ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

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

UNITED STATES DEPARTMENT OF DEFENSE

MAR 29 1983

Appeal of	)	
	)	OASD (HA) File 83-03
Sponsor:	)	
	)	FINAL DECISION
SSN:	)	
	)	

This is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 83-03 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, who was represented by her sponsor, a retired officer of the United States Army. The appeal involves the denial of CHAMPUS coverage for food desensitization injection material supplied by , M.D. of Norwalk, Connecticut, from May 16, 1979, through April 29, 1980. The amount in dispute involves charges of $303.00.

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 food desensitization injection material be upheld. The Hearing Officer found "The use of food desensitization injections are not medically necessary or appropriate medical care, constitute experimental or investigative treatment and were not provided in accordance with acceptable medical standards as indicated by the medical evidence contained in the record." The Director, OCHAMPUS, concurs in this finding. The Director, OCHAMPUS, in his Analysis and Recommendation notes that the Hearing Officer addressed an issue not integral to the Appeal when he specifically found that the treatment received by the beneficiary for her allergies from May, 1976 to November 11, 1978, was a covered medical service and allowable under the prior regulation governing the CHAMPUS Basic Program. The Director, OCHAMPUS nonconcurred in this finding.

The Acting Assistant Secretary of Defense (Health Affairs) 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 to deny cost-sharing as the FINAL DECISION. However, the Hearing Officer's finding that food desensitization injections were authorized CHAMPUS benefits prior to November 11, 1978 is rejected as not supported by law and regulation.

The FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) is therefore to deny CHAMPUS cost-sharing for food desensitization injection material. This decision is based on the finding that the medical treatment was not acceptable medical practice, was essentially an experimental treatment and was not provided in keeping with the generally acceptable norm for medical practice in the United States.

FACTUAL BACKGROUND

The beneficiary began receiving treatment consisting of regularly scheduled desensitization injections for hypersensitivities to foods and airborne particles by Dr. in 1976. The beneficiary stated that the claims for the first three years were cost-shared by CHAMPUS through its fiscal intermediaries, Connecticut General Life Insurance Company and Blue Shield of Massachusetts. On July 18, 1980 and August 4, 1980, respectively, the new CHAMPUS Fiscal Intermediary for Connecticut, Blue Shield of California, partially denied two seperate claims covering the period in dispute. Blue Shield allowed the charges for inhalents (airborne particles) and disallowed the charges for ingestants (food allergies). The billed charges totalled $713.00 of which $410.00 were for inhalents and the remaining $303.00 were for ingestants. The record establishes the beneficiary is afflicted with allergies which render her hypersensitive to many common foods and airborne particles. Prior to 1976, she had been treated by a number of allergy specialists, but did not receive any significant results. In May, 1976, she had her initial visit and diagnosis by Dr. . The physician described the treatment as:

> "a maintenance program which requires her to take regularly scheduled desensitization injections for her hypersensitivities to many common foods and airborne inhalants. [The beneficiary] takes a weekly injection for her sensitivity to many geographically common airborne inhalants and irritants. She is presently on a full-dose injection series for Dust Inhalants, Mold, Bacteria, Tree, Grass & Weed which is formulated from a combination of three extracts: Aqueous, Alum & Glycerin. The desensitization series for the food intolerances are also full-dose, and are formulated from an Alum Precipitated extract. [The beneficiary] receives desensitization injections for Baker's Yeast, Brewer's Yeast, and Onion."

The beneficiary testified that she would administer the injections on a weekly basis and that the treatment has been very successful. It was the treatment for desensitization for food intolerances which was disallowed.

The beneficiary submitted a CHAMPUS claim dated May 14, 1980 for the period from May 16, 1979 to July 23, 1979. The food desensitization supplies billed in the total amount of $120 were denied. The CHAMPUS claim dated May 13, 1980 covered the period from November 11, 1979 to April 29, 1980. The food desensitization material billed in the total amount of $183 was also denied by the fiscal intermediary. The sponsor appealed the denial and the fiscal intermediary's Informal Review denied the appeal on the basis that "antigens for food desensitization and the administration of them by any method is not a covered benefit." A second appeal to the fiscal intermediary also resulted in a Reconsideration decision denying the claim.

The beneficiary then requested a First Level Appeal from OCHAMPUS. The April 20, 1981 letter included copies of previous correspondence as well as a letter from Dr. . The Doctor stated:

> "We are demonstrating cause and effect relationships between the symptoms of many disorders and exposure to encountered substances which when eliminated give clinical relief. It is impossible to ignore the fasting technique practiced in Russia for controlling schizophrenia, which has been confirmed by , , , and myself. The initial findings of , of world reknown, in 1939 showed that the psychotic manifestations of pellagra could be completely eliminated by nutritional means, including use of Vitamin B_3, and within a year of his work, others demonstrated improvement in psychotic disorders where pellagra was not clinically evident.
>
> We have seen numerous patients who have been able to relate the actual onset of physical or mental disorders to specific chemical exposures - various petrochemical substances and coal tar substances, insecticides, food coloring, paint and a wide variety of household products.
>
> There is no doubt that in the future allergic, ecologic and nutritional factors are going to be routinely studied as part of

> the conventional, diagnostic study of all physical and mental disorders."

