ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

27 NOV 1984

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 84-34
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-34 pursuant to 10 U.S.C. 1071-1092, and DoD 6010.8-R, chapter X. The appealing party is the provider, St. Louis University Medical Center, represented by its attorney. The appeal involves the denial of CHAMPUS cost-sharing for heart transplant surgery and other services rendered in the treatment of congestive heart failure and cardiomyopathy from April 18, 1982, to October 23, 1982. The amount in dispute is $180,156.65.

The hearing file of record, the tape of oral testimony and the argument presented at the hearing, the Hearing Officer's Recommended Decision, and the Analysis and Recommendation of the Director, OCHAMPUS, have been reviewed. It is the Hearing Officer's recommendation that CHAMPUS deny the heart transplant surgery and the subsequent treatment for complications resulting from that surgery on the basis that (1) the initial surgery was experimental, and (2) the post-operative services are essentially similar to the noncovered heart transplant surgery and, consequently, are excluded under the CHAMPUS regulation. The Hearing Officer found that the original heart transplant surgery was an experimental procedure and ineligible for CHAMPUS cost-sharing. The Hearing Officer also found that the subsequent postoperative services could not be cost-shared by CHAMPUS because the services related to a complication resulting from a noncovered treatment and were essentially similar to the initial noncovered care.

The Director, OCHAMPUS, concurs in the Recommended Decision and recommends adoption of the Recommended Decision as the FINAL DECISION. The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, concurs in the recommendation of the Hearing Officer and hereby adopts the recommendation of the Hearing Officer as the FINAL DECISION.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS cost-sharing of the appealing party's claims for the medical services related to the heart transplant surgery and the subsequent postoperative services related to the transplant surgery. This determination is based on findings that: (1) the heart transplant surgery was considered an experimental procedure at the time of the beneficiary's surgery and (2) the postoperative care received by the beneficiary is excluded from CHAMPUS cost-sharing because the services related to complications which occurred after the surgery were similar to the noncovered care.

FACTUAL BACKGROUND

The beneficiary, the 39-year old spouse of an active duty enlisted member in the United States Air Force, received a heart transplant on April 18, 1982, at St. Louis University Hospital. The patient did well until 12 days after the operation when test showed a Grade IV rejection. Medications were administered and she remained hospitalized except for a weekend pass on May 29, 1982, until her discharge on June 25, 1982. On July 12, 1982, the patient was readmitted to the hospital for evaluation of progressive weight gain which was believed due to poor dietary management by the patient. She was carefully instructed on a 1200 calorie diet and discharged on July 19, 1982. On August 9, 1982, the patient was seen for a rapid heart beat and readmitted to the hospital after confirmation of an atrial flutter. An endocardial biopsy indicated mild to moderate rejection and she was treated with steroids until her discharge on August 17, 1982. On September 11, 1982, she was readmitted to the hospital with congestive heart failure and a class II - IV rejection episode. Although she was discharged on October 2, 1982, she was readmitted on October 3, 1982, with a diagnosis of "status post heart transplant; acute rejection." She remained hospitalized until her death on October 23, 1982.

A total of 72 CHAMPUS claims were received by the CHAMPUS Fiscal Intermediary for hospitalization, surgery, physician services, laboratory charges, radiological services, anesthesiology, and related outpatient services. The claims totalled $180,156.65, and the Fiscal Intermediary issued CHAMPUS payments of $94,100.56. Subsequently, the Fiscal Intermediary initiated recoupment action to recover the erroneously paid funds and has recovered $21,378.54 of the $94,100.56.

The Hearing Officer's Recommended Decision describes in detail the beneficiary's medical condition, the events leading to the heart transplant, and the subsequent complications which resulted from the initial noncovered heart transplant procedure. Because the Hearing Officer adequately discussed the factual record, it would be unduly repetitive to summarize the record, and it is accepted in full in this FINAL DECISION. The Hearing Officer has provided a detailed summary of the factual background, including the appeals that were made and the previous denials, the medical opinion of the OCHAMPUS Medical Director,

and the CHAMPUS policy which is based in part on the Uniform Medical Policy of the National Blue Cross/Blue Shield Associations.

