ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

APR 18 1983

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	OASD(HA) File 80-05
Sponsor:	)	
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 80-05 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the beneficiary as represented by her husband, an Officer in the United States Air Force. The appeal primarily involves the denial of CHAMPUS benefits for PUVA therapy (Photochemotherapy) rendered in the Republic of West Germany during the period May 17, 1977 through December 21, 1978 and continuing thereafter, for the treatment of psoriasis. The total amount in dispute is approximately DM 1.341,70. This amount exceeds $300.00 the jurisdictional amount required for a CHAMPUS hearing. The hearing file of record, the tapes of oral testimony and argument presented at the hearing, the Hearing Officer's Recommended Decision and the Memorandum of Concurrence from the Director, OCHAMPUS have been reviewed. It is the Hearing Officer's recommendation that OCHAMPUS denial of payment after June 1, 1977 be upheld. The Hearing Officer found PUVA to be an experimental modality and therefore excluded under DoD 6010.8-R, paragraph IV.G.16. The Hearing Officer further recommended that CHAMPUS payments for the treatment not be repaid by the beneficiary because CHAMPUS policy prior to June 1, 1977 was governed by Army Regulation (AR) 40-121 which the Hearing Officer found to be "at least ambigous and at best an authorizing document." The Director, OCHAMPUS, concurred in the Hearing Officer's Recommended Decision as to payments after June 1, 1977 but recommended that portions of the Hearing Officer's Recommended Decision dealing with care provided under AR 40-121 and the recoupment of erroneous CHAMPUS payments be rejected.

The Assistant Secretary of Defense (Health Affairs) after due consideration of the appeal record, concurs in the recommendation of the Hearing Officer to deny CHAMPUS payment and hereby adopts the recommendation of the Hearing Officer as modified, as the FINAL DECISION. The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny all

CHAMPUS cost-sharing for PUVA treatment of psoriasis. This decision is based on the finding that care provided was investigational and not generally accepted as being part of good medical practice.

FACTUAL BACKGROUND

The beneficiary underwent treatment for a condition diagnosed as psoriasis. Treatment was rendered in the Federal Republic of Germany at the , from May 16, 1977 through December 21, 1978. Three claims for this care were submitted on March 14, 1978, August 30, 1978 and October 10, 1978 to the CHAMPUS office in Europe (OCHAMPUSUER) with a statement that treatment was unavailable at United States military facilities. The first of these claims covered the time period of May 16, 1977 through December 31, 1977 and was described by the sponsor as light treatments and consultation, prescribed medicines and transportation for 30 visits to . On April 21, 1978 payment for this first claim, excluding transportation, was authorized. Subsequently, information was requested by OCHAMPUSEUR concerning the other claims. This information was supplied by the sponsor. OCHAMPUSEUR then submitted beneficiary's file for peer review, to a Medical Consultant, for an opinion as to the experimental nature of PUVA treatment. The consultant, a Department of the Army, physician concluded that:

> "PUVA therapy must be considered experimental and many questions about potential harm are unanswered. I have enclosed a statement from the Archives of Dermatology with which I concur."

The enclosed statement explained that a new treatment for psoriasis called "photochemotherapy" was investigational. This treatment involves taking psoralen tablets by mouth (8 - methoxypsoralen, also known as methoxsalen) followed by exposure to long wave ultraviolet light UVA,. The acronym "PUVA" is derived from the combination of psoralen plus UVA. Within the article was a warning to potential patients:

> "Please remember that the PUVA therapy is still investigational and is not by any means a cure."

Based on the peer review report, OCHAMPUSEUR notified the sponsor on December 5, 1978 that PUVA therapy was experimental and not a generally accepted valid medical treatment for psoriasis. Thus, the two pending claims were denied and a refund on the paid claim was requested. Upon request OCHAMPUSEUR reconsidered this

determination and reaffirmed its initial denial on January 5, 1979. The beneficiary appealed to OCHAMPUS. On April 26, 1979 OCHAMPUS affirmed the denials because PUVA treatments were considered experimental and thus excluded as Basic Program benefits.