This letter did not pertain to the beneficiary but, apparently, was intended to provide detailed information concerning services provided by the provider.

OCHAMPUS by letter dated June 30, 1981 issued its First Level Appeal denying cost-sharing. The determination included a statement that, "sublingual antigen therapy is a 'controversial and unproven method of treatment which should be considered unacceptable at present.'"

By letter dated August 15, 1981, the beneficiary requested a hearing. Since the beneficiary's treatment was by injection and not by sublingual antigen therapy as implied in the OCHAMPUS denial, the letter included the statement that:

> "Instead of a written reply, Dr. telephoned... providing a detailed discussion of his prescribed treatment procedure. He believes there was a serious mistake in the CHAMPUS letter of June 30 concerning the treatment procedure. He (Dr.) is unaware of the existence or practice by anyone of provocative sublingual food allergey therapy. His treatment procedure consists of periodic subcutaneous injections of allergenic extracts. ... He further pointed out that this procedure of subcutaneous injections of these allergenic extracts is a long-standing conventional method, accepted and practiced world wide."

In response to this statement, OCHAMPUS obtained from the Colorado Foundation for Medical Care a medical review of the treatment received by the beneficiary. The medical review was conducted by a specialist in internal medicine and occupational medicine. The medical reviewer stated:

> "The American Academy of Allergy Executive Committee has considered available data on the effectiveness of sublingual provocative testing and subcutaneous administration of food extracts and has recommended that these techniques should be reserved for use in controlled experiments only."

One of the specific questions asked by OCHAMPUS was:

> "Are antigens for food desensitization and their administration by any method in keeping

> with the generally acceptable norm for medical practice in the United States?"

The medical reviewer responsed:

> "Not at this time. The subcutaneous and sublingual methods of administration of food extracts have not been found to be effective and their use is not generally accepted by conventional allergists."

The reviewer went on to say, "The use of food antigen injections is essentially related to experimental treatment regimens at present."

OCHAMPUS by letter dated October 29, 1981, advised the beneficiary that even though the food antigens therapy was not administered sublingually [as stated in OCHAMPUS first level decision] but by means of periodic subcutaneous injections, the medical reviewer had given his opinion that "subcutaneous and sublingual methods of administration of food extracts have not been found to be effective and their use not generally accepted by conventional allergist." The letter went on to state that OCHAMPUS would proceed with the plan to hold a hearing.

The record also includes a letter from the provider dated December 3, 1981, which is after the review by the Colorado Foundation for Medical Care. The provider states:

> "Extracts of the offending foods containing the active substances that bother the patient are injected into the arm to stimulate the production of antibodies that will protect the respiratory tract the same way that pollen antibodies, etc. will protect the same individual.
>
> The Medical Peer Review Committee did not consider this matter in its broader clinical perspective. Food desensitization is the next logical step in the methods they already employ daily."

Prior to the hearing, the letter from the provider was reviewed by the OCHAMPUS Medical Director, who is a medical doctor. The Medical Director concurred with the opinion of the Colorado Foundation for Medical Care. He contended that the American Academy of Allergy would be eminently qualified to render a qualified judgment. The Medical Director noted that, the evidence on food disensitization injections to date is not adequately substantiated, predictable, or generally accepted by the medical profession as a standard of care.

The hearing was held on August 13, 1982 in Washington D.C. before OCHAMPUS Hearing Officer, Mr. . Both the beneficiary and the sponsor attended the hearing. 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 food desensitization injection material can be considered as being provided in accordance with accepted professional medical standards or whether it is still an experimental/investigational treatment.

The Department of Defense Appropriations Act, 1976, Public Law 94-212, prohibited 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 CHAMPUS Regulation in effect at the time of care in question in this appeal (May 16, 1979 through April 29, 1980), incorporated this limitation in chapter IV, DoD 6010.8-R, 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 "Medically necessary includes [the] 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."

In addition, the CHAMPUS regulation in chapter IV, C.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 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." DoD 6010.8-R, chapter II, B.68.

The Hearing Officer believed that the Claimant did receive substantial successful results from the medical services rendered by the treating physician. However, the Hearing Officer correctly stated that "The issue is whether such services are a covered benefit. The CHAMPUS guidelines [Regulation] are the measure of what services are allowable under the program."

To determine whether it was a covered treatment, it is necessary to determine whether the treatment was "in keeping with the generally acceptable norm for medical practice in the United States" and whether it was an experimental treatment.

The record reflects that, the American Academy of Allergy Executive Committee "has considered available data on the effectiveness of sublingual provocative testing and subcutaneous administration of food extracts and has recommended that these techniques should be reserved for use in controlled experiments only."

