ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

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

UNITED STATES DEPARTMENT OF DEFENSE

01 MAY 1984

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) No. 83-42
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 83-42 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, a retired officer of the United States Marine Corps. The appeal involves the denial of cost-sharing of intradermal inhalant and food allergy testing and subcutaneous neutralization therapy provided by Ira Finegold, M.D., Hollywood, Florida. The treatment in dispute commenced on February 22, 1978, and appears to have continued through 1983. Because the record contains itemized statements only for care received through January 11, 1982, the total amount in dispute is unknown.

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 Appeal Decision be upheld to the extent it denied CHAMPUS coverage of food allergens to be injected; however, he recommended that the OCHAMPUS First Level Appeal Decision be amended to cost-share services and supplies that include the intradermal testing, the extract to be injected, and the injections for treatment of inhalant allergies. The Hearing Officer also found the intradermal testing for food allergies to be an authorized benefit under CHAMPUS although the cost of the food allergens used in the treatment was not authorized. The Hearing Officer concluded that because the inhalant and food allergens were included in a single injection and because it is not practical to divide the cost of a single injection, CHAMPUS should cost-share the injections and drug coverage only of the food allergens used in the injections.

The Director, OCHAMPUS, nonconcurs with the Hearing Officer's Recommended Decision and recommends that the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) deny CHAMPUS coverage of the provocative food and inhalant allergy testing and neutralization therapy as experimental investigational treatment.

The Assistant Secretary of Defense (Health Affairs) after due consideration of the appeal record, rejects the Hearing Officer's Recommended Decision to cost-share the allergy testing and treatment. Under Department of Defense Regulation 6010.8-R, chapter X, the Assistant Secretary of Defense (Health Affairs) or his designee may reject the Hearing Officer's Recommended Decision and issue a FINAL DECISION based on the record. My rejection of the Recommended Decision in this appeal is based on findings that the Hearing Officer failed to adequately consider a prior FINAL DECISION of this office pertaining to the issues in this appeal and failed to apply applicable regulatory authority.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny cost-sharing of the intradermal provocative testing, the allergens, and the subcutaneous injections. This decision is based on findings the provocative intradermal testing and neutralization therapy for inhalant and food allergies are experimental investigational procedures and are excluded from CHAMPUS coverage.

FACTUAL BACKGROUND

The beneficiary had a history of severe allergic headaches and was receiving Sansert and Dilantin in February 1978 when first seen by Ira Finegold, M.D., an allergy specialist. Dr. Finegold initiated a regimen of intradermal testing and subcutaneous neutralization therapy as treatment for the diagnosed conditions of allergic rhinitis, allergic sinusitis, and allergic headaches. The subcutaneous injections included a mixture of inhalant and food allergens; however, Dr. Finegold has stated that the food component is quite significant and the allergy extracts principally contained foods.

CHAMPUS claims were submitted to the former CHAMPUS Fiscal Intermediary for California, Blue Shield of California, for the testing, allergen extracts, and injection charges during the period February 22, 1978, through November 28, 1980, in the amount of $2,172.05. Blue Shield of California issued partial payment on these claims and denied the remainder. The denials were affirmed upon Informal Review and Reconsideration Decisions based on findings the treatment was not generally accepted medical treatment. In addition, the fiscal intermediary initiated recoupment action on the erroneous payment of the beneficiary's claim.

The beneficiary appealed to OCHAMPUS and the OCHAMPUS First Level Appeal Decision upheld the previous denials on the bases the treatment was experimental and not in keeping with the generally accepted norm for medical practice in the United States. The testing and treatment of inhalant allergies was not separately addressed in this decision.

The beneficiary requested a hearing and waived his right to appear. The appeal file was submitted to Joseph E. Harvey,

OCHAMPUS Hearing Officer, for a hearing on the record. The Hearing Officer has issued his Recommended Decision and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether intradermal testing and subcutaneous neutralization therapy for treatment of food and inhalant allergies are experimental/investigational treatments.

