



ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT
SECRETARY OF DEFENSE (HEALTH AFFAIRS)
UNITED STATES DEPARTMENT OF DEFENSE

AUG 23 1983

Appeal of)	
)	OASD(HA) File 83-16
Sponsor:)	
)	FINAL DECISION
SSN:)	

This is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 83-16 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the estate of the deceased beneficiary, a retired officer of the United States Army. The estate was represented by the beneficiary's widow. As representative of the estate, the beneficiary's wife did not wish to be present at the hearing and waived the hearing, which was scheduled for January 20, 1983; therefore, a hearing was held only on the record. The appeal involves claims for a cardiac rehabilitation program undergone by the beneficiary from December 17, 1979 to January 28, 1981. The amount billed for the cardiac rehabilitation program totaled \$2,364.00. The beneficiary's private medical insurance paid \$1,683.20 of the billed charges, therefore, the amount in dispute is the remaining \$680.80.

The hearing file of record, 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 the First Level Appeal determination by OCHAMPUS denying coverage of the cardiac rehabilitation program be upheld. The Hearing Officer found there was not sufficient documentation to support the medical necessity of the cardiac rehabilitation program, that the documentation did not support a finding that the program constituted physical therapy, that the program came within the meaning of a general exercise program, that it constituted preventive care, and that it constituted education/training. The Director, OCHAMPUS concurs in these findings and recommends adoption of the Hearing Officer's Recommended Decision as the FINAL DECISION.

The Acting Assistant Secretary of Defense (Health Affairs) after due consideration of the appeal record concurs in the recommendation of the Hearing Officer to deny CHAMPUS cost-sharing and hereby adopts the recommendation of the Hearing Officer to deny cost-sharing as the FINAL DECISION.

The FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) is therefore to deny CHAMPUS cost-sharing for the cardiac rehabilitation program. This decision is based on the findings that the cardiac rehabilitation program was not generally accepted medical practice and, therefore, was not medically necessary, was not physical therapy, and was, in part, an educational program.

FACTUAL BACKGROUND

The beneficiary suffered an acute inferior wall myocardial infarction on October 18, 1979. He was hospitalized at Hospital from October 18, 1979 to November 7, 1979. Following his discharge, his cardiologist prescribed treatment at the cardiac rehabilitation program at the National Hospital for Orthopaedics and Rehabilitation, , Virginia. The program was started December 17, 1979 following the initial stress testing on November 15, 1979; the claims cover the period through January 28, 1981. The claims submitted by the beneficiary described the treatment as "physical therapy as ordered by doctor." The claims totaled \$2,364.00 of which \$1,683.20 has been paid by the beneficiary's private medical insurance. The amount in dispute is therefore \$680.80.

The then CHAMPUS fiscal intermediary for the State of Virginia, Blue Cross of Southwestern Virginia, initially advised the beneficiary that CHAMPUS does not allow payment for services provided by cardiac rehabilitation centers. Following reconsideration the fiscal intermediary allowed the first eight weeks of "physical therapy" treatments including the initial evaluation; the remainder of the program was denied. By letter dated July 17, 1981, the beneficiary appealed the partial denial to OCHAMPUS. The First Level Appeal determination, dated October 29, 1981, concluded the cardiac rehabilitation program was general exercise specifically excluded by Regulation, that weight reduction programs were also excluded and affirmed the fiscal intermediary's denial of coverage. In addition, the First Level Appeal determined that the claims paid as physical therapy were paid erroneously. The beneficiary, by letter dated December 11, 1981, requested a hearing by an independent Hearing Officer and claimed the cardiac rehabilitation program was physical therapy with cardiac monitor.

