



ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

DEC 9 1983

HEALTH AFFAIRS

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

Appeal of .)
Sponsor: .) OASD(HA) File 83-40
SSN:) FINAL DECISION

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS appeal OASD(HA) Case File 83-40 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party in this case is the sponsor.

This appeal involves the question of CHAMPUS coverage of chelation therapy provided the beneficiary on December 3, 11, and 15, 1980, while the beneficiary was in . The total charge for the chelation therapy incurred by the beneficiary for these dates was \$548.72. The appeal also involves a question of CHAMPUS coverage of office visits and lab tests associated with the chelation therapy. The dates of the office visits were November 26, 1980, and December 3, 5, 8, 11, 15, 16, and 17, 1980. The lab tests were conducted on November 28, 1980. The total charge for these services is included in the \$548.72. The CHAMPUS Fiscal Intermediary for the State of , Medical Service Association, denied coverage of the chelation therapy from November 26, 1980, to December 17, 1980, and the diagnostic tests provided on November 28, 1980, because these services are considered experimental for the treatment of the sponsor's diagnosis of arteriosclerotic heart disease.

At the hearing, it was disclosed that the beneficiary had previously received CHAMPUS cost-sharing of chelation therapy treatments from April 10, 1980, through May 12, 1980, while the beneficiary was in . The CHAMPUS Fiscal Intermediary for the State of . Blue Shield of California, after applying the appropriate cost-shares and deductibles, paid \$715.58 to the beneficiary for the chelation therapy.

The hearing file of record, the tape of oral testimony presented at the hearing, the Hearing Officer's Recommended Decision, and the Analysis and Recommendation of the Director, OCHAMPUS, have been reviewed. The total amount in dispute for the two episodes of care, is \$1,264.30. It is the Hearing Officer's recommendation that CHAMPUS coverage for the chelation therapy from November 26, 1980, to December 17, 1980, and the diagnostic

tests conducted on November 28, 1980, be denied based on a finding that the care was experimental for the treatment of arteriosclerotic heart disease and thus excluded as a CHAMPUS benefit. The Director, OCHAMPUS, concurs in the Recommended Decision and recommends its adoption as the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) insofar as it denies CHAMPUS coverage of the chelation therapy treatments and related services received by the beneficiary from November 26, 1980, to December 17, 1980. The Director, OCHAMPUS, recommends that the FINAL DECISION also deny CHAMPUS coverage of the chelation therapy and related services received by the beneficiary in from April 10, 1980, through May 12, 1980.

Under Department of Defense Regulation 6010.8-R, chapter X, the Assistant Secretary of Defense (Health Affairs) may adopt or reject the Hearing Officer's Recommended Decision. In the case of rejection, a FINAL DECISION may be issued by the Assistant Secretary of Defense (Health Affairs) based on the appeal record. The Acting Principal Deputy Assistant Secretary of Defense (Health Affairs), acting as the authorized designee for the Assistant Secretary of Defense (Health Affairs), and after due consideration of the appeal record, adopts the Hearing Officer's recommendation to deny CHAMPUS coverage of chelation therapy and the diagnostic tests provided the beneficiary from November 26, 1980, to December 17, 1980; however, to the extent the Hearing Officer's Recommended Decision failed to address CHAMPUS coverage of chelation therapy from April 10, 1980, through May 12, 1980, the Recommended Decision is rejected. Although the Hearing Officer indicated that documentation is unclear as to the fiscal intermediary's payment of the chelation therapy received from April 10, 1980, through May 12, 1980, the issue of CHAMPUS coverage of chelation therapy regardless of when received by this beneficiary should be addressed.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS coverage of chelation therapy and related services provided in the treatment of the beneficiary's arteriosclerosis. This decision is based on findings that the chelation therapy was improper care, not medically necessary, and not appropriate medical care. CHAMPUS claims for chelation therapy and related services, (i.e., diagnostic tests, lab tests, and office visits) from April 10, 1980, through May 12, 1980, and from November 26, 1980, to December 17, 1980, are denied cost-sharing under CHAMPUS.

