



HEALTH AFFAIRS

ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

DEC 27 1983

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

Appeal of)	
)	OASD(HA) Case File 83-39
Sponsor:)	FINAL DECISION
U.S. Army (Ret.))	
)	
SSN:)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) File No. 83-39. It is issued pursuant to the authority of 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party in this case is the beneficiary, a retired officer of the United States Army. The appeal involves claims for chelation therapy provided to the beneficiary for the treatment of arteriosclerosis from April 16, 1981, through July 30, 1981. The billed charges for this therapy were \$1,047.00 and the amount in dispute is \$785.25 (i.e., \$1047.00 less the 25% beneficiary cost-share).

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 OCHAMPUS First Level Review determination, which denied CHAMPUS coverage of chelation therapy, be upheld. The Hearing Officer's recommendation is based upon a finding that chelation therapy and related services in the treatment of arteriosclerosis were not "rendered in accordance with generally accepted professional medical standards" as required by the CHAMPUS regulation, Department of Defense Regulation 6010.8-R. The Director, OCHAMPUS, concurs in this Recommended Decision and recommends that it be adopted as the FINAL DECISION.

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 accepts the recommendation of the Director, OCHAMPUS, and adopts the Hearing Officer's Recommended Decision. The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs), therefore, is to deny CHAMPUS claims for chelation therapy services provided to the beneficiary in 1981. This FINAL DECISION is based upon the appeal record as stated above.

FACTUAL BACKGROUND

The beneficiary was diagnosed as suffering from arteriosclerotic vascular disease, and received EDTA-heparin IV solution ("chelation therapy") as a treatment for this condition on 15 occasions from April 16 through July 30, 1981. CHAMPUS claims totaling \$1,047.00 for these services were submitted to the CHAMPUS Fiscal Intermediary. The claims for services provided on nine occasions were allowed and paid by the fiscal intermediary. The claims for services provided on six occasions were denied as services not approved by CHAMPUS.

In August 1981, the beneficiary requested an informal review by the fiscal intermediary. That decision, issued in November 1981, held that the chelation therapy the beneficiary received was not a CHAMPUS benefit because it was unproven in the treatment of his diagnosed illness. The fiscal intermediary stated that the only diagnosis for which the chelation therapy could be cost-shared by CHAMPUS was lead poisoning. The beneficiary was informed that a recoupment of the amounts erroneously paid on the beneficiary's claim for chelation therapy was being initiated. The fiscal intermediary did not offer the beneficiary a right of further appeal.

By letter dated November 23, 1981, the beneficiary requested relief from the recoupment of monies erroneously paid by the fiscal intermediary. This letter was treated as a Reconsideration Request by the fiscal intermediary. The Reconsideration Decision issued on December 21, 1981, upheld the denial of the claims for chelation therapy and reaffirmed the propriety of the recoupment. This letter also offered the beneficiary the right of further appeal to OCHAMPUS. On December 29, 1981, the beneficiary wrote a letter to the OCHAMPUS Medical Director. Because this letter was not addressed to the proper office within OCHAMPUS, it was not treated as an appeal. Rather, the Medical Director responded to it as a routine inquiry, and provided a thorough explanation of the basis for the denial of CHAMPUS coverage of chelation therapy.

On March 18, 1982, the beneficiary wrote a letter to the OCHAMPUS Chief of Appeals and Hearings requesting a hearing. This hearing request did not specifically challenge the denial of the beneficiary's claims but requested relief from the recoupment action initiated by the fiscal intermediary. Because such recoupment actions are not the proper subject of CHAMPUS appeals, the Chief of Appeals and Hearings denied the beneficiary's hearing request on April 14, 1982.

On April 19, 1982, the beneficiary addressed a letter to the Office of the Assistant Secretary of Defense (Health Affairs) seeking an additional review. After reviewing the information supplied by the beneficiary, it was determined that denial of the beneficiary's claims for chelation therapy was properly

appealable. Therefore, on May 27, 1982, it was directed that the beneficiary's case be processed under the CHAMPUS Appeals and Hearings procedures.

The OCHAMPUS First Level Appeal Determination was issued on November 3, 1982. That decision found the chelation therapy provided to the beneficiary to be an unproven investigational procedure which did not meet the generally accepted standards for treatment of arteriosclerosis in the United States. It upheld the denial of CHAMPUS coverage of chelation therapy.

The beneficiary requested a hearing on December 15, 1982. The case was duly assigned to a Hearing Officer and the OCHAMPUS position statement was forwarded to the Hearing Officer and the beneficiary on February 1, 1983. On March 10, 1983, however, the beneficiary requested an indefinite postponement of the hearing. This request was based upon the beneficiary's desire to await the outcome of investigative studies which he stated were then under way. He also based his request on recent serious medical problems which had rendered him unable to participate effectively in a hearing.

On March 18, 1983, the hearing was postponed and the beneficiary was advised of available alternatives which would allow the hearing process to proceed in his absence. These alternatives included appointment of a representative to present his position at the hearing or issuance of a decision based on the written record and without personal appearances at a hearing. On May 27, 1983, the beneficiary requested that the hearing proceed on the basis of the written record. The Hearing Officer has issued his Recommended Decision. All levels of administrative appeal have been completed and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the chelation therapy received by the beneficiary qualified for coverage under CHAMPUS during the period of April 16, 1981, to July 30, 1981. In addressing this issue, it is necessary to consider the medical necessity and appropriateness of the care in question.

