ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

DEC 27 1983

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) FILE 83-41
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs), in the CHAMPUS Appeal OASD(HA) Case File 83-41 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 United States Army Officer. The appeal involves claims for a cardiac rehabilitation program undergone by the beneficiary from February 1982 through April 1982. The amount in dispute involves $611.00 in billed charges.

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 OCHAMPUS deny coverage for the beneficiary's cardiac rehabilitation exercise program based on findings the cardiac rehabilitation program was not medically necessary, was not physical therapy, and was preventive care. The Director, OCHAMPUS, concurs in the recommendation of the Hearing Officer and recommends its adoption as the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs).

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 the Baptist Medical Center, Jacksonville, Florida, during the period of February 1982 through April 1982. This FINAL DECISION is based on 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

In the summer of 1970 the beneficiary suffered an angina and, on the advice of a local physician, went to the University Hospital

at Birmingham, Alabama, for an evaluation. A heart catheterization resulted in a finding of blocked arteries and the beneficiary was informed that he was a candidate for open heart surgery sometime in the future. In the interim, he was prescribed an ergometric exerciser and aerobic activities.

The beneficiary followed an exercise treatment and drug program prescribed by his physician for approximately 11 years as treatment for arteriosclerosis. The beneficiary indicated that this treatment was generally successful until the summer of 1981 when another catheterization revealed that all of his arteries were blocked and that bypass surgery was necessary.

On August 31, 1981, the beneficiary underwent a triple bypass heart operation. In January 1982, his physician verbally prescribed postoperative cardiac rehabilitation treatment at Baptist Medical Center in Jacksonville, Florida. The treating physician on June 28, 1982, reduced this verbal prescription to writing wherein he stated:

> "It was then and is now my considered opinion that this treatment was advisable and necessary in your case in order to bring your condition back to normal following the trauma of your triple bypass heart operation . . . last August 31, 1981. The excellent results from this treatment obtained by you have validated my opinion."

A document describing the cardiac exercise treatment and rehabilitation program at Baptist Medical Center in March 1981 contains the following introduction:

> "Cardiac rehabilitation at Baptist Medical Center is designed to provide a readily available supervised program of exercise treatment primarily for patients with known cardiac disease. However, the program is designed to be sufficiently flexible to be used in other areas, such as patients with cardiopulmonary problems, as well as maintenance of optimal cardiopulmonary status in patients without known cardiac disease who might be at high risk.
>
> "The concepts of exercise training and cardiac rehabilitation have enjoyed great publicity and popularity recently, both in professional and lay literature. Baptist Medical Center has organized this program to meet the needs of the referring physician in accomplishing a supervised exercise program in order to improve the quality of the patient's life, either following a known cardiac event or prior to the onset of illness.

> "This is to be accomplished according to standard guidelines, as outlined by the American Heart Association as well as through information gained from pertinent medical literature and the advice of outside consultants.
>
> "The program consists basically of three parts: 1) Medical Assessment, 2) Educational Aspects, and 3) Exercise. However, the program should always be flexible and will be tailored to individual needs of each patient, as well as the goals and the desires of the referring physician. The program initially will be hospital based and will consist of a more intense therapeutic program, followed by a prolonged maintenance program with the eventual goal of continuing the maintenance program in the home environment of the participant."

According to the cardiac rehabilitation program guidelines of the Baptist Medical Center, the program consisted basically of three components: (1) medical assessment, (2) educational activities, and (3) exercise. The medical assessment portion of the program required that participants have a complete medical assessment and a referral from their physician. The medical assessment included a medical history, physical examination, basic blood work (including a CBC, astra, and lipid studies), and some form of a baseline medically supervised exercise test. The beneficiary's medical assessment also included a cardiac catheterization.

The educational component included a multidisciplinary approach including physicians, the cardiac rehabilitation nursing staff, and physical therapy, as well as dietitians, vocational rehabilitation counselors, and input from clinical psychologists and occupational therapists. The goals of the educational program are centered around identification and education as to coronary risk factors with the goal of favorably altering these factors according to each individual patient's records. The patient is also taught basic principles of exercise physiology with the goal of achieving the patient's exit from the supervised program into a home personal program. The educational program provides printed material from the American Heart Association, films, lectures, and group conferences. Involvement of the spouse and the family in the educational activities is desirable.

