



ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

NOV 21 1983

HEALTH AFFAIRS

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

Appeal of .)
Sponsor:) OASD(HA) File 83-31
SSN:) FINAL DECISION

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 83-31 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the beneficiary, a physically disabled and dependent child, as represented by his father, a retired officer of the United States Army. The appeal involves the denial of cost-sharing for oral, intramuscular, and intravenous administration of vitamins and metabolites provided November 1977 through October 1979 and described as "needle therapy" in the treatment of multiple sclerosis. The amount in dispute involves approximately \$6,201.57 in billed charges of which \$1,859.96 was paid by the fiscal intermediary. The beneficiary actually began "needle therapy" in February 1977; however, no CHAMPUS claims for the period February 1977 through October 1977 are included in the file.

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 denial be upheld. The Hearing Officer found the treatment was not medically necessary and not in keeping with generally accepted medical standards. The Director, OCHAMPUS, concurs in the Recommended Decision to deny cost-sharing and recommends its adoption as the FINAL DECISION with certain modifications. The modifications recommended are the expansion of the period in dispute to exclude CHAMPUS coverage of "needle therapy" treatment provided February through October 1977, and a statement of CHAMPUS policy pertaining to the general exclusion of coverage of vitamins.

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 Hearing Officer's Recommended Decision to deny cost-sharing of the "needle therapy" with the clarifications

recommended by the Director, OCHAMPUS. The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS cost-sharing of the treatment constituting "needle therapy" provided February 1977 through October 1979. This decision is based on findings the care was neither medically necessary nor appropriate medical care for treatment of multiple sclerosis and, further, is excluded under a regulatory provision pertaining to vitamins.

FACTUAL BACKGROUND

During 1974, the beneficiary's physical condition began to deteriorate. Then a sophomore in college, he was unable to continue in college athletics. In May 1976, he was diagnosed with multiple sclerosis at the Memorial Hospital, . He graduated from college and was briefly employed aboard a research vessel when continuing deterioration resulted in his collapse. Returned home by his parents, his condition worsened rapidly. He developed blurred vision, became generally weak, and could ambulate only with the aid of a cane. He was issued a Uniformed Services Identification Card with CHAMPUS eligibility based on a determination he was physically disabled and dependent upon his sponsor for support. He was 22 years old at this time.

In February 1977, he was seen by Dr.

Dr. , a 30-year advocate of the use of vitamins as treatment of many illnesses, prescribed a regimen of oral, intramuscular, and intravenous administration of vitamins and metabolites as treatment for the beneficiary's multiple sclerosis. The treatment plan is labeled by Dr. as "needle therapy" although oral administration is also utilized. The substances included in this treatment program include thiamin, niacin, riboflavin, vitamins A and E, amino acetic acid, ascorbic acid (Vitamin C), Theragra-M, vitamin B-12, magnesium, calcium pantothenate, and crude liver, for example. The treatment continued through October 1979; at that time, the beneficiary became employed, was no longer dependent upon his sponsor, and became ineligible for CHAMPUS benefits at age 25. According to the sponsor, the treatment continues through the hearing date.

Two CHAMPUS claims were filed by the beneficiary which included charges for office visits from multiple physicians, vitamins and metabolites, and syringes. The fiscal intermediary issued payment of \$1,859.96 on billed charges of \$3,185.61 on the first claim. The second claim of \$3,256.96 was denied, and recoupment was initiated on the erroneous cost-sharing of the first claim. The second claim included \$241.00 in charges for psychotherapy and treatment of a urinary tract infection. The recoupment action has been delayed pending the FINAL DECISION on the appeal. The psychotherapy and physician charges for the infection appear to have been denied also, but have not been discussed in the various appeal decisions.

The fiscal intermediary subsequently denied the claims upon Informal and Reconsideration Reviews. The OCHAMPUS First Level Appeal determination affirmed the denial on the bases the care was not medically necessary and not in keeping with the generally accepted norm for medical practice. The beneficiary appealed and requested a hearing.

