



ASSISTANT SECRETARY OF DEFENSE  
WASHINGTON, D. C. 20301

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HEALTH AFFAIRS

DEC 27 1983

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

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 83-43
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs), in the CHAMPUS Appeal OASD(HA) Case File 83-43 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party in this case is the beneficiary, a retired enlisted member of the U.S. Navy. The appeal involves the denial of CHAMPUS coverage of the beneficiary's cardiac rehabilitation program from March 12, 1981, through August 11, 1981. The amount in dispute is approximately \$1,424.00.

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 CHAMPUS deny coverage of the beneficiary's cardiac rehabilitation exercise program on the basis the care was not medically necessary.

The Director, OCHAMPUS, concurs in the recommendation of the Hearing Officer and recommends issuance of a FINAL DECISION denying CHAMPUS coverage of the beneficiary's cardiac rehabilitation program.

The Acting Principal Deputy Assistant Secretary of Defense (Health Affairs), acting as the authorized designee for the Assistant Secretary, after due consideration of the appeal record adopts the Recommended Decision of the Hearing Officer. The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs), therefore, is to deny CHAMPUS coverage of the cardiac rehabilitation exercise program provided at Hospital during the period of March 12, 1981, through August 11, 1981, and all services and supplies related to the program (i.e., treadmill tests and lab tests). This FINAL DECISION is based on the appeal record as stated above and precedential decisions of this office.

FACTUAL BACKGROUND

The beneficiary suffered a myocardial infarction in February 1981. The attending physician advised the beneficiary to enter the Cardiac Rehabilitation Program at Hospital, . The treating physician recommended the cardiac rehabilitation program because the beneficiary had not been involved in any conditioning exercise program at the time of the myocardial infarction and such a program would increase the strength of his heart; the exercise program would increase the beneficiary's physical confidence and reduce stress accumulated from his job as an air traffic controller; continued monitoring of blood pressure and other vital signs is important and can reduce the number of posthospitalization checks in his office; and, the cardiac monitoring during exercise and "mini stress testing" was indicated because the tests disclosed premature contractions.

The beneficiary registered in the cardiac rehabilitation program on March 12, 1981, and underwent a treadmill test. On March 21, 1981, he received laboratory tests consisting of HDL, blood sugar, cholesterol, and triglycerides. From March 16, 1981, through August 11, 1981, the beneficiary received 36 ministress tests and two additional treadmill tests.

The record in this appeal does not contain any reports from the rehabilitation program describing the service rendered. However, in a letter dated March 25, 1982, the beneficiary's spouse indicated that the rehabilitation clinic instructed the beneficiary on how to determine his heart and pulse rate and how to control the workload his heart would accept. In addition, she stated that during the treatment sessions a heart rate monitor and blood pressure monitor was attached to the beneficiary and that the beneficiary was under the supervision of either a cardiac specialist or a nurse trained in cardiac rehabilitation. The treatment also consisted of an education program where stress management and proper diet were explained to the beneficiary. Finally, she stated that when the beneficiary completed the program he was able to determine how fast his heart rate could get without pain or damage and how to manage his work activity to assure a "safe" range of exertion. The beneficiary subsequently continued the rehabilitation exercise program at home, including a walking program and use of an exercise bike with pulse monitor.

The beneficiary submitted a CHAMPUS claim in the amount of \$1,424.00 for the cardiac rehabilitation program, which included ministress tests, treadmill tests, and laboratory tests. The CHAMPUS Fiscal Intermediary for , Physicians Service, allowed CHAMPUS coverage of the three treadmill tests (\$510.00) and lab tests (\$56.00) and issued payment of \$424.50 after deducting the patient's cost-share. The charge for 36 ministress tests in the amount of \$858.00 was denied on the basis

that cardiac rehabilitation programs are exercise and educational programs and are not covered by CHAMPUS. The denial was upheld on Informal Review and Reconsideration Review by Physicians Service.

