ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE OF THE ASSISTANT
SECRETARY OF DEFENSE (HEALTH AFFAIRS)
UNITED STATES DEPARTMENT OF DEFENSE

MAR 29 1983

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File No 82-6
	)	
	)	FINAL DECISION
SSN:	)	
	)	
	)	

This is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) File No. 82-6. It is issued pursuant to the authority of 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party in this case is the beneficiary, as represented by her husband, a retired officer of the United States Army. The appeal involves claims for psoralen-ultraviolet (PUVA) therapy for psoriasis in calendar years 1978 and 1979. The amount in dispute is approximately $458.00

The Hearing File of Record, the recording of oral testimony 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 CHAMPUS First Level Review Determination be upheld. That determination denied CHAMPUS benefits for PUVA therapy administered to the beneficiary in 1978 and 1979. The Hearing Officer's recommendation is based upon a finding that PUVA therapy is experimental and not within the CHAMPUS Basic Program. The Director, OCHAMPUS concurs in this recommended decision and recommends that it be adopted as the FINAL DECISION. The Acting Assistant Secretary of Defense (Health Affairs) after due consideration of the appeal record accepts the Hearing Officer's Recommended Decision.

The FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) therefore is to deny CHAMPUS claims for PUVA therapy services provided to the beneficiary in 1978 and 1979 as having involved an investigational therapy or treatment regimen which is excluded from CHAMPUS coverage. This FINAL DECISION is based upon the appeal record as stated above.

FACTUAL BACKGROUND

The beneficiary was first treated for acute psoriasis in 1960. The record indicates that her treatment, both in military treatment facilities and from civilian facilities, followed prescribed treatments for psoriasis to include injections, prescription ointment, pills, and occlusive dressing. When these treatments failed to show adequate results, the patient's dermatologist prescribed ultraviolent light treatments on an outpatient basis. After a series of treatments without results, the patient was admitted as an inpatient in February of 1976 to receive "tarbath and ultraviolet light treatments twice a day." These treatments also proved ineffective and the beneficiary joined an investigational photochemotherapy program setup under the Investigational New Drug Studies of the Food and Drug Administration at Massachusetts General Hospital in August of 1976.

The beneficiary reported to have made slow but some progress under the new program before suffering a sudden reversal. In February of 1977 she was admitted to for inpatient treatments. Following intensive inpatient treatments, she continued to receive weekly outpatient treatments until November of 1978.

In November of 1978, the beneficiary transferred to a program under the directions of at . program also was a part of the Investigational New Drugs Studies conducted under the auspices of the Food and Drug Administration. During the period November 27, 1978 through May 8, 1979, the patient received PUVA therapy at .

PUVA therapy, the treatment modality involved in this case, is a regimen in which the drug methoxsalen is administered to the patient prior to exposure to high intensity ultraviolet light in a light cabinet. This treatment is used primarily in the treatment of psoriasis. "PUVA" is an acronym for "psoralen-ultraviolet," indicating that the light used consists of the long waves of the ultraviolet spectrum. The drug used in conjunction with the ultraviolet light, methoxsalen, is also known as psoralen; it is approved for use in the treatment of idiopathic vitiligo.

In October 1979, a CHAMPUS claim for pharmacy charges, clinic visits, and photochemotherapy treatments related to PUVA therapy was submitted to the CHAMPUS Fiscal Intermediary for Rhode Island, Blue Cross of Rhode Island. This claim was processed and denied by the fiscal intermediary on October 22, 1979. The basis for this denial was that PUVA was determined to be experimental and not a CHAMPUS Basic Program benefit. The

claimed charges were in the amount of $570.00 with another insurance payment of $356.00, leaving a maximum CHAMPUS liability of $214.00. The denial of this claim was affirmed upon informal review and reconsideration by the fiscal intermediary.