The Hearing was held on May 2, 1984, in St. Louis, Missouri, before OCHAMPUS Hearing Officer, Joseph L. Walker. Present at the Hearing were the attorney for the provider, the treating physician, the credit and collection manager of the hospital, and a representative from OCHAMPUS. The Hearing Officer has issued his Recommended Decision and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issues in this appeal are whether the cardiac transplant surgery and postoperative services provided the beneficiary were medically necessary and whether the postoperative services were essentially similar to a noncovered condition as to be excluded from CHAMPUS cost-sharing.

Medically Necessary

The CHAMPUS regulation, DoD 6010.8-R, chapter IV, A.1., provides the following general limitation to the basic program:

> "Subject to any and all applicable definitions, conditions, limitations, and/or exclusions specified or enumerated in this Regulation, the CHAMPUS Basic Program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury. . . ."

To interpret this Regulation, as it applies to the services in dispute, requires a review of what is meant by the term "medically necessary." The definition in DoD 6010.8-R, chapter II, provides in part that, "Medically necessary includes [the] concept of appropriate medical care." The definition of "appropriate medical care" requires that, ". . . the medical services performed in the treatment of a disease or injury . . . are in keeping with the generally acceptable norm for medical practice in the United States."

There is, in addition, a specific CHAMPUS regulation provision in chapter IV, G.15., that excludes, "Services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens."

As defined in the CHAMPUS regulation, chapter II, "experimental" means "medical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicological conditions) which does not meet the generally accepted standards of usual

professional medical practice in the general medical community. . . ."

In applying these limitations in cases involving the question of experimental or investigational procedures, this office has held that the disputed services must be adequate for the diagnosis and treatment of illness or disease and, correspondingly, constitute treatment of a disease or illness. In addition, the general acceptance and efficacy of the treatment must be supported by medical documentation or recognized and authoritative literature contemporaneous with the date of care in dispute. (See generally previous FINAL DECISIONS in OASD(HA) Files 83-16 and 83-17, and FINAL DECISIONS cited therein.)

In applying the above cited criteria to heart transplant procedures, the CHAMPUS policy was correctly presented at the hearing. Although CHAMPUS recognizes that the heart transplant procedure has been refined and improved since it was first attempted in humans in 1967, the CHAMPUS position to date remains that the evidence regarding heart transplant procedures indicates that it is not adequately predictable or generally accepted by the medical community as a standard of care.

The CHAMPUS position on the cardiac transplant procedure is based in part on the Uniform Medical Policy of the National Blue Cross/Blue Shield Associations which considers cardiac transplantation to be an investigational procedure. On June 23 and 24, 1983, the National Blue Cross/Blue Shield Association's Medical Advisory Subcommittee of the Cost Containment and Provider/Professional Affairs Committee met to develop a Uniform Medical Policy on the subject of heart transplantation. The Uniform Medical Policy Statement issued as a result of this meeting discussed the history of the Medical Advisory Subcommittee's stance on heart transplantation and the fact that they had met in April of 1980 and concluded that heart transplantation was experimental/investigative. The statement went on to discuss the effects of the use of Cyclosporin A on rejection problems following heart transplantation. The Subcommittee concluded that even though progress has been made in heart transplantation, several critical aspects of this procedure require further study. These aspects were specified as follows:

> "Cyclosporin A has improved survival at two institutions but the effects (near, middle, and long term) of its' use have not been assessed.
>
> "While it is clear that results are repeatable in one institution, these results are not consistently reproduced from center to center."

The Medical Advisory Subcommittee's conclusion was that heart transplantation, in view of the above stated concerns, be considered experimental/investigative. This recommendation was

adopted in the Uniform Medical Policy Manual, Section III, page 5.7, which states that benefits should not be provided for heart transplantation because it is considered experimental/ investigative.