The sponsor requested a hearing which was held March 27, 1980 before a Hearing Officer, in Los Angeles, California. The Hearing Officer has submitted his Recommended Decision. All prior administrative levels of appeal have been exhausted and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether PUVA therapy for the treatment of psoriasis is considered to be experimental and thus excluded under the CHAMPUS Basic Program during the period May 17, 1978 through December 21, 1978. The Department of Defense Appropriation Act for 1976, Public Law 94-212, prohibits the use of CHAMPUS funds to pay, among other matters,

> "... any other service or supply which is not medically necessary to diagnose and treat a mental or physical illness, injury, or bodily malfunction..."

All subsequent Department of Defense Appropriation Acts have contained similar restrictions.

The CHAMPUS regulation in effect at the time of enactment of Public Law 94-212, was a joint service regulation herein referred to as Army Regulation (AR) 40-121. That regulation authorized CHAMPUS coverage in paragraph 5-2, as follows:

> "... In general, any procedures and types of care, regardless of whether furnished on an inpatient or outpatient basis, which are generally accepted as being part of good medical practice..."

The regulation also defines necessary services in paragraph 1-3.c., as:

> "... Those services, consumable supplies, and supportive devices ordered by the provider of care as essential for the care of the patient or treatment of the patient's medical or surgical condition...."

Effective June 1, 1977, a new CHAMPUS regulation, DoD 6010.8-R, was implemented. In chapter II, B. 104., it defines medically necessary as:

> "... the level of services 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."

In Chapter II, B. 14., appropriate medical care is defined, in part, as:

> "... That medical care where 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 further explanation, DoD 6010.8-R lists in chapter IV, G. those services and supplies which are specifically excluded under the CHAMPUS Basic Program. Specifically cited are services which are:

> Not in Accordance with Accepted Standards: Experimental. Services and supplies not provided in accordance with the accepted professional medical standards; or related to essentially experimental procedures or treatment regimens."

The term "experimental" is defines in DoD 6010.8-R, chapter II, B.68, as:

> "Experimental. 'Experimental' means medical care that is essentially investigatory or an unproved procedure or treatment regimen (usually performed under controlled medical legal conditions) which does not meet the genreally accepted standards of usual professional medical practice in the general medical community .... Use of drugs and medicines not approved by the Food and Drug Administration for general use by humans (even though approved for testing on human beings) is also considerd to be experimental. However, if a drug or medicine is listed in the U.S. Pharmacopoeia and/or the National Formulary, and requires a prescription, it is not considered experimental even if it is under investigation by the U.S. Food and Drug Administration as to its effectiveness."

OCHAMPUS specifically addressed the applicability of these regulatory provisions to PUVA in an Interpretation issued on August 17, 1978. That interpretation states in part as follows:

> "Is photochemotherapy for psoriasis a covered service under CHAMPUS?
>
> . . . .

> Photochemotherapy considered Experimental. Photochemotherapy is a modality which employs the drug methoxsalen and a high intensity ultraviolet light of narrow wave length band in the treatment of psoriasis. Photochemotherapy is also known as PUVA.
>
> As the present time, this treatment is considered investigational. Aprroval by the FDA has not been granted. Therefore, no CHAMPUS benefits are payable for this treatment or related services." (CHAMPUS Interpretation 28-78-I).

The record in this case establishes the investigational nature of PUVA therapy. The record contains no evidence which directly contradicts the position adopted in the CHAMPUS Interpretation.

There is little question that PUVA is an effective therapy for severe psoriasis. However, substantial questions remain about its safety for long-term use. It is the concern over long-term effects which has until recently prevented FDA approval of this modality for general use. I recognize that an anomalous situaltion exists in the case of PUVA therapy because it is extensively used while it is still under investigation. This situation has arisen because both the drug and the light source component of this therapy are legally available and used for other purposes. This has resulted in PUVA therapy being available to patients both as a part of investigational studies and through the services of some physicians. As a result, in August 1978, the Food and Drug Administration took care to caution both doctors and patients that PUVA was still considered to be investigational for the treatment of psoriasis.

This case also involves the additional complicating fact that the beneficiary was treated in the Federal Republic of Germany where PUVA therapy has been as accepted modality for a number of years. However, the standard of care by which CHAMPUS benefits are determined is the generally accepted norm for medical practice in the United States (DoD 6010.8-R, paragraph II. B.14.) Thus, we must look to the standard of practice in the United States in resolving CHAMPUS appeals eventhough the care in question may have been provided in a foreign country with a different standard of practice.