FACTUAL BACKGROUND

The sponsor, a retired United States Air Force Chaplain, was in good health until 1978. At that time, he experienced a tingling sensation in his upper torso, loss of sensation in his arm and legs, and pains in his chest when engaged in physical exertion. He was diagnosed as "recent acute inferior myocardial infarction." Although hospitalization was recommended, the beneficiary followed a regimen of rest and home care. Although

he gradually returned to his normal lifestyle, concern about his health and restrictions on his activities resulted in a cardiac catheterization in April 1980.

As a result of the catheterization, the beneficiary was diagnosed as "arteriosclerotic heart disease manifested by antecedent inferior wall myocardial infarction and 3-vessel coronary artery disease." The patient was described as asymptomatic and bypass surgery was not recommended. The Fitzsimons Army Medical Center clinical record dated April 2, 1980, states:

"It was elected because of his good treadmill results to place him on antiplatelet agents consisting of aspirin two tablets po bid [sic] and given a prescription for Nitroglycerine with instructions to contact a physician if there is any change in his status whatsoever. In addition he will be followed up in the Cardiology Clinic with consideration of repeat treadmill to try and judge any acceleration of his underlying disease. He was also instructed to maintain a low cholesterol diet."

The patient indicates that in an effort to understand and correct his condition, he investigated chelation therapy. In chelation therapy the individual is fed intravenously the substance ethylenediaminetetraacetic acid (EDTA) which is intended to clear the arterial passages of calcium and other obstructions. The patient's CHAMPUS claims included charges for chelation therapy as well as office visits consisting of taking blood pressure and temperature, a short examination by the physician, and answering a series of questions. The patient, while in , received approximately 13 chelation treatments which were cost-shared by the OCHAMPUS Fiscal Intermediary, Blue Shield of . While in at his winter home, however, the claims for the chelation therapy received by the sponsor were denied by the Fiscal Intermediary for , Medical Service Association.

On July 18, 1981, the patient appealed the denial of his claim. During the informal review process, the fiscal intermediary referred the case to its medical reviewer who opined that chelation therapy is considered experimental for the treatment of arteriosclerotic heart disease. In the course of his review, the medical reviewer contacted the treating physician regarding the medical necessity of the frequent office visits. On the basis of the physician's description of the chelation therapy procedure, it was determined that the office visits and laboratory tests were related to the chelation therapy. In addition, it was determined that the medications involved in the treatment were actually minerals and vitamins. Based on the medical reviewer's opinion, the fiscal intermediary determined that chelation therapy for the beneficiary's arteriosclerotic heart disease was

experimental and, thus, excluded as a CHAMPUS benefit. In addition, the fiscal intermediary denied CHAMPUS coverage of claimed medications on the basis that minerals and vitamins are excluded from CHAMPUS coverage.

Following an appeal to OCHAMPUS, it was determined that chelation therapy was not considered to be appropriate medical care for the treatment of arteriosclerotic heart disease and was not provided in accordance with accepted medical standards. Specifically, the OCHAMPUS decision stated that the use of EDTA for clearing the arteries of calcium and cholesterol was not approved by the Federal Drug Administration as effective and safe for human use in the treatment of generalized arteriosclerotic conditions. Because of the CHAMPUS denial of cost-sharing of the chelation therapy treatments, the related charges for the office visits and lab work were also denied.

On November 3, 1982, the sponsor requested a hearing. In his request for a hearing, the sponsor cited recent developments in the administration of the Medicare program. Specifically, the sponsor referenced a policy decision by the Health Care Financing Administration, U.S. Department of Health, Education and Welfare, which set forth procedures for granting faster approval of drugs which have been recently approved by the Federal Drug Administration. The sponsor also noted a conversation he had with the Director of Coverage, Policy and Medical Services, indicating that the previous Medicare exclusion of EDTA in the treatment of atherosclerosis/arteriosclerosis was rescinded on May 15, 1980. It is the contention of the sponsor that CHAMPUS should follow the same policy as established by Medicare.

The hearing was held by Ms. [redacted], Hearing Officer, on July 21, 1983. The Hearing Officer has submitted her Recommended Decision, and all prior levels of administrative review have been exhausted. Issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the chelation therapy and diagnostic tests received by the beneficiary in the treatment of arteriosclerotic heart disease are authorized care under CHAMPUS. In resolving this issue, it must be determined whether the care rendered during the periods in issue was medically necessary and appropriate medical care.

