



ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

NOV 30 1983

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of)	
)	
Sponsor:)	OASD(HA) File 83-35
)	FINAL DECISION
SSN:)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 83-35 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, the wife of a retired enlisted member of the United States Air Force. She was represented at the hearing by her husband. The appeal involves the denial of CHAMPUS coverage for chelation therapy for treatment of diminished visual acuity of the right eye caused by a combination of cataractous changes in both eyes and senile macular degeneration. The amount in dispute is approximately \$980.00.

The hearing file of record, the tape of oral testimony and the argument presented at the hearing, 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 denial of cost-sharing for chelation therapy be upheld. The Hearing Officer found that the use of chelation therapy in the treatment of macular degeneration is not in keeping with the generally accepted norm for medical practice in the United States and is therefore not appropriate medical care or medically necessary. The Director, OCHAMPUS, concurs in the Recommended Decision and recommends adoption of the Recommended Decision as the FINAL DECISION.

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

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is therefore to deny CHAMPUS cost-sharing of chelation therapy for treatment for macular degeneration because it is not

in keeping with the generally accepted norm for medical practice in the United States and therefore under the CHAMPUS regulation is not appropriate medical care or medically necessary.

FACTUAL BACKGROUND

The record reflects that the beneficiary was initially seen by _____, D.O., a specialist in diseases and surgery of the eye, on February 22, 1980. The beneficiary had been referred to Dr. _____ by _____, D.O. Dr. _____, in a letter to the referring physician, stated:

"[the beneficiary] states she did have good visual acuity until about one year ago when she began to notice gradual reduction in her central visual acuity. She is, as you know, quite myopic, and is able to remove her glasses and see J-1 print at four to six inches.

"The visual acuity today with her correction is 20/200 O.D. and 20/40 O.S. That vision is improvable with about 1 1/2 diopters of myopic correction on the O.D. over her existing refraction to 20/30.

"Her applanation tonometry is 20 and there are early cataractus [sic] changes in both eyes. It appears that the primary reason for the reduction in her visual acuity of the right eye is not cataract but senile macular degeneration.

"[The beneficiary] was informed of the above and was asked to recheck in this office in three months after utilizing Lipotriad capsules which will sometimes increase the vascular supply to the embarrassed foveal region."

It was stated at the hearing that the beneficiary, at the suggestion of her husband, also sought chelation therapy at the _____ Clinic in _____, after seeing Dr. _____. The sponsor testified that he previously had been treated for angina at the _____ Clinic with chelation therapy. Other than billing information, there is no correspondence in the file from the treating physician, _____, D.O.

The sponsor testified at the hearing that the beneficiary received 14 chelation therapy treatments on a weekly basis beginning in early March 1980 and continuing for 14 straight weeks. He further testified that the charge for each treatment was \$70.00. The billing records in the file from Dr. _____, however, show treatments on September 18, 1980, and November 13, 1980, as well as treatments in March and April of 1981. The

CHAMPUS claims in the record cover a period of therapy from July 15, 1980, to April 9, 1981. Therefore, it is not clear from the record whether there were a total of 14 treatments or whether there were more than 14 treatments.

The number of treatments and related services do not affect the issue under consideration; the number of treatments only affects the amount in dispute. The previously noted amount in dispute (\$980.00) is based on the sponsor's reported 14 treatments at \$70.00 per treatment.

On June 8, 1980, the beneficiary returned to Dr. , who in a letter of the same date, again wrote to the referring physician, Dr. . In his letter Dr. stated:

"[The beneficiary] was seen back in the office today for a recheck concerning the cataractus [sic] densities in both eyes. She interestingly enough has been under kelation [sic] therapy by a local physician and claims that during this intravenous anti-cholesterol therapy that she began to note an improvement in her visual acuity in both eyes.

"Her visual acuity is 20/30 now for distance in the right and left eye, and I do notice what appears to be an improvement in the vascular state of the right eye, which may be the reason for the improvement in visual acuity in this one eye."

The record also includes a "health appraisal exam summary" signed by the Director of the Clinic in , dated April 1983, that stated the beneficiary's vision was normal.

The claims submitted indicate the beneficiary had other health insurance through Blue Cross and Blue Shield of . The chelation therapy was not covered by this insurance; therefore, the CHAMPUS claims were submitted.

The beneficiary was informed, in a letter dated September 22, 1981, by the CHAMPUS Fiscal Intermediary that:

". . . we find that chelation therapy is not a covered benefit. According to information available to us, chelation therapy is not approved by the Food and Drug Administration (FDA) for the treatment of circulation loss. In accordance with Chapter IV, G-15: 'Services and supplies not provided in accordance with accepted professional medical standards are not covered by CHAMPUS.'"