The CHAMPUS position also takes into account the fact that Medicare considers cardiac transplantation to be an investigational procedure and, therefore, not covered under that program. The Health Care Financing Administration (HCFA) is currently funding a cooperative study involving several major heart transplant programs in the United States, called the National Heart Transplantation Study. This study is considering several aspects of the heart transplant procedure including the potential need for the procedure, the survival rate of recipients, the availability of donor hearts, the cost of the procedure, the rehabilitation and quality of life of recipients, and the legal and ethical aspects of heart transplantation. CHAMPUS will give consideration to the results of this study once they become available; however, currently, there is no information available which documents that cardiac transplantation is safe, efficacious, and generally accepted by the medical community as an acceptable service. As such, CHAMPUS considers heart transplantation to be an experimental/ investigational procedure which does not meet the criteria for coverage under DoD Regulation 6010.8-R.

The Hearing Officer summarized the appealing party's position on the experimental/investigational nature of heart transplant procedures as follows:

> "In his October 24, 1983, letter to [the attorney for the appealing party], the attending surgeon wrote that 'cardiac transplantation is no more experimental than kidney transplantation.' He added that while the early transplants were generally unsuccessful, the success rate has risen to nearly 80% through improved patient selection, better diagnosis of rejection, antiplatelet therapy, and the use of Cyclosporin.
>
> "At the hearing, the attorney stated that it is the provider's position that the heart transplant was not in any way experimental or investigatory and that the procedure constituted necessary and vital treatment to sustain life. Dr. John Codd testified at length regarding cardiac transplantation in general and as it applies to the present case. With regard to the question of heart transplants being experimental, the physician said that there is now an 80% success rate compared to a survival rate of 'zero' for patients with lung cancer or an esophogeal

tumor. Over 400 heart transplants have been performed since 1968, and presently patients are re-employed 90% of the time and are able to return to an active life. The physician stated that he has met with the Medicaid administrators in Missouri and plans to meet with the House Ways and Means Committee on Transplants. According to the physician, heart transplants are not experimental 'among the knowledgeable', which he defined as those involved with major institutions.

"Subsequent to the hearing, the provider submitted for the record a copy of a December 7, 1979, memorandum (in draft form) from the Deputy Director, National Heart, Lung, and Blood Institute (a branch of the U.S. Public Health Service) to the Director, Coverage Assessment Staff, National Center for Health Care Technology. The final version of the memorandum, dated January 21, 1980, was also submitted. The memorandum concerns Medicare coverage for heart transplants. One of the issues addressed was whether heart transplants were still considered experimental. The memorandum concerns Medicare coverage for heart transplants. One of the issues addressed was whether heart transplants were still considered experimental. The Deputy Director responded as follows:

> 'For patients meeting the Stanford criteria, the Stanford procedure in the hands of the Stanford group yield reproducibly safe and effective results. Thus, the basic procedure in this patient group is no longer 'experimental'.'

"The Deputy Director recommended Medicare reimbursement at those centers which 'demonstrate the expertise, resources, logistical plans, and anticipated continuing concentration of experience necessary for high quality results' and for patients 'who fulfill the 'Stanford criteria' for patient selection, and whose therapeutic and evaluative procedure include at least the minimum components of the 'Stanford protocol' or acceptable equivalents.'"

The Hearing Officer, in his Recommended Decision, correctly stated the issues and correctly referenced the applicable law and regulations. The Hearing Officer found that:

> "In determining whether or not heart transplants are experimental, it is important to once again review the definition employed in DoD 6010.8-R. A part of that definition directs that a service would be experimental if it 'Does not meet the generally accepted standards of usual professional medical practice in a general medical community.' It has been shown that the heart transplants are a fairly routine occurrence at the provider's own medical facility and at Stanford University Medical Center. It has not been shown, however, that heart transplants are a routine accepted practice at other than a very few of the thousands of hospitals in this country. Heart transplants are not reasonably available to most patients at this time and thus cannot be considered 'usual professional medical practice in the general medical community.'

I concur with the Hearing Officer and adopt his finding in the case. Under the CHAMPUS appeal procedure, the appealing party has the responsibility of providing whatever facts and documentation are necessary to support opposition to the CHAMPUS determination. The record in this appeal does not establish the general acceptance and efficacy of heart transplant procedures as supported by medical documentation or recognized and authoritative literature contemporaneous with the dates of the beneficiary's care. Therefore, I must conclude the beneficiary's heart transplant procedure was not medically necessary and was excluded from CHAMPUS coverage as experimental/investigational care.