Medical Necessity/Appropriate Level of Care

The Department of Defense Appropriation Act of 1976, Public Law 94-212, prohibits the use of CHAMPUS funds to pay, among other matters,

". . . any other service or supply which is not medically necessary to diagnose and treat a mental or physical illness, injury, or bodily malfunction"

All subsequent Department of Defense Appropriation Acts have contained similar restrictions.

This restriction is incorporated into the CHAMPUS regulation, DoD 6010.8-R, chapter IV, A.1., as follows:

"Scope of Benefits. 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"

Specifically excluded from CHAMPUS coverage are all "services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury." (DoD 6010.8-R, chapter IV, G.1.)

The CHAMPUS regulation, DoD 6010.8-R, chapter II, B.104., defines medically necessary in part, as:

". . . 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 the concept of appropriate medical care."

"Appropriate medical care" is defined in DoD 6010.8-R, chapter II, B.14, in part, as:

"a. That medical care where 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 CHAMPUS Basic Program includes benefits for the treatment of arteriosclerotic vascular disease. However, under the provisions cited above such benefits are not available when the treatment prescribed is beyond what is in keeping with the generally acceptable norm for medical practice in the United States. This general principle is also incorporated in the more specific regulation provisions relating to experimental treatments.

CHAMPUS excludes treatment modalities which are not provided in accordance with accepted professional medical standards, or related to essentially experimental, investigatory, or unproven treatment regimens. (DoD 6010.8-R, chapter IV, G.15.) The term "experimental" is defined, in part, in DoD 6010.8-R, chapter II, B.67., as :

". . . (M)edical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal conditions) which does not meet the generally accepted standards of

usual professional medical practice in the general medical community Use of drugs and medicines not approved by the Food and Drug Administration for general use by humans (even though approved for testing on human beings) is also considered to be experimental. However, if a drug or medicine is listed in the U.S. Pharmacopeia or the National Formulary and requires a prescription, it is not considered experimental even if it is under investigation by the U.S. Food and Drug Administration as to its effectiveness."

The evidence of record establishes that the chelation therapy provided to the beneficiary consisted of a series of injections of the drug ethylenediaminetetraacetic acid (EDTA). This drug is approved by the U.S. Food and Drug Administration in the treatment of heavy metal poisoning. The drug appears in the U.S. Pharmacopeia and the National Formulary as a drug acceptable for some human use. There is no evidence in the file, however, that supports the use of EDTA in the treatment of arteriosclerotic heart disease.

The fiscal intermediary's medical reviewer opined that the care furnished the beneficiary was not medically necessary for the removal of calcium or cholesterol in the arteries. While the patient may have required some treatment, chelation therapy was not essential for his care or for the treatment of arteriosclerotic heart disease. I specifically concur with the Hearing Officer's Recommended Decision wherein she states:

"The issue of medical necessity; appropriate care and experimental procedures was discussed in a previous final decision by the Assistant Secretary of Defense (Health Affairs) who held: '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 opinions.' (ASD(HA)-01-81). The decision goes on to state that the care which was at issue was not medically necessary based upon 'lack of medical documentation, authoritative medical literature, and recognized professional opinions sufficient to establish the general acceptance and efficacy of the program at the time the care was received.' The specific CHAMPUS regulation bears repeating as appropriate medical care is defined as where the medical services performed 'are in keeping with the generally acceptable norm for medical practice in the United States.'

"OCHAMPUS has determined that chelation therapy is an experimental procedure and thus specifically excluded from coverage. The CHAMPUS regulation in Chapter X 16(h) that 'the appealing party has the responsibility of providing whatever facts are necessary to support the opposition to the CHAMPUS determination,' and the burden of producing evidence to refute the medical opinions contained in the record is on the appealing party (paragraph 16(i)). There is no medical literature in the record showing the efficacy of chelation therapy for arteriosclerotic heart disease nor any evidence of controlled studies proving its value and safety. The only medical opinions are some quotes made by Dr. Gordon in his book and these were concerned more with insurance coverage than the treatment itself. Even [the beneficiary] at the hearing said it was a controversial procedure. The medical opinion of [the fiscal intermediary's medical reviewer] who did the peer review was that chelation treatment for arteriosclerotic heart disease was experimental. The record shows that the Colorado Foundation for Medical Care had previously found 'There is no adequate evidence to indicate that this type of therapy is effective for other than acute toxicity due to heavy metal (e.g. lead poisoning). Claims that chelation therapy is effective for arteriosclerosis, removal of valve calcifications, and treatment of rheumatic disorders are without foundation. There are no controlled scientific studies that demonstrate the efficacy of chelation therapy in treating these disorders. Further, there is evidence of significant nephrotoxicity and case reports of other adverse effects associated with the use of EDTA.'"

