

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Third-level Grievance

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

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

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

AR p. 675 (emphasis added).³⁴

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

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

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

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

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

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

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

experimental/investigational.” Id. (emphasis added).

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

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

AR p. 540. The results of the various grievances were summarized as follows:

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

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

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

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

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

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

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

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

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

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

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

The record also contains a Grievance Hearing Summary Sheet⁴¹ (presumably provided to the third-level grievance panel). This summary restates the grievance issue in a manner similar to the way the issue was stated in the August (second-level) Summary Sheet, although it is modified to indicate that two prior grievances were upheld (both based on the Experimental Exclusion and HAYES rating of "C"). AR p. 536. The summary then explains:

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

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

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