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. 84-03
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPVA Appeal OASD(HA) Case File 84-03 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is a beneficiary of the Civilian Health and Medical Program of the Veterans Administration (CHAMPVA) as the widow of a deceased 100% disabled veteran. CHAMPVA is administered under the same or similar limitations as the medical care furnished certain beneficiaries of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). By agreement between the Administrator, Veterans Administration, and the Secretary of Defense, pursuant to the provisions of Title 38, United States Code, section 613, CHAMPVA claims are processed and appealed under rules and procedures established by the CHAMPUS regulation, DoD 6010.8-R.

The appeal involves the denial of CHAMPVA cost-sharing for radioallergosorbent testing (RAST) and provocative intradermal testing and neutralization therapy provided by Al Johnson, D.O., and William J. Rea, M.D., Dallas, Texas, from August 3 through October 13, 1981. The amount in dispute involves $2,845.00 in billed charges for these services. 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. The Hearing Officer found OCHAMPUS correctly determined the provocative intradermal testing, and 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 with modifications. The modifications recommended are that 1) the charges for inpatient care at Brookhaven Medical Center also be denied CHAMPUS coverage as relating to noncovered treatment, 2) the claims in the appeal record for RAST, provocative intradermal testing, and neutralization therapy provided during 1979-80 also be denied CHAMPUS coverage.

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 food testing, neutralization therapy, and RAST. The modifications recommended by the Director, OCHAMPUS, are also adopted in the FINAL DECISION.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny cost-sharing of the intradermal food, inhalant, and chemical testing, neutralization therapy, and the RAST provided August 3 through October 13, 1981, and December 4, 1979, through February 14, 1980. Cost-sharing of the charges for inpatient care at Brookhaven Medical Center August 3 through August 14, 1981, is also denied. The amount in dispute totals $3,179.25 for these services excluding charges for Brookhaven Medical Center which are not evidenced in the appeal file.

FACTUAL BACKGROUND

The appeal record reflects this beneficiary's history of multiple allergies dating from 1973. Symptoms have included bloating, coughing, choking, diarrhea, constipation, headaches, neck pain, fatigue, watering eyes, and sinus congestion. She underwent scratch testing in 1977 and received antigen injections from 1977 until approximately 2 months prior to the treatment by Doctors Rea and Johnson. She had 12 RAST in December 1979 and food neutralization therapy December 15, 1979, through February 14, 1980, from Dr. Robert Stroud, Dallas, Texas. On August 3, 1981, the beneficiary was admitted by Dr. William Rea to Brookhaven Medical Center, Dallas, Texas. She was placed in an environmentally controlled room of aluminum and fasted for 4 days. She was given milk of magnesia which eliminated her "bloated" feeling and bowel distension. Chest x-ray, upper GI, and barium enema were negative. EKG was normal; T and B lymphocytes were depressed. She underwent provocative intradermal food, inhalant, and chemical testing and radioallergosorbent testing. Allergens tested included cedar, various foods - grapefruit, tomato, wheat, eggs, pork, corn, cantaloupe, and fish, perfume, phenol, molds, and grasses. Sensitivities were noted to phenol, ethanol, cigarette smoke, perfume, grapefruit, tomatoes, and other foods. Diagnoses were gastroenteritis, myositis, immune deficiency, and food and chemical sensitivities. Following her discharge on August 14, 1981, the beneficiary received outpatient treatment from Doctors Rea and Johnson of provocative neutralization therapy through October 13, 1981. From the medical records, the neutralization therapy (antigen injections) consisted primarily of food and chemical antigens (cigarette smoke and perfume). Inhalant allergy injections of ragweed and cedar were given on September 14 and October 13, 1981, and December 4, 1979. Two CHAMPUS claims were filed for 12 RAST, neutralization therapy, laboratory charges, and office visits provided December 4, 1979, through February 14, 1980, in the amount of $334.25. The appeal

file reveals CHAMPUS paid $54.00 after calculation of the allowable charge and application of the beneficiary cost-share. Five claims were filed for treatment provided by Doctors Johnson and Rea from August 3 through October 13, 1981. Eliminating duplicate charges, the total claimed is $2,845.00. The appeal file does not contain a claim for inpatient care provided at Brookhaven Medical Center from August 3 through 14, 1981.