The hearing was held on June 7, 1983, in _____, before _____, Hearing Officer. The Hearing Officer has submitted his Recommended Decision and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issues in this appeal are (1) whether "needle therapy" constitutes medically necessary and appropriate medical care for treatment of multiple sclerosis, (2) whether the care is excluded from coverage under the CHAMPUS general exclusion of vitamins, and (3) whether the period in issue should include care received from February through October 1977 in addition to care received from November 1977 through October 1979.

Medically Necessary/Appropriate Medical Care

Under the Department of Defense Regulation governing CHAMPUS, DoD 6010.8-R, services and supplies which are not medically necessary are excluded (DoD 6010.8.R, chapter IV., G.1). Medically necessary is defined as:

" . . . the level of services and supplies (that is, frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury, including maternity care and well-baby care. Medically necessary includes concept of appropriate medical care."

(DoD 6010.8-R, chapter II, B.104.)

Appropriate medical care is defined, in part, as:

"a. That medical care where the medical services performed in the treatment of a disease or injury, or in connection with an obstetrical case or well-baby care, are in keeping with the generally acceptable norm for medical practice in the United States;

. . . ."

Services and supplies not provided in accordance with accepted professional medical standards are also excluded under DoD 6010.8-R, chapter IV, G.15.

Applying these authorities to the facts in this appeal, the "needle therapy" prescribed by Dr. _____ must constitute a generally accepted and adequate medical treatment for multiple

sclerosis. The Hearing Officer found the "needle therapy" did not meet these standards, and I agree. There is no medical evidence of record indicating the treatment is a generally accepted norm for medical practice. Peer review opinions by physicians associated with the Colorado Foundation for Medical Care clearly opine that "needle therapy" is considered neither medically necessary nor a generally accepted treatment of multiple sclerosis. The article authored by Dr. [redacted] entitled "Response of Peripheral and Central Nerve Pathology to Mega-doses of the Vitamin B-Complex" was specifically reviewed by the Colorado Foundation for Medical Care. The peer reviewer pointedly found the article was "completely without merit and a series of rationalizations based on some data and a great deal of supposition." The phrase "medical quackery" was applied to the treatment. The reviewing physician also noted that no modern text recommends vitamin therapy for other than a general nutritional supplement. The article, "Inside MS," Spring 1983, indicated vitamin therapy clinical trials were still in progress in 1982. An article entitled "Use Vitamin C to Fight Disease, Better Nutrition," May 1983, does not cite any independent clinical studies to support vitamin therapy and additionally indicates widespread skepticism for Dr. [redacted] treatment of viral pneumonia, polio, flu, measles, and hepatitis, for example, with Vitamin C. The Hearing Officer found no support for the treatment in these articles, and I concur. As noted by the Hearing Officer, Dr. [redacted] does not even appear to suggest his "needle therapy" is generally accepted.

The beneficiary's representative argued a treatment is medically necessary if it helps the patient. While I sincerely hope the vitamin therapy helped this beneficiary, I am constrained by statutory and regulatory authorities to expend Department of Defense funds only for those treatments which are proven successful and are accepted by recognized medical authorities. I understand the need for a beneficiary to hope for medical breakthroughs in the treatment of diseases such as multiple sclerosis; however, I cannot sanction, through CHAMPUS cost-sharing, treatments outside the generally acceptable norm for medical practice.

In summary, following my review of the appeal record, I accept the Hearing Officer's Recommended Decision that "needle therapy" was not medically necessary, not a generally accepted norm of medical practice, and not appropriate medical care for treatment of multiple sclerosis.

Exclusion of Vitamins

Under DoD 6010.8-R, chapter IV, G.60, food, food substitutes, vitamins, or other nutritional supplements are excluded from CHAMPUS coverage. The Hearing Officer, following an extensive discussion, concludes essentially that vitamins used as treatment

are not excluded under this provision. As the Hearing Officer determined the care in issue was excluded under other provisions, the discussion is not central to the decision in this appeal. However, to clearly delineate the CHAMPUS policy on vitamins, a brief discussion is in order.