The OCHAMPUS First Level Appeal decision affirmed the prior determinations on the bases that: (1) the treatment was a general exercise program which does not qualify as physical therapy and is specifically excluded under CHAMPUS regulation, DoD 6010.8-R; (2) the care is not generally accepted treatment for postmyocardial infarction in accordance with the standard for medical practice within the United States; and (3) the treatment is excluded as preventive care. This decision also found that the lab tests and treadmill tests were directly related to the cardiac rehabilitation program and were excluded from CHAMPUS coverage.

Although the beneficiary requested a hearing, he waived his right to personally appear at the hearing and requested that the Hearing Officer render his Recommended Decision based on the record. Included in the record is a written statement from the beneficiary which responds to the OCHAMPUS Position Statement prepared for the hearing and states the beneficiary's position regarding CHAMPUS coverage of the claims. The Hearing Officer has issued his Recommended Decision, and all prior levels of administrative appeal have been completed. 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 by Hospital from March 12, 1981, through August 11, 1981, was medically necessary and whether the program constituted a general exercise program or was a covered physical therapy program.

#### 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":

". . . means the level of services and supplies (that is, frequency, extent and kinds) adequate for the diagnosis and treatment of illness or injury . . . . Medically necessary includes 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."

Under the CHAMPUS appeal procedure, the appealing party has the responsibility of providing whatever facts are necessary to support the opposition to a CHAMPUS determination. In view of the above cited hearing decisions concerning cardiac

rehabilitation programs, the appealing party must establish the general acceptance and efficacy of the program in the treatment of postmyocardial infarction as supported by medical documentation or recognized professional opinion and authoritative literature contemporaneous with the dates of care.

Although the dates of care in this appeal (March 12, 1981, through August 11, 1981) were subsequent to the dates of care involved in OASD(HA) Case File 01-81, substantial evidence has not been presented which contradicts the findings in the earlier decision or establishes that medical norms for cardiac rehabilitation programs had changed at the time of the beneficiary's care. In addition, the record does not contain conclusive evidence that the cardiac exercise programs improve survival; that is, reduce mortality or prolong life.

The beneficiary did submit letters dated December 1982 from the Acting President, \_\_\_\_\_ Hospital, and \_\_\_\_\_, M.D., a specialist in cardiovascular disease, in support of his cardiac rehabilitation program. Dr. \_\_\_\_\_ opined in his letter that:

" . . . sufficient data already exist to justify the recommendation of endurance training to enhance and maintain physical and emotional fitness among well individuals and to achieve specific goals in patients with selected medical problems . . . . While it seems likely that physically active persons can indeed expect greater longevity and lower cardiovascular morbidity, this potential benefit of endurance training must continue to be regarded as speculative."

The letter from \_\_\_\_\_ Hospital advised that cardiac rehabilitation programs were being covered by many insurance companies and third party payers, including Medicare. The letter states:

" . . . it is safe to assume that there is a great deal of support in cardiac rehabilitation services through the payment process . . . . [C]ardiac rehab is more than just recreational activity, . . . it serves to meet the emotional and physical well-being of patients suffering cardiac problems."

The Hearing Officer evaluated the evidence of record, in part, as follows:

"There appears to be no evidence in the record which would substantiate the sponsor/beneficiary's position that these medical services are the generally acceptable norm for medical practice in the United

States. His response to the position statement states that he has been informed by all medical professionals involved in his treatment that the current medical opinion is generally favorable to these (cardiac rehabilitation) programs as a value, he mentioned newspaper articles involving the opening of these type [sic] of clinics in the midwest, the expansion of the program at Hospital, but he does state that the programs are relatively new forms of post-MI treatment and therefore may not be upheld by years of documented results in medical literature. Coverage for services under the CHAMPUS program is limited, however, to services which are medically necessary in the treatment of disease or illness, and such treatment must be documented by authoritative medical literature and recognized professional opinion.