Based upon the evidence of record and the specific provisions of the CHAMPUS regulation, it is clear that the drug used in the beneficiary's chelation therapy is not experimental, i.e., it is approved for some uses in humans. The evidence, however, is also clear that in this case the use of chelation therapy in the treatment of arteriosclerotic heart disease was not in keeping with the generally acceptable norm for medical practice in the United States. At the time these services were provided to the beneficiary, chelation therapy in the treatment of arteriosclerosis was an unproven treatment regimen whose efficacy and safety had not been established. Consequently, I find that chelation therapy in the treatment of arteriosclerosis does not qualify as a benefit under CHAMPUS.

This finding is supported by the overwhelming weight of the evidence as applied to the specific regulatory provision of CHAMPUS. The evidence of record establishes that as of April 1980 there were no controlled scientific studies demonstrating the efficacy of chelation therapy in treating arteriosclerosis. There was, however, evidence of significant nephrotoxicity, and there were reports of other adverse effects associated with the use of EDTA. Without the scientifically validated evidence which only such studies can produce, any positive perceived outcomes can only be considered as no different from those resulting from any other "placebo effect." That is, without the independent scientifically validated evidence, there is no way to objectively evaluate chelation therapy to determine if it is safe and effective and if it meets the generally accepted standards for practice in the general medical community. For this reason, I find that chelation therapy does not qualify for CHAMPUS benefits because it is essentially an unproven treatment regimen, the safety, efficacy, medical necessity, and appropriateness of which have not to date been demonstrated.

The beneficiary has failed to demonstrate that chelation therapy is recognized by national medical professional organizations or that its use is in keeping with the generally accepted norm for medical practice in the United States. On the contrary, the beneficiary admitted at the hearing that his cardiologist at Fitzsimons Army Medical Center had advised him that chelation therapy was not effective for arteriosclerotic heart disease.

While the Department of Defense recognizes that individuals may perceive improvement as resulting from chelation therapy programs, I am constrained by law and regulation to authorize benefits only for services which are generally accepted in the medical community. Such acceptance must be documented by authoritative medical literature and recognized professional opinion. The evidence herein and the professional reviews of the Colorado Foundation for Medical Care and the fiscal intermediary medical reviewer disclose no evidence of the documented effectiveness of chelation therapy in the treatment of arteriosclerosis at the time the care in question was rendered. Instead, the file clearly indicates its unproven nature.

In view of the above, I find that the chelation therapy and all related services and supplies furnished in the treatment of the patient's arteriosclerotic heart disease were not in keeping with the generally accepted norm for medical practice in the United States, were not appropriate medical care, and were not medically necessary. CHAMPUS cannot cost-share any of the patient's claims for chelation therapy and all related services and supplies.

At the hearing the beneficiary stated that if the chelation treatments were denied he felt that office visits to see a doctor and have certain tests administered is a separate matter and should be CHAMPUS cost-shared. However, "[a]ll 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 medications as well as office visits wherein the beneficiary's vital signs were recorded, physician examinations were performed, and the beneficiary answered a series of questions are excluded from CHAMPUS cost-sharing as services and supplies related to noncovered chelation therapy.

The hearing file of record establishes that one fiscal intermediary may have made some payments on the claims for chelation therapy services provided to the beneficiary in 1980. Therefore, the Director, OCHAMPUS, is required to review this case based upon this FINAL DECISION and take appropriate action under the Federal Claims Collection Act in regard to any erroneous payments for chelation therapy or any related services or supplies.