Under CHAMPUS, all oral vitamins are excluded. Vitamin injections, such as vitamin B-12, are covered only if the injection constitutes a specific treatment for a medical condition and the vitamin cannot be taken orally. Specifically, under CHAMPUS Interpretation 5-78-I, vitamin B-12 injections are covered under CHAMPUS in the treatment of multiple sclerosis only during the acute phase or acute exacerbation of the condition. The Hearing Officer further found the beneficiary was not in an acute exacerbation of multiple sclerosis to allow cost-sharing of vitamin B-12 injections under CHAMPUS Interpretation 5-78-I. This conclusion is apparently based on finding an acute exacerbation would not be present for the long period of time included within the appeal. The Hearing Officer notes an acute exacerbation might have been present in February 1977 when treatment began, but declined to consider this period at issue in this appeal. As discussed below, this closure of the period in issue was erroneous.

I decline to cost-share any vitamin B-12 injections even for the care provided November 1977 through October 1979. An acute exacerbation refers to a life threatening onset of an illness where, in the case of multiple sclerosis, the beneficiary is physically debilitated. While this situation may have been present in February 1977, the refusal of the beneficiary's representative to discuss CHAMPUS claims in that period deprives me of information on which to find an acute exacerbation existed. The burden to submit evidence in support of a claim rests with the beneficiary. A favorable decision will not be rendered when the beneficiary refuses to provide information available to the beneficiary which is necessary to the decision making process.

An acute exacerbation does not appear to have existed in November 1977 and thereafter. Therefore, I find CHAMPUS cost-sharing of vitamin B-12 injections cannot be authorized based on the evidence of record.

In summary, I find that the issue regarding the exclusion of vitamins, as noted by the Hearing Officer, is merged with concepts of medically necessary and appropriate medical care. Herein, the vitamins are excluded from CHAMPUS coverage under the specific Regulation exclusion as the treatment is not medically necessary or appropriate medical care for multiple sclerosis.

Period in Dispute

The record in this appeal clearly establishes CHAMPUS claims were filed and denied for "needle therapy" treatments provided November 1977 through October 1979. The appeal file also

reflects treatment began in February 1977; some invoices for care during early 1977 are included in the record. However, no CHAMPUS claims appear in the record for charges incurred February through October 1977.

During the hearing, the OCHAMPUS representative questioned the sponsor representing the beneficiary regarding any CHAMPUS claims filed for charges incurred from February through October 1977. The sponsor refused to answer these questions replying only that this period was not at issue. The Hearing Officer appears to agree with the sponsor that only care provided November 1977 through October 1979 was at issue. The Hearing Officer and sponsor are patently in error. The appeal file clearly indicates the "needle therapy" began in February 1977 and is part of the entire episode of care and treatment for this beneficiary. Any determination of coverage or noncoverage of the care during November 1977 through October 1979 would apply equally to similar care previously received. The beneficiary's representative cannot claim surprise by this inquiry as he obviously has knowledge concerning this care. The inquiry was entirely proper, and I find the representative's responses to be intentionally evasive on this issue.

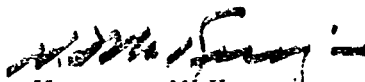
The period in issue is, therefore, determined to be February 1977 through October 1979 subject to discovery of claims filed for care during February through October 1977.

SUMMARY

In summary, it is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) that the oral, intramuscular, and intravenous administration of vitamins and metabolites, described as "needle therapy," provided February 1977 through October 1979 was not medically necessary or appropriate medical care and was not provided in accordance with accepted professional medical standards. CHAMPUS cost-sharing is, therefore, denied for these services and supplies. I further find the specific exclusion from CHAMPUS coverage of vitamins also requires denial of CHAMPUS claims for the care received from February 1977 through October 1979.

As psychotherapy charges and charges relating to a urinary tract infection were included with these claims for vitamins, I direct OCHAMPUS to determine appropriate cost-sharing of these charges. This decision results in denial of care previously cost-shared; therefore, the matter of recoupment of the funds is also referred to the Director, OCHAMPUS, for appropriate action under the Federal Claims Collection Act, including offset of any amounts payable for the psychotherapy and charges for treatment of the urinary tract infection. I also direct OCHAMPUS to determine if claims were filed and cost-shared for the period February 1977

through October 1977 and refer these amounts for possible recoupment. 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