The record contains copies of the cardiac and pulmonary tests that the beneficiary underwent as well as the results of the cardiac rehabilitation program. There is a minimum of evidence regarding the cardiac rehabilitation program itself. The record includes a letter dated July 15, 1981 from the beneficiary's cardiologist, Dr. that states:

"[the beneficiary] sustained a massive inferior wall myocardial infarction, had major arrhythmias and a cardiac arrest in October 1979. I the undersigned am his cardiologist and prescribed that he be treated in the cardiac rehabilitation program at the National Orthopaedic Hospital. This cardiac rehabilitation program is directed by _____, a cardiac rehabilitation nurse specialist. She is under my direct supervision at all times in the care of my referred patients.

For [the beneficiary] this cardiac rehabilitation was a medical necessity. ... The cardiac rehabilitation has permitted [the beneficiary] to resume all his previous employment activities and to live a reasonably normal life. It has also increased the chances of [the beneficiary] surviving a myocardial infarction and decreased his chances of sustaining another infarct."

A brochure from the National Hospital for Orthopaedics and Rehabilitation entitled "Exercise for the Heart at the Center for Cardiac Rehabilitation" provides the following description of the program:

"The purpose of the Center for Cardiac Rehabilitation is to provide cardiovascular exercise and education programs for patients, family members and the community.

Medically supervised, monitored exercise programs for those with diagnosed coronary artery disease, heart attack, angina or coronary bypass surgery. Semi-supervised exercise maintenance programs for those who have completed a medically supervised exercise program. Planning, instruction and follow-up exercise programs conducted at home. Group patient and family educational sessions on risk-factor modification, coronary artery disease, diet, smoking, stress reduction, medications, CPR, Emergency Cardiac Care. Individual counseling when indicated for dietary, vocational, social, financial, psychiatric, sexual or other problems. Preventive exercise programs for those without diagnosed coronary artery disease. Physician referral is not necessary."

The brochure described the modalities available as, "exercise room, axial resistors, rowing machine, bicycle ergometers, wall pulleys, treadmill, track-field, cybex." It further states that, "the cardiac nurses and exercise technicians are always present and a staff cardiologist is available during treatment hours."

A hearing was scheduled to be held on January 20, 1983 in , Virginia before OCHAMPUS Hearing Officer, . The wife of the beneficiary as representative of the estate of the deceased beneficiary elected to waive her right to a hearing and have a decision issued based on the record. The Hearing Officer has issued her 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 rehabilitation program provided the beneficiary was medically necessary and whether the program constituted physical therapy.

Medically Necessary

The CHAMPUS regulation DoD 6010.8-R provides in chapter IV, A.1. as follows:

"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 treatment 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."

The Office of Assistant Secretary of Defense (Health Affairs) has in two previous FINAL DECISIONS considered the medical necessity of cardiac rehabilitation exercise programs. In OASD(HA) case file 01-81, dated May 21, 1982, it was stated:

"To constitute a CHAMPUS covered service, the cardiac rehabilitation program must therefore be adequate for the diagnosis and treatment of illness or disease and correspondingly, constitute treatment of a disease or illness. ... The acceptance and efficacy of the

treatment of post-myocardial infarction by the cardiac rehabilitation program must therefore be documented."

This earlier decision involved a program that consisted of monitored exercise under the supervision of nurses that was similar to the program addressed in this appeal. It was concluded in OASD(HA) 01-81 that:

"... the general acceptance and efficacy of the program in the treatment of post-myocardial infarction is not supported by medical documentation nor recognized professional opinion and authoritative medical literature contemporaneous with the dates of care."

In OASD(HA) 01-81 medical reviews requested by OCHAMPUS from the Colorado Foundation for Medical Care were discussed. In commenting on the medical reports, this Office stated:

"These reports reveal a change in thinking by the reviewing physicians regarding the medical necessity of the [cardiac rehabilitation] program based on evidence which suggests the program might contribute to a reduction in death in the first six months following an acute myocardial infarction and the increasing acceptance of the programs by the general medical community. However, the opinions clearly state cardiac rehabilitation programs remain an unproven modality. are not a standard of care in every community, and evidence does not support a reduction in heart disease as a result of the programs.