Experimental/Investigational

Under the Department of Defense Regulation governing CHAMPUS, DoD 6010.8-R, chapter V, G.15., services and supplies related to essentially experimental procedures or treatment regimens are excluded from CHAMPUS coverage. The Regulation in chapter II, B.68., defines "experimental," in part, as:

> ". . . 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 . . . ."

Under this authority, the intradermal testing and subcutaneous neutralization therapy for treatment of food and inhalant allergies must be shown to be a proven procedure meeting generally accepted standards. The evidence of record clearly indicates the treatment does not qualify for CHAMPUS cost-sharing under this standard. The Hearing Officer found the treatment by subcutaneous injection of food allergens was investigational. This finding includes the cost of the extract of foods to which the beneficiary was allergic. The Hearing Officer, however, found the intradermal testing with food allergens to be an accepted practice and payable under CHAMPUS. While I concur with the Hearing Officer's finding regarding the injections and extract (treatment), I must disagree that the intradermal testing is a covered benefit.

Regarding the investigatory nature of subcutaneous neutralization therapy for the treatment of food allergies, there appears no real medical dispute. While the beneficiary argued the treatment was beneficial, the attending physician does not challenge its designation as experimental. Dr. Finegold has stated in submissions for the record:

> "The subcutaneous injection has been scrutinized by several studies and the results have not been convincing. This does not necessarily mean that the technique or system is incorrect, just that we are not able to clearly show that there is a difference in treated and non-treated groups.

> "There has been much discussion as to the validity of the results, however, the Academy of Allergy and the College of Allergy of which I am a member, I believe takes the position that it is up to the investigators who are using the technique to prove their [sic] efficacy and this is the status of the situation at this time."

In another submission, Dr. Finegold states the treatment ". . . is definitely controversial and is considered an unproven technique." The OCHAMPUS Medical Director and a Colorado Foundation for Medical Care medical reviewer agree.

This office has previously considered the issue of CHAMPUS coverage of food desensitization injections (neutralization) and found the treatment to be experimental and excluded from CHAMPUS coverage. (See OASD(HA) File 83-03.) There is no evidence of record in the present hearing to warrant reversal of this position.

Dr. Finegold does maintain provocative intradermal testing for food allergies is an accepted procedure. The Hearing Officer agreed and recommended cost-sharing by CHAMPUS. I reject this finding by the Hearing Officer based on the evidence of record and applicable CHAMPUS regulatory authority.

In OASD(HA) File 83-03, the record included a 1981 report of the Office of Health Research, Statistics, and Technology, Public Health Service, Department of Health and Human Services, entitled Intracutaneous (Intradermal) and Subcutaneous Provocative and Neutralization Testing and Neutralization Therapy for Food Allergies. This report, based on extensive research including assistance of the American Academy of Allergy and the American College of Allergists, concluded:

> "Intracutaneous (interdermal) [sic] and subcutaneous provocation 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."

The treatment involved in this appeal commenced on February 22, 1978, and, therefore, was contemporaneous with the publication of professional opinion and medical literature which held the treatment to be experimental. No substantive information has been submitted for the record by the appealing party which would

support a finding that the treatment is no longer considered experimental. The Hearing Officer based his recommendation on statements submitted by Dr. Finegold and citations to medical articles. I have reviewed this discussion and conclude the references do not establish the reliability (proven nature) of the tests. In fact, one reference quoted by Dr. Finegold clearly indicates the intradermal test is limited in reliability in that the test can neither establish nor confirm a definitive diagnosis of clinically significant food allergy. In addition, the reference states that intradermal tests should be used only for antigens which produce negative scratch tests.

My conclusion, however, is based on additional available evidence. As noted above, the Public Health Service concluded both intracutaneous (intradermal) provocation testing and subcutaneous neutralization therapy was experimental. Of interest in this assessment is the discussion of a study by L. W. Draper, Food Testing in Allergy: "Intradermal Provocative v. Deliberate Feeding," Archives of Otolaryngology. vol. 95, page 169 (1972). This study concluded that the intradermal provocative test should not be solely relied upon for diagnosing food allergies and questioned the accuracy of negative intradermal tests as well. Other articles cited in this assessment reach essentially the same conclusion. As noted above, the American Academy of Allergy, the primary body of medical allergists, also supports the experimental nature of testing and neutralization therapy at this time.