The CHAMPUS Fiscal Intermediary for the State of Texas, Wisconsin Physicians Service, paid $588.45 in partially cost-sharing the RAST, provocative testing, and neutralization therapy. The beneficiary appealed. The fiscal intermediary determined the payments for the allergy testing and treatment were in error and requested repayment, finding the treatment was not generally accepted medical practice. The OCHAMPUS First Level Appeal Decision affirmed the fiscal intermediary appeal decisions and found the RAST, the provocative intradermal testing, and neutralization therapy were investigational and did not meet generally accepted standards of practice.

The beneficiary appealed and requested a hearing. The hearing was held before Harold H. Leeper, Hearing Officer, on September 15, 1983, in Dallas, Texas. 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 are experimental/investigational procedures and (2) whether the provocative intradermal testing, neutralization therapy, and radioallergosorbent testing (RAST) are medically necessary/appropriate medical care.

Experimental/Investigational

Under chapter 17, title 38, section 613, United States Code, the Administrator, Veterans Administration, is directed to provide for medical care, in the same or similar manner and subject to the same or similar limitations as CHAMPUS, for dependents of 100% service-connected disabled veterans and dependents of deceased disabled veterans. Pursuant to this authority, the Civilian Health and Medical Program of the Veterans Administration (CHAMPVA) was established which, by agreement, is administered by the Department of Defense, Office of the Civilian Health and Medical Program of the Uniformed Services. CHAMPVA claims are processed and appealed under rules and procedures established by CHAMPUS regulation, DoD 6010.8-R.

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 regimens (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 provocative intradermal testing and neutralization therapy for treatment of allergies must be shown to be proven procedures meeting generally accepted standards. The evidence of record does not establish the care meets these criteria. The Hearing Officer found the care was experimental and I agree.

This office has considered cost-sharing of provocative intradermal food and inhalant testing and neutralization therapy in three previous FINAL DECISIONS. In OASD(HA) File 83-03, the Assistant Secretary of Defense (Health Affairs) determined that food desensitization injections (neutralization therapy) were experimental and not in keeping with the generally accepted norm for medical practice. In OASD(HA) File 83-42, this office found intradermal food and inhalant testing and neutralization therapy to be excluded from CHAMPUS coverage. Finally, in OASD(HA) File 84-01, it was again determined that this treatment is experimental and not appropriate medical care. I note the same physician group provided the treatment in OASD(HA) File 84-01 and in the present appeal.

In previous decisions, 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 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 spans the period of 1980-81 and, therefore, was contemporaneous with the publication of recognized professional opinions and authoritative medical literature which opined the treatment to be experimental. Further, in OASD(HA) File 84-01, the record includes a May 1983 letter from the Director, Office of Health Technology Assessment, advising no new assessment of the procedures has been made and the conclusion reached in the 1981 assessment has not been revised. In this appeal, a 1979 opinion is included from the Colorado Foundation for Medical Care, a medical review organization, stating provocative intradermal food testing is controversial and not generally accepted.

As in OASD(HA) File 84-01, the attending physicians submitted publications, several authored by these physicians, dealing with food and chemical sensitivities and presenting treatment case histories. These publications, although useful in understanding the techniques employed, offer no indication of acceptance by authoritative medical bodies or the majority of allergists in the United States. The Hearing Officer also noted these publications do not provide evidence on the issue in this appeal of whether the care is the generally accepted norm for medical practice. At the hearing, Dr. Donald Sprague, a physician who practices with the attending physician in this appeal, testified three medical societies support provocative testing and neutralization therapy. The societies named were American Academy of Otolaryngologic Allergy, Pan American Allergy Society, and the Society for Clinical Ecology. No documentation was submitted for the record from two of these organizations; however, a statement from the American Academy of Otolaryngologic Allergy is in evidence. As this office noted in OASD(HA) File 84-01 regarding a similar statement, this statement does not reveal the basis of its opinion nor cite any studies which support the opinion. Further, this group is a surgical subspecialty organization and not the primary body of medical allergists. The Hearing Officer in the present appeal also concluded there is no evidence of approval of the procedures by the professional organization who represents the majority of allergy specialists. The Public Health Service assessment, cited above, acknowledged assistance in its research from the groups supporting the treatment in issue.

The Hearing Officer found the care was experimental and I adopt this finding. I find no evidence of record in this appeal to warrant reversal of the previous decisions on this issue.