While PUVA may have proven effective and safe in the short-term through the investigational studies which have been in progress since 1974, the Food and Drug Administration withheld approval of PUVA because of significant concerns over the long-term effects of this therapy. These concerns are compounded by the fact that PUVA does not cure psoriasis and as a result some patients will continue the therapy for many years. Chief among the potential long-term risks are ocular effects (cataracts) carcinogenesis, mutagenicity, effects on the immune system and actinic damage.

The beneficiary contended that she continued treatment with the understanding that it would be reimbursed by CHAMPUS after the initial claim was paid. This appears to raise an estoppel argument against CHAMPUS. However, even if estoppel were applicable in such cases, the derimental reliance required to support an estoppel has not been established in this case because the beneficiary concedes that she elected to continue treatment after she was notified that CHAMPUS would not cost-share PUVA.

The Department of Defense recognizes individual preference for certain services and the possible improvement in a patient's condition which may be perceived as a result of such services. However, I am constrained by statutory and regulatory authorities to authorize CHAMPUS benefits only for services which are generally accepted in the treatment of disease or illness and are documented by authoritative medical literature and recognized professional opinion. The evidence in the Hearing File of Record indicates that at the time the services were rendered (May 1977 through December 1978), PUVA therapy was an investigational procedure and was recognized as such by the Food and Drug Administration as well as competent peer reviewers.

The beneficiary asserted that PUVA has been accepted and in widespread use in Europe. I am convinced that the concerns over the long-term safety of PUVA therapy which have been prevented its earlier approval in the United States were substantial and genuine. Admittedly, medical regulatory authorites in some countries may be less conservative than the medical establishment in the United States; however, the cautious approach of the Food and Drug Administration generally is in the best interest of and will ultimately promote, the general public health. Regardless, under DoD 6010.8-R, chapter II, B.14., appropriate medical care under CHAMPUS is based on the "generally accepted norm for medical practice in the United States."

The Hearing Officer found PUVA therapy to be an experimental or investigatory treatment which is excluded as a benefit of the CHAMPUS Basic Program under DoD 6010.8-R. He also found, however, that the provisions of Army Regulation 40-121 were less specific and recommended that the beneficiary not be required to refund the erroneous CHAMPUS Payments for treatment received prior to June 1, 1977, the effective date of DoD 6010.8-R. I have considered this recommendation and find that the provisions of Army Regulation 40-121, particularly when read in conjunction with the Department of Defense Appropriations in effect at the time, are sufficiently clear to allow an exclusion of investigatory or experimental treatment regimens. Experimental treatments cannot, by definition, be considered to be generally accepted as being part of good medical practice. (AR 40-121, paragraph 5-2.) For this reason I reject the Hearing Officer's recommendation with respect to treatments provided prior to June 1, 1977.

Therefore, I find that the PUVA therapy treatments provided to the beneficiary from May of 1977 through December 1, 1978

including any related ancillary services, were a part of an experimental treatment regimen and are excluded from coverage in the CHAMPUS Basic Program under the authorities cited above. During the time period in question, PUVA therapy was not generally accepted as being part of good medical practice and therefore was not considered medically necessary and appropriate in the treatment of psoriasis.

During the pendancy of this appeal, the Food and Drug Administration approved PUVA therapy for general use, recommending the treatment only for severe, recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy. The findings of the Food and Drug Administration have been reviewed under the cited provision of the Regulation and a new policy issued concerning CHAMPUS Interpretation 28-78-I effective May 7, 1982. The new policy authorizes CHAMPUS coverage of PUVA treatment received on or after the date of approval by the Food and Drug Administration. The policy is not retroactive because the treatment was considered investigational prior to the date of FDA approval. The general acceptance, saftey and efficacy of a treatment at the time of care determines CHAMPUS coverage.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that the PUVA therapy provided to the beneficary from May of 1977 through December of 1978, was not a covered procedure under CHAMPUS. This determination is based on findings that, at the time of the care in question, PUVA therapy was not generally accepted as being part of good medical practice, the long-term safety of the procedure has not been established, and the treatment was investigational. The appeal of the beneficiary is therefore denied. The Director, OCHAMPUS shall review the claims file and take appropriate action under the Federal Claims Collection Act in regards to payment of any CHAMPUS claims for PUVA therapy. Issuance of this FINAL DECISION completes the administrative appeals process as provided 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