SECONDARY ISSUE

Inconsistent Federal Policies

The beneficiary has raised the issue of inconsistency of various Government agencies and the private sector in regard to medical coverage of chelation therapy. As noted by the Hearing Officer:

"[The beneficiary] discussed in detail a policy decision by the Health Care Financing Administration distributed to all Medicare regional offices on May 15, 1980, concerning a change in Section 2050.5 of the Medicare Carriers Manual This concerned drugs and biologicals and the Coverage Issues Appendix. It discusses FDA drugs covered as a benefit and, if other applicable coverage requirements are met in a questionable case, it allows Medicare contractors to pay for them after FDA approval even if only recently approved. It appeared to be an attempt to speed up approval for coverage of drugs. It also states 'Drug treatment must still be determined reasonable and necessary during individual cases, etc.'. My reading of this section quoted by [the beneficiary] would indicate it is really more for coverage of the actual drug itself rather than treatments. Both the fiscal intermediary and the medical advisor stated chelation therapy was a medically acceptable treatment for lead poisoning but that it was experimental as a treatment for arteriosclerotic heart disease."

I agree with the Hearing Officer. As previously noted in this DECISION, EDTA is not an experimental drug; i.e., it is approved for use by humans. The evidence, however, is that the use of

chelation therapy (EDTA) in the treatment of arteriosclerotic heart disease is not in keeping with the generally accepted norm for medical practice in the United States. The Health Care Financing Administration (HCFA) requirement that "(d)rug treatment must still be determined reasonable and necessary during individual cases" is consistent with the CHAMPUS requirements of medical necessity and appropriateness of medical care.

Irrespective of the general policy in the Medicare program regarding the coverage of drugs and despite the beneficiary's contention that Medicare rescinded the coverage exclusion of EDTA in the treatment of arteriosclerosis, Medicare does not cover chelation therapy in the treatment of arteriosclerosis. The most recent Medicare policy pronouncement on this subject is as follows:

"Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. The application of chelation therapy using ethylenediamine-tetra-acetic acid (EDTA) [sic] for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered.

Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section." See Medicare and Medicaid Guide, ¶ 27,201. (March 15, 1982)

Finally, I concur with the Hearing Officer's findings on this issue.

". . . whether or not Medicare or Travelers or any other insurance company provides benefits for coverage is not germane to the issue we are dealing with in this hearing. Different companies and governmental entities providing benefits for health care services all have different rules and regulations governing the coverage they provide

What treatment is given a particular patient is a personal choice made by the patient and his doctor. A CHAMPUS claim must be allowed or denied based upon the CHAMPUS law and regulation."

I am convinced that in adopting a more conservative approach and in taking a firm stand on unproven, experimental, or investigatory treatments or procedures, CHAMPUS is acting in the best interests of the Program and its beneficiaries. Experimental or investigatory treatment regimens are by definition unproven in one or more aspects. I do not believe it appropriate for the Department of Defense, through the payment of CHAMPUS claims, to encourage beneficiaries to seek or accept unproven treatments which may involve unnecessary or unwarranted complications and risks. In addition, I am constrained by law and regulation to authorize CHAMPUS coverage only for care which is determined to be medically necessary and appropriate medical care.

RECOUPMENT

Estoppel/Recoupment

The beneficiary has raised the issue of estoppel based on an assertion that similar claims for chelation therapy received from April 10, 1980, through May 12, 1980, had been paid by a CHAMPUS Fiscal Intermediary. This issue of estoppel has been addressed in previous FINAL DECISIONS and consistently rejected as not applicable to the Government and its officers or agents. There clearly is no evidence in the record to support a finding that the Government engaged in any affirmative misconduct.

As noted by the Hearing Officer, it is not entirely clear from the record what care was paid for by the CHAMPUS Fiscal Intermediary. If any payment was made for chelation therapy or related services and supplies, it was erroneous. Therefore, the Director, OCHAMPUS, is directed to review the claims records and, if erroneous payments were made, take appropriate recoupment action under the Federal Claims Collection Act.

SUMMARY

In summary, it is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) that chelation therapy in the treatment of arteriosclerosis is excluded from CHAMPUS coverage. This determination is based upon findings that, at the time of care in question in this case, chelation therapy in the treatment of arteriosclerosis was not generally accepted as being part of good medical practice, the safety and efficacy of the procedure had not been established, and the treatment was unproven. The beneficiary's claims for chelation therapy and all related services and supplies received from April 10, 1980, through May 12, 1980, and from November 26, 1980, through December 17, 1980, are, therefore, denied CHAMPUS coverage as not being medically necessary or appropriate medical care. The matter of

erroneous payments is returned to the Director, OCHAMPUS, for appropriate action under 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.



Vernon McKenzie

Acting Principal Deputy Assistant Secretary