This letter from the fiscal intermediary addressed claims for services by Dr. [redacted] from July 15, 1980, through April 9, 1981, in the amount of \$340.00. As noted above, the sponsor testified at the hearing that the treatments started in March 1980 and continued for 14 weeks. To avoid confusion, this decision will hereinafter refer to the chelation therapy received without giving specific dates, since the specific dates of treatment are not material in deciding the appeal. I would, however, conclude that the billing records are probably more accurate than the sponsor's memory.

The September 22, 1981, letter from the fiscal intermediary also determined that the beneficiary's claims for chelation therapy previously paid were paid in error and requested repayment of \$179.43. As confirmed by the sponsor's testimony at the hearing, the money was repaid as requested by the fiscal intermediary.

The fiscal intermediary continued to deny the beneficiary's claims for chelation therapy after reviewing the case on appeal, and the sponsor filed an appeal with OCHAMPUS on behalf of his wife. OCHAMPUS, in its First Level Appeal Determination issued September 22, 1982, stated:

"Patient has macular degeneration of the right eye. The eye specialist told her that there was nothing that could be done and she would have to accept her condition.

"The patient went to a Doctor of Osteopathy (D.O.) for Chelation Therapy. After 14 treatments, the patient's vision went from 20/200 to 20/30. Her eye specialist stated that he had another patient who had the same results. However, the eye doctor did not recommend this form of therapy to his patients because it is not accepted by his peers."

In view of the sponsor's contention that several medical insurance companies pay for this type of therapy and that it is commonly used in Europe for circulatory problems, the OCHAMPUS determination went on to state:

"The following recommendation was issued by the Colorado Foundation for Medical Care: 'In response to claims that Chelation Therapy using EDTA (ethylene tetraacetic acid) is effective for a variety of disorders, 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.'

"Based upon this opinion and in absence of documentation of a contrary view, the treatment of macular degeneration by Chelation Therapy is not in keeping with the generally acceptable norm for medical practice in the United States. Thus, it also is not appropriate medical care, as defined in chapter II, B.14.a and, as such, is not medically necessary care as defined in chapter II, B.104.

"As to the experimental nature of treatment, EDTA appears in the current U.S. Pharmacopeia and the National Formulary as a drug requiring prescription by a physician. The drug is not considered to be experimental even if it is under investigation by the U.S. Food and Drug Administration as to its effectiveness."

The First Level Appeal Determination denied cost-sharing, and a hearing was requested by the beneficiary.

The hearing was held on April 21, 1983, in , before OCHAMPUS Hearing Officer, . The beneficiary, who was not present at the hearing, was represented by the sponsor.

The Hearing Officer in his Recommended Decision summarized, as follows, the testimony by the sponsor at the hearing:

". . . Chelation therapy consists of administering a chemical which has ions which make a chemical bond with certain other chemical substances and cause those substances to thereby be removed from the body; [the sponsor's] familiarity with Chelation therapy predated his wife's vision difficulties; he became aware of Chelation therapy when he had a condition which had been diagnosed as angina and for which he was told he would probably have to have by-pass surgery; in discussing his personal physical ailment with various people, he heard of the Clinic and Chelation therapy and went there for that purpose; his therapy there was successful, relieving his circulatory problem which he understood to be angina; Chelation therapy consists of taking the particular chemical, EDTA (ethelyne tetracetic [sic] acid) in dosages of one pint in four hours intravenously; his wife was diagnosed as having vision problems, with visual acuity at 20/200, diagnosed as being caused by macular degeneration; she went to

the Clinic for the Chelation therapy and her treatment consisted of fourteen sessions over a course of so many weeks; after that treatment was completed, Dr. tested her vision and showed her visual acuity was then at 20/30; Dr. has told [the sponsor] that he had other patients who had similar results but that he did not prescribe this treatment because it was considered unacceptable by his peers; [the sponsor's] understanding of why the Chelation therapy worked in his and his wife's cases was that the particular chemical removes the calcium deposits in the vascular system; . . . [the sponsor] feels that the medical community and the American Medical Association do not approve of Chelation therapy because it is an office procedure, does not require hospitalization, does not require surgery, and does not generate the substantial fees associated with those procedures."

The Hearing Officer has issued his Recommended Decision and issuance of a FINAL DECISION is proper.

PRIMARY ISSUE AND FINDINGS OF FACT

The primary issue in dispute is whether the chelation therapy can be considered as being provided in accordance with accepted professional medical standards or whether it is still considered an experimental/investigational treatment.