The physicians cite improved function capacity to perform activities of daily living with less fear, earlier return to work and increased understanding by the patient of the need for management of hypertension and stress as supporting the medical necessity.

* * *

The evidence herein and the peer review opinions given at the time the services were rendered disclose no evidence of the documented effectiveness of the exercise programs in the treatment of myocardial infarction (coronary heart disease); instead the file clearly indicates its unproven nature."

In OASD(HA) case file 20-79 it was said:

"Further, it is acknowledged that the program may very well have produced beneficial results for the individual party -- as would be anticipated for any individual, with or without a heart condition, who undertook a program of structured exercise and weight reduction. We do not concur, however, that the exercise/weight reduction regimen constituted specific treatment. Further, the fact that a physician orders, prescribes or recommends that a patient pursue a certain course does not in itself make it medically necessary treatment. A physician in caring for his or her patient may, and properly so, advise and recommend in many areas beyond specific treatment. This is particularly true relative to encouraging changes in lifestyle -- i.e. increased exercise, elimination of smoking, weight reduction, etc."

The program followed by the beneficiary that is the subject of this appeal was from December 17, 1979 to January 28, 1981; the initial stress test was November 15, 1979. Thus, the program was entered only a short time after the time period considered in OASD(HA) 01-81, which was from July 10, 1978 to August 13, 1979. The record in this appeal does not establish the general acceptance and efficacy of the program in the treatment of post-myocardial infarction as supported by medical documentation or recognized professional opinion and authoritative literature contemporaneous with the dates of care. In addition, the record does not contain conclusive evidence that the cardiac exercise programs improve survival; that is, reduce mortality or prolong life. Under the appeal procedure, the appealing party has the responsibility of providing whatever facts are necessary to support the opposition to the CHAMPUS determination. The time frame under consideration in this appeal occurred only shortly after the decision in OASD(HA) 01-81 and no substantial evidence has been presented which contradicts the findings in the earlier decision or establishes that medical norms for such programs had changed at the time of the beneficiary's care. Therefore, I must conclude the beneficiary's cardiac rehabilitation program was not medically necessary and excluded from CHAMPUS coverage as previously determined in OASD(HA) case files 01-81 and 20-79.

Physical Therapy

A determination that the program was not medically necessary prevents CHAMPUS coverage. However, because the beneficiary in his claims described the program as "physical therapy as ordered by doctor" and in his request for a hearing he described it as "physical therapy with cardiac monitor," it is appropriate to address the issue of physical therapy.

Under DoD 6010.8-R, chapter IV, B.3.g., physical therapy is a CHAMPUS benefit when provided by an authorized physical therapist. Under chapter II, B.134, a "physical therapist" means:

"... A person who is specially trained in the skills and techniques of physical therapy (that is, the treatment of disease by physical agents and methods, such as heat, massage, manipulation, therapeutic exercise, hydrotherapy and various forms of energy such as electrotherapy and ultrasound), who has been legally authorized (that is, registered) to administer treatments prescribed by a physician and who is legally entitled to use the designation, 'Registered Physical Therapist.'"

The record reflects that the exercise program was conducted and monitored by cardiac nurses and that a cardiologist was available. There was no indication in the record that a physical therapist was ever present or involved in the treatment. The initial treatment plan gives an "exercise prescription" with the following frequency, "3 x week/60 min. in clinic 1-2+ week at home." The treatment plan included the following types of exercises: flexibility and stretching, upper extremity strengthening (axial, pullups, rowing), bicycle ergometer (principally), treadmill, and walking.

The finding by the Hearing Officer, that "The program was not one of physical therapy" is supported by the record and I adopt that finding. Based on the evidence of record, I must conclude the cardiac rehabilitation program herein consisted primarily of activities which were not, at that time, widely accepted as therapeutic following a myocardial infarction. Therefore, consistent with my finding above that this program was not medically necessary, I further find that the program does not meet the definition of physical therapy (i.e., the treatment of disease by physical agents and methods) set forth in DoD 6010.8-R. CHAMPUS coverage of "therapy" cannot be authorized unless the general acceptance and efficacy of the treatment at the time of care is established.