One of the exhibits included at the Hearing was a "Public Health Service Assessment of Intracutaneous (Intradermal) and Subcutaneous Provocative Testing and Neutralization Therapy for Food Allergies (1981)." The Public Health Service concluded that:

> "Intracutaneous and Subcutaneous provocative and neutralization testing and neutralization therapy for food allergies are widely used but lack scientific evidence of effectiveness. No known immunologic mechanism can account for the neutralization of provoked symptoms by dilute solutions of food antigens. Intracutaneous and Subcutaneous provocative and neutralization testing and neutralization therapy for food allergies should be considered experimental at this time."

A letter, dated December 3, 1981, from the treating physician included the following statement:

> "The AMA Board of Trustees stated that there were many areas in the field of allergy that have not, in their opinion, been completely worked out and they concluded that any qualified allergist, such as myself with board certification, should be compensated

> for services rendered. My colleagues and I get clinical results. We are not engaged in experimental treatments. Our patients suffering from this form of illness are the experts concerning the effectiveness of food treatments...."

Neither in this letter, nor any of the other correspondence by the treating physician, does it state that the American Medical Association or any nationally recognized medical group has endorsed food desensitization treatment as being "in keeping with the generally acceptable norm for medical practice in the United States." Rather it is described, in one instance, as "the next logical step." The treating physician does not quote the results of controlled scientific studies, but refers to the experts as being his patients. The only reference to the treatment being conventional is from the beneficiary, who stated she was quoting the provider.

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 a determination that it was not a covered benefit pursuant to the CHAMPUS regulation.

The Hearing Officer found it "normally natural to give a treating physician's evidence more weight in this type of situation based upon the fact that he has examined the patient; has treated her, and is familar with her on a personal basis than a physician who would be reviewing only medical reports." In this instance, such a presumption would not be appropriate, since the medical reviewer only addressed whether the particular treatment was within the generally acceptable norm for medical practice in the United States and whether it was considered experimental. A nontreating physician could most competently review whether the treatment regimen was widely recognized within the medical profession or whether it was considered experimental.

This FINAL DECISION has given primary weight to the conclusion of the American Academy of Allergy Executive Committee. However, even without this opinion the failure of the treating physician or beneficiary to offer evidence that this treatment was "within the generally acceptable norm of medical practice in the United States" would be sufficient to deny the claim. Until evidence can be presented that this particular treatment was, at the time of treatment, a standard of practice and within the acceptable norm for medical practice in the United States, it must be concluded that it is not covered treatment under the CHAMPUS regulation and considered investigational treatment.

SECONDARY ISSUE

An issue also addressed by the Hearing Officer was whether similar claims previously allowed by a CHAMPUS fiscal intermediary for treatment received from May 26, 1976, to November 11, 1978, would estop CHAMPUS from now denying subsequent claims. The Hearing Officer correctly concluded that the claims were properly denied based on the DoD 6010.8-R, chapter I, N.4, which provides that:

> "Claims for outpatient care or new inpatient cases (or new inpatient episodes of an ongoing case) received on or after the effective date of this Regulation, and which includes services and/or supplies provided after the effective date of this Regulation, shall be adjudicated on the basis of this Regulation irrespective of the transistional authority granted in this Section N."

In previous FINAL DECISIONS, estoppel arguments have been addressed and consistently rejected on the basis that errors by an agent are not binding upon the government. However, the Hearing Officer in his findings concluded that:

> "The claimant received treatment for her allergies from May, 1976 to November 11, 1978 which was a covered medical service and allowable under the prior regulation governing the CHAMPUS Basic Program."

This conclusion is clearly erroneous based on law and regulation.

As previously cited, the Department of Defense Appropriations Act for Fiscal Year 1976, Public Law 94-212, prohibited 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." The CHAMPUS regulation in effect in fiscal year 1976 and up to May 31, 1977, Army Regulation 40-121, implemented this legal restriction by authorizing CHAMPUS payment for, "...any procedures and types of care [not otherwise excluded]... which are generally accepted as being part of good medical practice...."

The beneficiary's treatment for food desensitization is determined to be experimental and not generally accepted as part of good medical practice. Therefore, it was not allowable from May 1976, to May 31, 1977 under AR 40-121 or subsequent to June 1, 1977, under DoD 6010.8-R, even though the CHAMPUS Fiscal Intermediary may have paid the claims. The Hearing Officer's

finding that it was allowable under the prior regulation was clearly erroneous. The Director, OCHAMPUS should cause the claims records to be reviewed and appropriate recoupment action initiated under the Federal Claims Collection Act.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that food desensitization injections be denied CHAMPUS coverage as the treatment is found to be experimental and not in keeping with the generally acceptable norm for medical practice in the United States. Therefore, the claims on the dates in issue and the appeal of the beneficiary are denied. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

John Beary

John F. Beary, III, M.D.
Acting Assistant Secretary