Post Operative Services

The CHAMPUS regulation, DoD 6010.8-R, chapter IV, E.9., also excludes from CHAMPUS coverage services related to complications from noncovered initial surgery or treatment which are essentially similar to the initial noncovered care.

The regulation states:

> "Complications (Unfortunate Sequelae) Resulting from Non-Covered Initial Surgery/Treatment. Benefits are available for otherwise covered services and supplies required in the treatment of complications resulting from a noncovered incident of treatment (such as nonadjunctive dental care, transsexual surgery, and cosmetic surgery), but only if the subsequent complication represents a separate medical condition such as a systemic infetion, cardiac arrest, or acute drug reaction. Benefits may not be

> extended for any subsequent care or procedure related to the complication that is essentially similar to the initial noncovered care. Examples of complications similar to the initial episode of care (and thus not covered) would be repair of facial scarring resulting from dermabrasion for acne or repair of a prolapsed vagina when in a biological male who had undergone transsexual surgery."

In addition, DoD 6010.8-R, chapter IV, G.67., excludes from CHAMPUS coverage, "All services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment; . . ."

The OCHAMPUS Medical Director reviewed the documentation of record and issued an opinion for the record that "All of the services and supplies provided this patient following the heart transplantation procedure appear to have been appropriate and medically necessary." He added, however, that, "each of the admissions were solely and exclusively for the treatment of complications caused by the noncovered heart transplantation which were not uncommon or unexpected." He said that, "the heart failure, the arrhythmias, the problems with weight gain and clearly the other complications of rejection that soon followed were all related to the heart transplantation." He concluded that, "each of these complications were expected, usual complications of heart transplantation and were the reasons for the patient's readmission to the hospital."

After reviewing all the evidence and applicable law and regulations, the Hearing Officer found that:

> "The requirements of the regulation . . . seemed quite clear to the Hearing Officer. In order to be a covered CHAMPUS service, a post-operative complication must be a separate medical condition - unrelated to the original noncovered care. The position of the appealing party that the post-operative hospital and medical services were medically necessary is well taken, but that point is not in dispute. The services rendered are certainly 'otherwise covered services' as defined [in the regulation] and the medical need for them has not been questioned. The matter under consideration is whether those services were related to a separate medical condition from the transplantation. The Hearing Officer has been unable to locate, either in the medical file of record, or in the verbatim record any contention by the provider that the post-operative services were unrelated to the surgery. In point of

> fact, Dr. Codd testified during the Hearing that the beneficiary was 'readmitted on several occasions for persistent rejection episodes . . . proven by endocardial biopsy.'"

It is the Hearing Officer's opinion that the weight of the evidence establishes that the postoperative hospital and medical treatment of the beneficiary was a direct result of the noncovered heart transplantation procedure, essentially similar to the noncovered condition, and excluded from CHAMPUS cost-sharing. I concur in the Hearing Officer's findings and recommendations and adopt them as the FINAL DECISION in this case.

SECONDARY ISSUES

Several secondary issues were raised by the appealing party during the hearing. In my review, I find the Recommended Decision of the Hearing Officer adequately states and analyzes the issues, applicable authorities, and evidence in this appeal. The findings are supportable by the Recommended Decision and the appeal record and additional analysis is not required. The Recommended Decision is acceptable for adoption with regards to the Secondary Issues as the FINAL DECISION by this office.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS cost-sharing of the April 18, 1982, heart transplant and related medical expenses for the heart transplant because the procedure was experimental and not eligible for CHAMPUS cost-sharing at the time of care. Further, it is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) to deny CHAMPUS cost-sharing of the postoperative services because these services related to complications resulting from a noncovered incidence of treatment which services were essentially similar to the initial noncovered care. Because I have found the heart transplant to be a noncovered service and the postoperative care to be related to a noncovered procedure, the Director, OCHAMPUS, is directed to review this case for appropriate recoupment action in accordance with the Federal Claims Collection Act. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

for William Mayer, M.D.