The Department of Defense Appropriation Act, 1976, Public Law 94-212, prohibits the use of CHAMPUS funds for, ". . . any service or supply which is not medically or psychologically necessary to diagnose and treat a mental or physical illness, injury, or bodily malfunction" This same limitation has been in all subsequent Department of Defense Appropriation Acts.

The Regulation governing CHAMPUS, DoD 6010.8-R, incorporates this limitation in Chapter IV, 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 review of what is meant by the term "medically necessary." The CHAMPUS regulation, DoD 6010.8-R, chapter II, defines "medically necessary," in part, as:

". . . 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."

In defining "appropriate medical care," the Regulation 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."

In addition, the Regulation in chapter IV, G.15, specifically excludes, "Services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens." The definition of experimental in chapter II, B.68, provides, in relevant part, that:

"'Experimental' means medical 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."

The Hearing Officer concluded that it was not possible to determine from the evidence whether the beneficiary's treatment at the Clinic caused the improvement in her visual acuity, whether the prescription from Dr. caused the improvement, or whether something else caused the improvement. Whether or not the chelation therapy benefited the beneficiary is not at issue. The issue is whether such treatment is a covered benefit under CHAMPUS.

The Regulation is the measure of what services are allowable under the CHAMPUS Basic Program. To determine whether chelation therapy was a covered benefit, it is necessary to determine whether the treatment was "in keeping with the generally acceptable norm for medical practice in the United States."

The record reflects that pursuant to a request by OCHAMPUS, the Health Care Standards Committee of the Colorado Foundation for Medical Care reviewed the subject of chelation therapy and issued the following recommendation on April 7, 1981:

"In response to claims that Chelation Therapy using EDTA (ethylene tetraacetic acid) is effective for a variety of disorders, 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 Further, there is

evidence of significant nephrotoxicity and case reports of other adverse effects associated with the use of EDTA."

The testimony of the sponsor indicated that the eye specialist his wife was seeing would not recommend chelation therapy to his patients as it was not accepted by his peers. In addition, the CHAMPUS claims indicate that the beneficiary's other insurance would not cover her chelation therapy. The sponsor's support for the contention that chelation therapy should be covered by CHAMPUS appears to be limited to the results obtained by the beneficiary in this case, his experience with chelation therapy, several treatment reports related to him by other individuals who had received chelation therapy, and his understanding that chelation therapy is commonly used in Europe for circulatory problems.

There is nothing in the record from any physician or nationally recognized medical group or association that endorses chelation therapy for macular degeneration as being "in keeping with the generally acceptable norm for medical practice in the United States." There is no evidence in the record from any medical source that recommends chelation therapy for treatment of macular degeneration. No comments or evidence were submitted by the treating physician. The only substantive medical evidence in the record was provided by the Colorado Foundation for Medical Care pursuant to a request by OCHAMPUS.

The efficacy of a treatment must be established and be recognized by nationally recognized professional organizations and the medical profession, not by individual patients. A failure to establish that the treatment was "in keeping with the generally acceptable norm for medical practice in the United States" must result in the determination that it was not a covered benefit under the CHAMPUS regulation. The Regulation further excludes "all services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment"

In view of the above, I concur with the Hearing Officer and adopt his Recommended Decision, as the FINAL DECISION, to deny CHAMPUS coverage of the appealing party's care that consisted of chelation therapy for macular degeneration and for any related services.

SECONDARY ISSUE

Success of the Treatment

There is no testimony or evidence in the record to contradict the sponsor's statement that the beneficiary benefited from the chelation therapy. Neither is there any clinical evidence submitted that substantiates his statement regarding the success of the chelation therapy. However, whether or not the treatment in question was or was not successful is moot. Assuming that it was successful, payment of CHAMPUS benefits is not dependent on a

treatment being successful or a cure effected. Success of treatment is not a consideration in terms of an individual case. Benefits are predicated on an overall "effectiveness" basis; i.e., that a treatment is considered effective and appropriate by the general medical community. This showing has not been made for chelation therapy.

The patient is free to seek that medical care she believes to be necessary in the treatment of her medical condition. However, I am constrained by law and regulation in determining what care is authorized for payment under CHAMPUS.

SUMMARY

In summary, it is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) that the chelation therapy received by the appealing party for treatment of macular degeneration be denied CHAMPUS cost-sharing. This decision is based on findings that the treatment was not in keeping with the generally acceptable norm for medical practice in the United States, that the treatment was not medically necessary or appropriate, and that the drug used, EDTA (ethylene tetraacetic acid), was not recognized by the medical profession for other than treating heavy metal (e.g., lead) poisoning at the time of the appealing party's treatment. 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 McJenzie
Acting Principal Deputy Assistant Secretary