The exercise component consisted of a therapeutic program in the structured environment of the rehabilitation center followed by a maintenance program in the patient's home. The exercise format, although designed to be flexible according to the needs of each patient, is basically as follows:

"A. Warmup activities including flexion and extension exercises for five to ten minutes, supervised by physical therapists.

"B. Dynamic exercise, with intervals of exercise at six to eight different exercise stations. Each station employs isotonic exercise of a slightly different type, including the bicycle ergometer, the treadmill, arm crank ergometers, or barbells. The heart rate is monitored during dynamic exercise with the goal of achieving a heart rate in the range of 50-70% of that obtained by the patient at the time of his diagnostic exercise test during medical assessment.

"C. A 'cool down phase' of five to ten minutes, consisting of further isotonic exercise at a lower level of activity or further flexion and extension exercises as the heart rate returns toward baseline."

On May 25, 1982, a CHAMPUS claim was submitted to the CHAMPUS Fiscal Intermediary for Florida, at that time, Blue Shield of California, for the cardiac rehabilitation services provided from February 1, 1982, through April 30, 1982. The claim consisted of 24 therapy sessions billed at $24.00 per session for a total of $576.00 and one physical examination session billed at $35.00. The fiscal intermediary denied all cardiac rehabilitation sessions but allowed coverage of the physical examination. After deducting the applicable cost-share, the hospital was issued a payment in the amount of $26.25 for the physical examination.

The beneficiary appealed the denial of his claim for cardiac rehabilitation, and the fiscal intermediary affirmed the denial of CHAMPUS coverage of cardiac rehabilitation. The beneficiary then appealed to OCHAMPUS. Based on FINAL DECISIONS issued in similar hearing cases by the Assistant Secretary of Defense (Health Affairs), the OCHAMPUS First Level Appeal determination denied the beneficiary's claim and appeal because cardiac rehabilitation programs are not deemed medically necessary in view of the lack of authoritative medical literature and recognized professional opinion documenting the general acceptance and efficacy of the program at the time the care was received. The OCHAMPUS First Level Appeal determination also found that the physical examination preparatory to participation in the cardiac rehabilitation program was directly related to the noncovered treatment; therefore, the $26.25 paid by the fiscal intermediary for the claim for the physical examination was determined to be an erroneous payment.

The beneficiary requested a hearing on January 26, 1983. In that request, the beneficiary stated that cardiac rehabilitation treatment for postoperative heart patients has become a generally accepted specific treatment for cardiac conditions. In support

of this assertion, he provided a medical center publication, dated January 1983, wherein it states that cardiac rehabilitation treatment has become standard treatment for postoperative heart patients in the Jacksonville, Florida, area. Based on this, it is the opinion of the beneficiary that when cardiac rehabilitation is prescribed as necessary medical treatment by a treating physician following open heart surgery CHAMPUS coverage should be allowed.

The beneficiary also provided a letter from Dr. James B. Strachan, a cardiologist in Jacksonville, Florida, dated February 1, 1983. In the letter, this cardiologist stated:

> "[The beneficiary] has a long history of arteriosclerotic heart disease with angina pectoris. On 8-31-81 he underwent coronary bypass surgery at the University of Alabama, performed by Dr. Karp.
>
> "Upon return to Jacksonville, and after an appropriate convalescence, [the beneficiary] was enrolled in the cardiac rehabilitation program at Baptist Hospital at my suggestion. In this city, cardiac rehabilitation has become standard practice in rehabilitation of both patients with acute myocardial infarction and cardiac bypass surgery.
>
> "In [the beneficiary's] instance, his recovery was greatly expedited as a result of the cardiac rehab program and in my practice, as well as those of all other cardiologists with whom I associate, this is now 'appropriate medical care.'"

A hearing was held on March 30, 1983 in Jacksonville, Florida, before OCHAMPUS Hearing Officer, Don F. Wiginton. At the hearing, in addition to the testimony of the beneficiary, the following individuals testified: Diane S. Rains, a registered nurse with advanced training in cardiac rehabilitation, who serves as Chief of Cardiac Rehabilitation at Baptist Medical Center; Dr. A. Larson Hardy, a general practitioner in Jacksonville, Florida, specializing in cardiology, who regularly refers patients for cardiac rehabilitation at Baptist Medical Center; and Dr. Paul H. Dillahunt, the Medical Director of the Heart Center of Baptist Medical Center, a specialist in cardiovascular diseases and a Board Certified Cardiologist.

