 **[*114]** 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 review at any stage of the Plan's grievance process. Indeed, it appears that the original decision-maker, Dr. Hutt, influenced the entire process, **[*115]** 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 **[*116]** 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. n63 These errors demonstrate that the Plan failed to provide a full and fair review.

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n63 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 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.

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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 n64 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.

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n64 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.

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IT IS SO ORDERED.

s/ Cameron McGowan Currie

UNITED STATES DISTRICT JUDGE

Columbia, South Carolina
December 27, 2006