"The issue of the medical appropriateness and necessity of cardiac rehabilitation programs is not new to the CHAMPUS Basic Program. Two previous CHAMPUS Hearing Cases treated this issue. In Final Decisions rendered in cases by the Office of Assistant Secretary of Defense in Case Number OASD(HA) 20-79 dated November 24, 1980 and Case Number OASD (HA) 01-81 dated May 21, 1982 the conclusion was reached that cardiac rehabilitation programs were not medically necessary because the exercise regimens were not documented in authoritative medical literature and recognized professional opinion as a generally accepted specific treatment of myocardial infarction. Both of these decisions whose factual pattern follows closely to the case at hand conclude that although an individual improvement in the quality of life may occur through cardiac rehabilitation programs and although physicians who endorse these program [sic] believe that they assist individual patients, regulatory authorities prohibit the authorization of benefits for services which are not generally accepted in the treatment of a disease or illness and are not documented by authoritative medical literature and recognized professional opinion."

I agree with the Hearing Officer. By law and regulation CHAMPUS can cost-share medically necessary care; i.e., services and supplies adequate for the treatment of illness or injury. Although cardiac rehabilitation programs are increasing in

popularity and coverage by other third party payers is being expanded to include such programs, the effectiveness of cardiac rehabilitation programs in the treatment of postmyocardial infarction patients has not been established.

The exercise programs in the above referenced FINAL DECISIONS are similar to the program involved in this appeal; i.e., monitored exercise programs under the supervision of skilled health care professionals. Therefore, the cardiac rehabilitation program furnished in this case (March 12, 1981, through August 11, 1981) suffers the same deficiencies as in the previous FINAL DECISIONS; i.e., the general acceptance and efficacy of the program in the treatment of postmyocardial infarction is not supported by medical documentation nor recognized professional opinion and authoritative medical literature contemporaneous with the dates of care.

While the Department of Defense recognizes that individual improvement in quality of life may occur through cardiac rehabilitation programs, I find that potential improvement in the quality of life does not constitute medically necessary care under CHAMPUS. While some physicians may endorse programs they believe may assist individual patients, I am constrained by regulatory authorities to authorize benefits only for services which are generally accepted in the treatment of disease or illness and are documented by authoritative medical literature and recognized professional opinion. The appeal record in this case discloses no evidence of the documented effectiveness of the exercise programs in the treatment of myocardial infarction (coronary heart disease); instead, the file indicates its unproven nature. I must, therefore, conclude that the beneficiary's cardiac rehabilitation program was not medically necessary and was excluded from CHAMPUS coverage in accordance with previous decisions in OASD(HA) 20-79, OASD(HA) 01-81, OASD(HA) 83-16, and OASD(HA) 83-17.

The OCHAMPUS First Level Appeal Decision found that all services in connection with the patient's cardiac rehabilitation program were excluded from CHAMPUS coverage. This finding was based, in part, on the CHAMPUS regulation exclusion (DoD 6010.8-R, chapter IV, G.66.) of "services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment."

The beneficiary's claim originally was partially allowed by the CHAMPUS Fiscal Intermediary when the charges for lab tests and treadmill tests were paid in the amount of \$424.50. The beneficiary contends that these services should be allowed by CHAMPUS as normal posthospital care of a myocardial infarction patient.

The Hearing Officer discussed this issue as follows:

"In his Response to the [OCHAMPUS] Position Statement [the beneficiary] stated that his wife telephoned the area CHAMPUS office,

discussed this program in depth with a representative and inquired about coverage for this program in advance of his entering it. He further stated that the CHAMPUS representative indicated that the treadmill test, HDL, blood sugar, cholesterol, and triglyceride etc. would be covered care regardless of whether he was involved in a rehabilitation program or not, as those items would be normal post hospital dismissal care ordered by the physician in charge. It is difficult to reach such a conclusion concerning this ancillary matter because there is no evidence in the record which would concur with the sponsor/beneficiary's position. The services which were rendered were billed as part of the overall cardiac rehabilitation program which has been determined to be not covered."