Medical Necessity

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 Regulation defines "medically necessary" as "the level of services and supplies (that is, frequency, extent and kinds) adequate for the diagnosis and treatment of illness or injury Medical necessity includes the concept of appropriate medical care." (DoD 6010.8-R, chapter II, B.104.) "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 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.68., 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 medicine 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 and/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. The administration of the drug was performed by Richard Kaplan, D.O., and the beneficiary states that these services were provided upon the recommendation of his regular physician, R. O. Warton, M.D.

In his letter of January 25, 1982, the OCHAMPUS Medical Director cited a number of authorities in support of his opinion that chelation therapy for arteriosclerosis does not qualify for CHAMPUS coverage. These included the U.S. Food and Drug Administration which has not approved EDTA for the treatment of arteriosclerosis; the Colorado Foundation for Medical Care, a CHAMPUS medical policy consultant group, which opined there was no scientific evidence supporting the use of chelation therapy in the treatment of arteriosclerosis; the Medical Letter of Drug Therapeutics, which also reported there to be no acceptable evidence of the drug's effectiveness; and the American Medical Association Department of Drugs, which indicates that metal antagonists such as EDTA have been used unsuccessfully in the treatment of arteriosclerosis.

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 arteriosclerosis 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 1981 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.

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 OCHAMPUS Medical Director, 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.

The hearing file of record establishes that the Fiscal Intermediary made some payments on the claims for chelation therapy services provided to the beneficiary in 1981. 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 regards to these erroneous payments.

SECONDARY ISSUES

Inconsistency in Federal Policies

The beneficiary maintained that there is inconsistency in the guidelines of various Government agencies and the private sector in regard to medical insurance coverage for chelation therapy as a treatment for arteriosclerosis. He specifically maintained that the OCHAMPUS interpretation differs from that of other Government agencies. In support of this contention, the beneficiary provided a number of documents from other agencies and a private insurance company. Included among these documents are the following three letters:

- o Veterans Administration does not proclaim any singular position on the efficacy of chelation therapy or other treatment modalities in the management of . . . arteriosclerosis. It is VA's position that any medical treatment rendered to VA beneficiaries must be in keeping with acceptable standards of medical practice. However,

judgments pertaining to the diagnosis of medical problems and the type of treatment to be rendered are the responsibility of the veteran's treating physician.

- o A January 2, 1981, letter from the Department of Health and Human Services, Health Care Financing Administration (HCFA), stating that the question of the safety and efficacy of chelation therapy for the treatment of arteriosclerosis was then under study by the Public Health Service. The letter also states that:

". . . effective May 15, 1980, Medicare's general policy on the coverage of drugs was changed so that any use prescribed by a physician of a drug approved for sale by the . . . (FDA) . . . may be covered if the Medicare contractor . . . determines it is 'reasonable and necessary' for the individual patient and all other coverage requirements are met."

The HCFA letter also states that a special policy on chelation therapy may be forthcoming depending on the recommendation from the medical consultants. It also states that Medicare contractors are required to take into consideration "accepted standards of medical practice" in determining whether Medicare's coverage requirements are met.

- o A December 19, 1980, letter from New York Life Insurance Company stating that:

"'Chelation Therapy' is a recognized and covered form of medical treatment under all N.Y. Life group policies."

After reviewing the evidence submitted by the beneficiary, I remain convinced of the soundness of the CHAMPUS policy with respect to investigatory or unproven treatment regimens in general and the CHAMPUS policy with respect to chelation therapy in particular. In fact, I do not find that the CHAMPUS standards differ substantially from those of the other Federal agencies cited by the beneficiary. Both the Veterans Administration and the Department of Health and Human Services related their policy to standards of reasonableness, medical necessity, and acceptable standards of medical practice. These standards derive from the same basic principles of medical necessity and appropriateness of medical care which control the coverage of care under CHAMPUS. Furthermore, irrespective of the general policy in the Medicare Program in 1981 regarding the coverage of drugs, 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 [sic] (EDTA) 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)

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

The Hearing Officer specifically placed in issue and made findings on the question of the recoupment of the beneficiary's claims for chelation therapy which had been paid by the fiscal intermediary. The question of the recoupment of erroneous CHAMPUS payments is governed by the Federal Claims Collection Act and the Claims Collection Standards promulgated jointly by the Department of Justice and the General Accounting Office. The Claims Collection Standards set out specific criteria for the collection, suspension, compromise, and termination of collection action of Government recoupments. While it is true that the outcome of a CHAMPUS appeal may affect the agency's determination with respect to a pending recoupment, such recoupment matters are

not the proper subject of consideration in a CHAMPUS appeal. The placing in issue and consideration of this matter by the Hearing Officer was erroneous. The case is returned to the Director, OCHAMPUS, for 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 provided to the beneficiary from April 16 through July 30, 1981, cannot be cost-shared under CHAMPUS. This determination is based upon findings that, at the time of the care in question, 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 CHAMPUS claims for chelation therapy and the appeal of the beneficiary, therefore, are denied. The Director, OCHAMPUS, shall review the claims file and take appropriate action under the Federal Claims Collection Act in regard to payment of any CHAMPUS Claims for chelation therapy and related services. Issuance of this FINAL DECISION completes the administrative appeal process as provided under DoD 6010.8-R, chapter X, and no further administrative appeal is available.


Vernon McKenzie

Acting Principal Deputy Assistant Secretary