SECONDARY ISSUES

Educational/Training

I consider it appropriate to comment on the educational aspect of the program which appears to be undisputed. The Regulation at chapter IV, G.43 excludes:

"Educational services and supplies, training, nonmedical self-care/self-help training and any related diagnostic testing or supplies.

(This exclusion includes such items as special tutoring, remedial reading, and natural childbirth classes.)"

The program offered by the Center for Cardiac Rehabilitation at the National Hospital for Orthopaedics and Rehabilitation was a comprehensive program. The purpose of the program as described by the provider is, "to provide cardiovascular exercise and education programs for patients, family members and the community." The program included, "group patient and family educational sessions on risk-factor modification, coronary artery disease, diet, smoking, stress reduction, medications, CPR, emergency cardiac care." Based on the program description included in the provider's brochure, it appears that it is undisputed that parts of the program were educational in nature. One of the interim reports to the cardiologist states, "patient has been instructed on low sodium, low fat diet by staff and dieting. He has participated in group diet lectures." Had it not been concluded that the cardiac rehabilitation program was not a covered benefit under CHAMPUS, those activities of the program specifically related to educational activities would have to be identified as they are specifically excluded from coverage.

Related Charges

"All services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment" are excluded from CHAMPUS cost-sharing by DoD 6010.8-R, Chapter IV, G.66. Therefore, the monitoring and stress testing that was performed as a part of the cardiac rehabilitation program is excluded from CHAMPUS cost-sharing.

Erroneous Payment

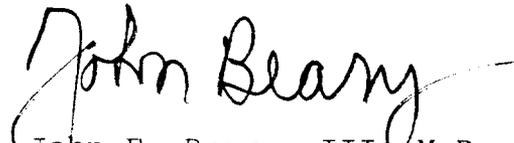
The fiscal intermediary after initially denying the claims for participation in the cardiac rehabilitation program allowed eight weeks as physical therapy. Based upon the above determination that the care was not authorized under CHAMPUS, the fiscal intermediary payments were erroneous.

The amount in dispute is \$680.80. The record does not specify what portion of this amount was paid. The amount is not significant to questions regarding CHAMPUS coverage of cardiac rehabilitation exercise programs, however, the actual dollar figure paid must be determined in any action to recover erroneous payments. This matter is referred to the Director, OCHAMPUS for appropriate recoupment action under the Federal Claims Collection Act.

SUMMARY

In summary, based upon the record in this appeal, I find the beneficiary's cardiac rehabilitation program was not medically necessary in the treatment of post myocardial infarction based on the lack of medical documentation, authoritative medical

literature and recognized professional opinion sufficient to establish the general acceptance and efficacy of the program at the time the care was received. I further find that the program does not meet the definition of physical therapy set forth in DoD 6010.8-R and CHAMPUS coverage of "therapy" cannot be authorized unless the general acceptance and efficacy of treatment at the time of care is established. Finally, I find that certain aspects of the program were educational in nature and are specifically excluded from CHAMPUS coverage by Regulation. Because charges for treatments or services that are related to a noncovered condition or treatment are not payable, such items as the stress monitoring as related to the exercise program are also excluded. The claims for participation in a cardiac rehabilitation program from December 17, 1979 to January 28, 1981, including the initial stress test on November 15, 1979, and the appeal of the beneficiary are therefore denied. The case is returned to the Director, OCHAMPUS for appropriate action under the Federal Claims Collection Act to finalize the recoupment of erroneous payment of some of the claims in this case. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

A handwritten signature in black ink that reads "John Beary". The signature is written in a cursive style with a long horizontal stroke extending to the right.

John F. Beary, III, M.D.
Acting Assistant Secretary