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 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":

> ". . . 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 the Assistant Secretary of Defense (Health Affairs) has in four 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 programs 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.
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> "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 appealing 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 [sic] may, and properly so, advise and recommend in many areas beyond specific treatment. This is particularly true relative to encouraging changes in lifestyles--i.e., increased exercise, elimination of smoking, weight reduction, etc."

Three published medical reports are included in the appeal record. One report published in April 1981 documented an investigation of the "exercise trainability of post-MI patients as compared with coronary heart disease patients who had not suffered an infarct and those who had undergone coronary bypass surgery." The study indicates that:

> "The exercise trainability of MI patients referred to a rehabilitation program is equivalent to that of cardiac patients who have not suffered an infarction. The same seems to be true of CAB patients, but our numbers of such cases was [sic] small and conclusive statements should await studies on a larger sample."

A second report published in June 1978, investigated the effects of aortocoronary bypass surgery and 32 months of physical conditioning on the patient's treadmill performance. The observations made in a small group of conditional bypass subjects suggested that "participation for at least four months in a supervised exercise program should further enhance the initial improvement in symptoms, exercise tolerance, and presumably quality of life seen following aortocoronary bypass surgery."

A third report published in July 1981 documented a study of the effects of a supervised exercise program on mortality and cardiovascular morbidity in patients after a myocardial infarction. The results of the study suggested that "a program of prescribed supervised physical activity may be beneficial in reducing subsequent mortality, but the evidence is not convincing." The study also resulted in "no suggestion of benefit from the exercise program in relation to cardiovascular morbidity . . . ." The report concluded that: "The case for exercise in persons with known myocardial infarctions is neither proved nor disproved."

The three medical reports are consistent with findings of the Assistant Secretary of Defense (Health Affairs) in previous hearing cases. All the studies start with the premise that physical activity or exercise generally improves health and quality of life. The record does not contain conclusive evidence that cardiac exercise programs improve survival; that is, reduce morbidity or prolong life.

CHAMPUS coverage of care is limited to medically necessary supplies and services; i.e., services and supplies adequate for the diagnosis and treatment of illness or injury. While the record in this appeal reflects an expansion of cardiac rehabilitation programs across the country, the general acceptance and efficacy of the program in the treatment of postmyocardial infarction or arteriosclerotic heart disease following bypass surgery is not supported by authoritative medical literature and recognized professional opinion contemporaneous with the dates of care in this case. Under the appeal procedure, the appealing party has the responsibility of providing whatever facts are necessary to support the opposition to the CHAMPUS determination. Although the dates of care under consideration in this appeal (February 1982 through April 1982) occurred after the decision in OASD(HA) 01-81, 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 was excluded from CHAMPUS coverage as previously determined in OASD(HA) Case Files 01-81 and 20-79.

Physical Therapy

A determination that the cardiac rehabilitation program was not medically necessary prevents CHAMPUS coverage. However, because the beneficiary in his appeal contends the cardiac rehabilitation program is physical therapy, it is appropriate to address this issue.

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 (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 record reflects that the exercise program was conducted and monitored by a registered nurse with advanced training in cardiovascular medicine. The treatment session included the following types of exercises: treadmill, bicycle, arm ergometer and weights, and blood pressure and pulse recordings during a cool down phase. The 1½-hour sessions included continuous EKG monitoring, and initial blood pressure and pulse recordings. At the hearing, the Chief of the Cardiac Rehabilitation Program at Baptist Medical Center testified that the physical therapist used in the cardiac rehabilitation program served as a consultant. The duties of the physical therapist included monitoring patients and setting machines. She stated that this service could be performed by a registered nurse and no manipulative physical therapy was used in the benficiary's program.

Although Dr. Dillahunt testified that the cardiac rehabilitation program was in the nature of physical therapy as opposed to general exercise, he also stated that use of a physical therapist was not mandatory and that manipulation was not involved.

