ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

4 APR 1984

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) No. 84-01
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-01 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, the dependent child of an active duty officer of the United States Air Force, as represented by his mother. The appeal involves the denial of cost-sharing of intradermal provocative testing, neutralization therapy, and immunotherapy provided by Donald E. Sprague, M.D., and William J. Rea, M.D., from May 21 through July 20, 1981. The amount in dispute involves $332.15 in billed charges.

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 denying CHAMPUS cost-sharing of the patient's intradermal provocative testing, neutralization therapy, and immunotherapy be upheld. The Hearing Officer found OCHAMPUS correctly determined the provocative intradermal testing, neutralization therapy, and immunotherapy were experimental and not appropriate medical care. The Director, OCHAMPUS, concurs in the Hearing Officer's Recommended Decision and recommends its adoption as the FINAL DECISION.

The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, adopts the Hearing Officer's Recommended Decision to deny cost-sharing of the intradermal provocative testing, neutralization therapy, and immunotherapy.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny cost-sharing of the intradermal testing, neutralization therapy, and immunotherapy. This decision is based on findings the care is excluded from CHAMPUS coverage as investigational/experimental care and is not considered appropriate medical care of the patient.

FACTUAL BACKGROUND

According to the beneficiary's mother, the beneficiary suffered allergic reactions and was referred to Dr. William Sprague and Dr. William Rea by her family physician. The patient's initial diagnosis of Tourette's syndrome was reportedly made by a neurologist, although clinical findings and test results to support the diagnosis, including a history and a report of physical examination, do not appear in the appeal record.

The beneficiary received an initial examination by Dr. Sprague on May 21, 1981, including laboratory testing of T-lymphocytes, total eosinophil, and blood count. On July 9, 1981, the next reported date of service in the record, Dr. Sprague conducted an environmental examination and intradermal titration (provocative) testing and neutralization. Additional neutralization, intradermal testing, and immunotherapy were provided on July 10 and July 20, 1981.

The appeal file contains neither a history or report of physical examination by Dr. Sprague nor the findings of the environment examination. Laboratory testing results were also not furnished; however, at the hearing, Dr. Sprague testified that the white blood count was 4000 and the T-lymphocytes were 1100. Both measurements were considered low for the age of the beneficiary and indicated a breakdown in the beneficiary's immune system according to Dr. Sprague.

Results of the intradermal testing also do not appear in the file. Therefore, I am unable to determine what allergies (inhalant, food, chemical, etc.) were tested and to what substances the beneficiary reacted. Dr. Sprague testified the beneficiary's nose, sinuses, eyes, and brain (vascular cephalgia) were affected by his allergies and related the beneficiary's illness to moving to a new home containing new carpet and particle board which emitted formaldehyde. His testimony indicated provocative intradermal testing was limited in his practice to food and chemicals. Dr. Sprague further testified his practice was more than treatment of allergies and included environmental medicine; the treatment team included specialists other than allergists.

A CHAMPUS claim of $496.15 was submitted by the beneficiary for the services and supplies discussed above. The diagnoses stated on the claim form were Tourette's syndrome and vascular cephalgia. The CHAMPUS Fiscal Intermediary for the State of Texas, Wisconsin Physicians Service, allowed $91.40 on billed charges of $164.00 for the initial office visit, laboratory tests, and July 9, 1981, environmental examination. After deduction of the beneficiary's cost-share, the fiscal intermediary issued payment to the beneficiary of $33.12. The remaining charges of $332.15 for the intradermal testing and neutralization therapy were denied. This partial denial of cost-sharing was affirmed upon informal and reconsideration reviews by the fiscal intermediary based on findings the care was

not provided in accordance with accepted professional standards. Following an appeal to OCHAMPUS, the OCHAMPUS First Level Appeal Decision affirmed the denial of cost-sharing based on findings the care was experimental and did not meet the generally accepted medical standards for treatment of allergies.

The beneficiary requested a hearing which was held on April 6, 1983, before Harold H. Leeper, OCHAMPUS Hearing Officer. The Hearing Officer has issued 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 provocative intradermal testing and neutralization therapy for treatment of allergies is an experimental/investigational treatment, and (2) whether the treatment is medically necessary/appropriate medical care.

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 provision, the intradermal testing and neutralization therapy for treatment of allergies must be shown to be a proven procedure meeting generally accepted standards.

The evidence of record does not establish the care in dispute meets these criteria. The Hearing Officer found the care was experimental and I agree.

This office has previously considered cost-sharing of food desensitization injections (neutralization therapy) in OASD(HA) File 83-03. Therein, the Assistant Secretary of Defense (Health Affairs) determined that care was experimental and not in keeping with the generally acceptable norm for medical practice. 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 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 decision in OASD(HA) File 83-03 also was based on a statement from the American Academy of Allergy published in Allergy and Clinical Immunology, Vol. 67, No. 5, pages 333-338 (1981). Therein, the American Academy of Allergy concluded that subcutaneous provocation and neutralization for treatment and diagnosis of allergic disease have no plausible rationale or immunologic bases and should be reserved for use only in controlled experiments.