The evidence of record supports the Hearing Officer's conclusion. The Hospital's itemized statement indicates the beneficiary registered in the cardiac rehabilitation program on March 12, 1981, and that the treadmill tests and lab tests followed. The statement included charges for the lab tests and treadmill tests as part of the cardiac rehabilitation program.

In view of the fact that cardiac rehabilitation is a noncovered treatment under CHAMPUS, all services and supplies related to such a program are also excluded from CHAMPUS coverage. I find, therefore, that the beneficiary's lab tests and treadmill tests were directly related to the cardiac rehabilitation program and are excluded from CHAMPUS coverage. The case file will be returned to the Director, OCHAMPUS, for appropriate action under the Federal Claims Collection Act regarding the erroneous payment of the lab tests and treadmill tests.

#### Physical Therapy

A determination that the beneficiary's cardiac rehabilitation program was not medically necessary prevents CHAMPUS coverage. The beneficiary, however, challenged the OCHAMPUS First Level Appeal decision which denied CHAMPUS coverage of his cardiac rehabilitation program as a general exercise program. The CHAMPUS regulation, DoD 6010.8-R, chapter IV, G.45., provides the following exclusion:

"G. Exclusions and Limitations. In addition to any definitions, requirements, conditions and/or limitations enumerated and described in other CHAPTERS of this Regulation, the following are specifically excluded from the CHAMPUS Basic Program:

\* \* \* \*

": "47. Exercise. General exercise programs, even if recommended by a physician and regardless of whether or not rendered by an authorized provider. In addition, passive exercises and range of motion exercises are also excluded except when prescribed by a physician and rendered by a physical therapist concurrent to, and as an integral part of, a comprehensive program 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; however, general exercise programs are excluded. A "physical therapist" is defined in DoD 6010.8-R, chapter II, B.134., as:

". . . a person who is specifically trained in the skills and techniques of physical therapy (i.e., 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 (i.e., registered) to administer treatments prescribed by a physician and who is legally entitled to use the designation registered physical therapist. . . ."

The Hearing Officer evaluated the evidence of record on this point as follows:

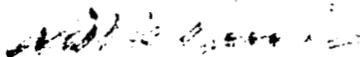
"In reviewing the evidence contained in the file, there appears to be no indication of the type of physical therapy which is defined in the [CHAMPUS regulation]. The cardiac rehabilitation program in which the sponsor/beneficiary was involved, by his description, falls into a category of general exercise and as such is excluded under the CHAMPUS Basic Program. Specific reference is made to the letters from both Dr.                      and Dr.                      who both endorse this program but in essence describe it as either a 'condition exercise program' or a 'supervised exercise program.'"

I agree with the Hearing Officer. The record does not indicate that a physical therapist was ever present or involved in the beneficiary's treatment. In fact, the beneficiary's wife indicates that her husband was under the supervision of a cardiac specialist or nurse trained in cardiac rehabilitation. The beneficiary's exercise program, therefore, does not qualify for CHAMPUS coverage as physical therapy.

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.

#### SUMMARY

In summary, I find the beneficiary's cardiac rehabilitation program from March 12, 1981, through August 11, 1981, was not medically necessary in the treatment of postmyocardial infarction based on the lack of medical documentation, authoritative medical literature, and recognized professional opinions sufficient to establish the general acceptance and efficacy of this program at the time the care was received. I further find the program does not fit the definition of physical therapy under CHAMPUS and, therefore, the beneficiary's exercise program cannot be cost-shared by CHAMPUS as physical therapy. In addition, I find the treadmill tests and lab tests provided by the Cardiac Rehabilitation Program to be directly related to the noncovered treatment and, therefore, are excluded from CHAMPUS coverage. The Director, OCHAMPUS, is directed to take appropriate action under the Federal Claims Collection Act regarding recovery of any erroneous payments issued in this case. The appeal of the beneficiary is denied. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

  
Vernon McKenzie

Acting Principal Deputy Assistant Secretary