The finding by the Hearing Officer, that "cardiac rehabilitation treatment is not physical therapy within the meaning of CHAMPUS regulation 6010.8-R, chapter II, subsection B.132." is supported by the record, and I adopt that finding. I am persuaded by the Hearing Officer's comparison of this cardiac rehabilitation program to a general exercise program even though the exercises were monitored by a registered nurse or physical therapist. As stated by the Hearing Officer:

> "The Hearing Officer does not question that there is considerable medical benefit to the patient undergoing the cardiac rehabilitation treatment. However, from the testimony, it is clear that the program is a general exercise program especially tailored to be administered to patients with a precarious medical condition. The patient is 'rated for stress' by his physician based on a medical examination which includes a 'stress EKG'. It is generally accepted medical practice for anyone over the age of forty (40) to begin a program of exercise only after a similar medical examination with their physician. It is common knowledge that any exercise facilities also disseminate generally accepted nutritional and life style information and make such literature available to its participants. I find no substantive difference between a general exercise program and the cardiac rehabilitation program at Baptist Medical Center, Jacksonville, Florida, except that

> :: the rehabilitation program monitors the patient's progress more closely in view of their [sic] medical history."

Therefore, I conclude that the beneficiary was not receiving physical therapy even though a physical therapist may have been present during the exercise sessions. Mere presence by a physical therapist does not a fortori make the treatment physical therapy.

The CHAMPUS regulation, chapter IV, G.45., excludes CHAMPUS coverage of passive exercises and range of motion exercises except when prescribed by a physical therapist concurrent to, and as an integral part of, a comprehensive program of physical therapy. As previously noted, physical therapy is defined in DoD 6010.8-R, chapter II, B.134., as treatment of disease by physical agents and methods such as heat, massage, manipulation, hydrotherapy, and various forms of energy such as electrotherapy and ultrasound.

My review of the record does not indicate that the exercises conducted as a part of this cardiac rehabilitation program were prescribed by a physical therapist as an integral part of a comprehensive program of physical therapy. In fact, the record documents that the physical therapist did not provide the type of professional services outlined in the Regulation. There is no indication that the disease was treated by physical agents and methods such as heat, massage, manipulation, therapeutic exercise, hydrotherapy, and various forms of energy such as electrotherapy and ultrasound.

Based on the evidence of record, I must conclude that the cardiac rehabilitation program did 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 the cardiac rehabilitation program as physical therapy, therefore, must be denied.

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.45., 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 Baptist Medical Center as described in the record was a comprehensive program consisting of three components: (1) medical assessment, (2) educational aspects, and (3) exercise. As described in the protocol utilized by the cardiac rehabilitation center, the educational component consisted of:

> ". . . a multi-disciplinary approach including physicians, the cardiac rehabilitation nursing staff, physical therapy, as well as dietitians and vocational rehabilitation counselors. Input from clinical psychologists and occupational therapists will also be employed. Educational goals will be primarily centered around identification and education as to coronary risk factors, with the goal of favorably altering these according to each individual patient [sic] needs. In addition, educational activities are centered around teaching the patient basic principles of exercise physiology with the goal of eventually achieving his exit from the supervised program into a home personal program where regular exercise is carried out with a minimum of direct medical supervision. Educational resources include the personnel mentioned above, and printed standard material obtained from the American Heart Association, as well as films, lectures, and group conferences. Involvement of the patient's spouse and family in educational activities is also considered highly desirable.

Based on the program description described in the protocol, it appears, and it is undisputed, that parts of the program were educational in nature. In the absence of a decision denying CHAMPUS coverage of the beneficiary's cardiac rehabilitation program, those activities of the program specifically related to educational activities would have to be identified and 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 physical therapy examinations to determine the beneficiary's tolerance for more strenuous exercise performed as a part of the cardiac rehabilitation program are excluded from CHAMPUS cost-sharing as directly related to the noncovered treatment.

The fiscal intermediary, although denying the claims for participation in the cardiac rehabilitation program, allowed cost-sharing of the physical therapist's evaluation. Based upon the above determination that the care was not authorized under CHAMPUS, the fiscal intermediary's payment of $26.25 was erroneous. Therefore, 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 arteriosclerotic heart disease following bypass surgery 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 the cardiac rehabilitation program cannot be authorized as physical therapy. 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 directly related to a noncovered treatment are not payable, the physical examination related to the exercise program is also excluded from CHAMPUS coverage. The claims for participation in a cardiac rehabilitation program from February 2, 1982, through April 30, 1982, including the physical therapist's evaluation, 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 regarding the erroneous payment portions 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.

Vernon McKenzie
Acting Principal Deputy Assistant Secretary