Based on this evidence, I conclude the intradermal provocation test for food allergies is unproven at this time and an experimental procedure.

Finally, CHAMPUS cost-sharing of the intradermal provocation testing would not be permitted under DoD 6010.8-R, chapter IV, G. 66. Under this provision, services and supplies related to a noncovered treatment are excluded from coverage. The facts in this appeal indicate the testing was performed specifically as a precondition to the neutralization therapy. The results of the testing formed the bases for the therapy. Therefore, the testing is related to the noncovered neutralization treatment and is excluded from coverage under CHAMPUS.

The Hearing Officer additionally found intradermal provocative testing and neutralization therapy for inhalant allergies was medically necessary and recommended cost-sharing. OCHAMPUS did not contest the medical necessity of inhalant testing and treatment based on opinion from the Colorado Foundation for Medical Care. However, following my review of the evidence, I reject this finding and hold provocative inhalant allergy testing and neutralization therapy is experimental and not CHAMPUS covered. The Colorado Foundation opinion addresses only intradermal desensitization injections for inhalant allergies which is an accepted procedure. Provocation testing and treatment is not addressed. Provocation testing utilizes increased concentrations of allergens to provoke symptoms. When

the symptom producing dose is reached, a neutralizing dose is given. It is this method that is experimental; as is stated by the Public Health Services and American Academy of Allergy, no known immunologic mechanism can account for neutralization of provoked symptoms.

The appeal file in OASD(HA) File 83-03 also included a statement from the American Academy of Allergy published in Allergy and Clinical Immunology, Vol. 67, No. 5, pages 333-338 (1981) which concluded the provocative testing and neutralization method was experimental with no distinction between foods and inhalants. Therefore, I find the provocative intradermal food and inhalant allergy testing and neutralization treatments experimental and excluded from CHAMPUS coverage.

Additionally, the Hearing Officer found the injections included both food and inhalant allergens and were not severable into covered and noncovered costs. He, therefore, concluded the entire cost of the injections should be covered by CHAMPUS as the cost included a nonseverable covered charge. Had I determined provocative inhalant treatment was a covered benefit, I would have rejected this recommendation. I cannot authorize cost-sharing of an experiment treatment (food extract) even if combined with a payable treatment. To do so would establish a dangerous precedent requiring cost-sharing of potentially harmful treatments when combined with medically necessary services. Further, Dr. Finegold stated the injection principally contained foods; therefore, the treatment primarily involved an experimental treatment of food allergies and would be excluded from coverage for that additional reason.

Medically Necessary

Under DoD 6010.8-R, chapter IV, A.1, CHAMPUS will cost-share medically necessary services. Medically necessary is defined as:

> ". . . the level of service and supplies (that is, frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury . . . ." (Chapter II, B. 104.)

As I have concluded above that intradermal testing and subcutaneous neutralization therapy for treatment of food and inhalant allergies is unproven, I must also conclude this diagnosis and treatment is not medically necessary. The Hearing Officer also found the treatment for food allergies failed the test of medical necessity.

As I have rejected the Hearing Officer's recommendation on cost-sharing of the inhalant allergy testing and treatment and found this procedure to be experimental, I must equally find a lack of medical necessity. Care that is unproven cannot qualify as necessary treatment of illness or injury. Provocative

intradermal testing and neutralization therapy is found to be not medically necessary and excluded from coverage on that basis also.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS coverage of services and supplies for intradermal provocation testing and subcutaneous provocation (neutralization) therapy as treatment for food and inhalant allergies as these procedures are not medically necessary and are experimental procedures. As some claims have been cost-shared for the excluded services and supplies, the matter of potential recoupment is referred to the Director, OCHAMPUS, for consideration under the Federal Claims Collection Act. This FINAL DECISION applies to all intradermal inhalant and food allergy testing and subcutaneous neutralization therapy received by the beneficiary since February 22, 1978. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

for William Mayer, M.D.