As discussed above, the appeal file contains two claims and copies of explanations of benefits pertaining to provocative intradermal testing and neutralization therapy provided by Dr. Robert Stroud, an associate of Doctors Rea and Johnson, during

December 1979 through February 1980. The explanations of benefits indicate CHAMPUS cost-shared both provocative food and inhalant allergy neutralization therapy. As I have found food and inhalant neutralization therapy to be experimental, cost-sharing of these services and supplies was erroneous. Additionally, as noted above, the appeal file does not contain a claim from Brookhaven Medical Center for the inpatient care from August 3-14, 1981. As this inpatient care is related to experimental procedures (i.e., provocative intradermal testing), cost-sharing is excluded under DoD 6010.8-R, G.66. Therefore, if a claim was filed for this care and cost-shared, the cost-sharing was erroneous.

In summary, I find the intradermal food, inhalant, and chemical testing and neutralization therapy provided December 4, 1979, through February 14, 1980, and August 3 through October 13, 1981, to be experimental and not covered by CHAMPUS.

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 the 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 intradermal food, inhalant, and chemical testing and neutralization therapy are experimental (do not meet generally accepted standards of medical practice), I also must find the care does not qualify as appropriate medical care under the criteria of treatment in keeping with the generally acceptable norm for medical practice. 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 or appropriate care. The care is therefore excluded from CHAMPUS coverage on these additional bases.

The Hearing Officer also found the RAST to be inappropriate medical care in this appeal and I adopt this finding. Further, the Recommended Decision finds this care to be experimental. For the reasons explained below, I reject this finding. Medical review opinions by the Colorado Foundation for Medical Care recommended in 1979 that CHAMPUS cost-share RAST in three circumstances:

a. When direct skin testing is impossible because of the patient's extensive dermatitis or marked demographism;

b. When direct skin testing is impossible because of the patient's young age (less than 3 or 4 years of age);

c. When direct skin testing is inconclusive and a further diagnostic testing is desirable.

These guidelines for cost-sharing were developed because of the unreliable results produced by RAST. Medical literature of evidence in this appeal supports the primary reliance on direct skin testing and use of RAST as an additive, not as a replacement for skin testing. Testimony at the hearing by Dr. Donald Sprague appears to support the use of RAST following direct skin testing. From the record, it is clear the beneficiary does not meet either of the first two guidelines for cost-sharing of RAST. The beneficiary did not have dermatitis or dermographism and is not less than 3 or 4 years of age. As discussed above, the record reveals the beneficiary had extensive direct skin (scratch) testing in 1977 for pollens, molds, animal products, and foods and subsequently received allergy injections. Skin testing revealed allergies to ragweed and mountain cedar and phenol, for example, and some reaction was provoked to foods such as egg and tomato. The RAST performed at Brookhaven Medical Center by Doctors Rea and Johnson also tested grasses, weeds, trees, molds, and foods. Therefore, it appears the RAST essentially tested the same potential allergens as the previous scratch testing. Medical review by the Colorado Foundation for Medical Care opined the medical necessity of the RAST was not documented in the records and no particular problems were noted with the skin testing. Further, I find no evidence the previous skin testing was inconclusive. Therefore, I find the third circumstance

justifying cost-sharing of RAST has not been documented and CHAMPVA coverage must be denied. These findings also extend to the RAST performed by Dr. Stroud in December 1979.

SECONDARY ISSUES

Prior CHAMPVA Payment

At the hearing the beneficiary testified that the previous payment of the RAST and intradermal testing and neutralization therapy led her to believe she would be paid for the 1981 care. This is essentially an estoppel argument. This office has held in numerous decisions that the doctrine of estoppel does not apply to erroneous payments made by an agent (fiscal intermediary) of the Government. The care was not CHAMPVA covered in 1979-80 and cost-sharing was erroneous. Therefore, I find no merit in this argument.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPVA coverage of services and supplies for intradermal food, inhalant, and chemical provocative testing and neutralization therapy provided December 4, 1979, through February 19, 1980, and August 3 through October 13, 1981, as treatment for allergies as these procedures are experimental, not medically necessary, and not appropriate medical care. As the hospitalization at Brookhaven Medical Center from August 3 through 14, 1981, is related to this excluded care, I also find a CHAMPVA claim for cost-sharing of the institutional charges must also be denied. As this decision results in denial of coverage for services previously cost-shared, potentially including an institutional claim, the matter of recoupment of the erroneous payments is referred to the Director, OCHAMPUS, for appropriate action under the Federal Claims Collection Act. 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.