These opinions were also placed in evidence in the present appeal. The treatment involved in this appeal commenced on May 21, 1981, and, therefore, was contemporaneous with the publication of recognized professional opinions and authoritative medical literature which opined the treatment to be experimental. Further, in May 1983 in response to an inquiry by OCHAMPUS, the Director, Office of Health Technology Assessment, National Center for Health Technology, advised that no new assessment of the procedures had been made and that the conclusion reached in the 1981 assessment has not been revised.

In OASD(HA) File 83-42, the Assistant Secretary of Defense (Health Affairs) again considered this issue. Therein, the Assistant Secretary determined interdermal provocative food and inhalant testing and neutralization therapy were experimental.

The appeal record also contains additional medical opinions and professional publications dealing with environmentally related illness and allergies. The Hearing Officer found that this evidence contained virtually no evidence or comment concerning whether the procedures at issue are experimental. Following my review of the evidence, I agree. The majority of the articles do not concern the procedures at issue in this appeal, i.e., intradermal provocative testing and neutralization therapy. A paper entitled Controversies in Allergy: A Critical Review of the Methods of Provocation and Neutralization by Richard N. Podell, M.D., M.P.H., does appear relevant. This paper reviewed the various studies of provocative testing and neutralization therapy and concluded regarding intracutaneous neutralization that:

> "Conforming studies still need to be done. Nevertheless, the preponderance of currently published, assessments supports the validity of intrauitaneous [sic] neutralization. However, the studies are of relatively and selected subjects, no inference can be made about neutralization's effectiveness for general populations."

The author, previously a visiting research associate at the clinic involved in this appeal, calls for additional studies and recognizes the controversial nature of the procedures and that the issue of the validity of the procedure is unsettled. Clearly, this paper does not establish provocative testing and neutralization therapy to be an accepted practice but emphasizes the unsettled nature of the studies and validity of the procedures.

The appeal record also contains a 1981 letter from the American Academy of Otolaryngologic Allergy supporting the provocative food testing and related allergic techniques provided by the attending physicians in this appeal. The Hearing Officer apparently considered this opinion as well as the opinion of the American Academy of Allergy in concluding the beneficiary produced no evidence of approval of the procedures by the professional organizations who represent the majority of American physicians who specialize in the treatment of allergies. At the hearing, Dr. Sprague focused on this point when he questioned the OCHAMPUS reliance on the American Academy of Allergy and the Public Health Service to the exclusion of other recognized groups. Dr. Sprague further challenged the opinion of the American Academy of Allergy as that association is composed, according to Dr. Sprague, of "classical" allergists.

A determination under the CHAMPUS regulation provision excluding experimental procedures is a factual one and depends significantly on medical opinions from authoritative sources. The American Academy of Allergy is certainly an authoritative source. The American Academy of Otolaryngologic Allergy is also an association of qualified physicians; however, as noted by the OCHAMPUS Medical Director, that organization is a surgical subspecialty organization and not the primary body of medical allergists. The opinion of the Academy of Otolaryngologic Allergy does not state the basis of its opinion nor cite any studies which support the opinion. Therefore, based on the above, I conclude the American Academy of Allergy represents the more authoritative source whose opinion is based on published analysis of studies of the procedures in issue. In reference to Dr. Sprauge's concerns over the composition of the American Academy of Allergy and its alleged reluctance to consider his views, the assessment of the Public Health Service would constitute an independent evaluation which also found the procedures to be experimental.

In summary, I find no evidence of record in this appeal to warrant reversal of the position this office established in OASD(HA) Files 83-03 and 83-42. Physicians and beneficiaries utilizing provocative food and inhalant testing and neutralization therapy bear the burden of establishing the validity of these procedures. It is clear the area is unsettled and additional scientific studies are required. OCHAMPUS and this office are receptive to changes in medical opinion when the weight of scientific study and medical opinion recognize the validity of new procedures. At present, I find intradermal provocative testing and neutralization therapy for food and inhalant allergies to be experimental care, not generally accepted practice, and excluded from CHAMPUS coverage.

Appropriate Medical Care
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 . . . . medically necessary includes concept of appropriate medical care." (Chapter II, B.104.)

Appropriate medical care is defined 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;
>
> "b. The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training and education and is licensed and/or certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards; and
>
> "c. The medical environment in which the medical services are performed is at the level adequate to provide the required medical care." (Chapter II, B.14.)

As I have concluded the care at issue is not generally accepted medical practice, I also must find the care is not in keeping with the norm for medical practice and fails to meet the criteria for medically necessary and appropriate medical care. The Hearing Officer also found the care was not appropriate medical

care, and I adopt this finding. Care that is unproven and not in keeping with the norm for medical practice cannot be determined medically necessary nor appropriate care. The care is, therefore, excluded from CHAMPUS coverage on these additional bases.

In reviewing this file, I have also noted the absence of documentation that allergies are connected with Tourette's syndrome, a neurological disease, and that neutralization therapy is an accepted treatment of Tourette's syndrome. Without some evidence of the medical necessity of the services/supplies for the treatment of Tourette's syndrome, I must decline cost-sharing on this 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 neutralization therapy, and immunotherapy as treatment for food and inhalant allergies as these procedures are experimental, not medically necessary, and not appropriate medical care. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

William Mayer, M.D.