The Hearing File of Record contains documentation of two claims for PUVA treatment at from October 4, 1978 through December 6, 1978, being filed with the fiscal intermediary for the State of Massachusetts, Blue Shield of California. The fiscal intermediary allowed the claimed $110 charge for services received in October of 1978 and paid $45 after taking a $65 deductible and patient cost-share. The fiscal intermediary denied the $110 claim for PUVA therapy from November 8, 1978 through December 6, 1978, and a claim for an eye examination specifically related to PUVA therapy. Therefore, the total amount in dispute for claims contained in the Hearing File of Record is approximately $458.00.

The claim denied by Blue Cross of Rhode Island was appealed by the beneficiary. The beneficiary's representative, the sponsor, has stated that a separate appeal of the claims denied by Blue Shield of California was not deemed necessary. The sponsor assumes that a decision on the appealed claim will apply to all similar claims.

Following appeal to OCHAMPUS, an OCHAMPUS First Level Review Decision was issued on September 22, 1980 denying coverage of the PUVA therapy. The sponsor, acting on behalf of the beneficiary, requested a hearing which was held on June 3, 1981, in The Hearing Officer has issued his Recommended Decision. All levels of administrative appeal have been completed and issuance of a FINAL DECISION is proper. Claims for all PUVA related therapy, whether paid or denied by CHAMPUS fiscal intermediaries are in dispute.

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 August 1976 through May 1979. 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 defined 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 generally 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 considered 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.
>
> At the present time, this treatment is considered investigational. Approval 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 is replete with evidence which 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 situation 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.

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 record in this case establishes that the therapy programs in which the beneficiary took part were a part of Investigational New Drug Studies conducted under the auspices of the Food and Drug Administration. In fact, the beneficiary's attending physician in
is listed as one of the compilers of a report on the status of oral PUVA therapy for psoriasis. That report, which appears in the August 1979 issue of the Journal of the American Academy of Dermatology concludes:

> "Currently, PUVA is an <u>investigational treatment</u> that should be carried out only under the auspice of FDA approval. Individual physicians should obtain an IND number from the FDA before establishing a PUVA treatment program. Prior to beginning treatment, each patient should be given full information on the risks and benefits of PUVA treatment. An informed consent should be obtained. (emphasis added)"

In this appeal, the Department of Defense has been urged to adopt an exception to the CHAMPUS rule on investigative or experimental treatment modalities in the case of PUVA therapy.

This exception is urged because of the proven efficacy and short-term safety of PUVA and because PUVA is stated to be the only effective alternative for thousands of patients who suffer from sever, debilitating psoriasis and for whom other treatment modalities are substantially less effective. CHAMPUS is also urged to relax the rule in the case of PUVA because the treatment is allowed by a number of other third-party payors. I am convinced, however, that in adopting a conservative approach and in taking a firm stand on experimental or investigatory treatments or procedures, CHAMPUS is acting in the best interests of the program and its beneficiaries. Experimental treatment regimens are by definition unproven in one or more aspects. I do not believe it appropriate for the Department of Defense through the payment of CHAMPUS claims to lend tacit encouragement to its beneficiaries to seek or accept unproven treatments which may involve unnecessary or unwarranted complications and risks. I believe the wisdom of this approach is illustrated by the recent experience of the Food and Drug Administration in approving two drugs for the treatment of psoriasis. The FDA reports this experience as follows:

> "Therapies for severe psoriasis frequently involve difficult decisions in weighing benefits and risks. This is because of the debilitating nature of the disease and the significant hazards several treatment methods have posed. Sometimes only time and wide use have given the needed answers to benefit risk dilemmas about psoriasis drugs.
>
> Two recent examples involve approvals for methotrexate and azarabine (Trazure). FDA approved both of these drugs for psoriasis with strict limits on use and target populations. New information from expanded use following approval showed unexpected side effects that led to removal of azarabine from the market. But general marketing of methotrexate has not uncovered unexpected problems, and it remains a useful therapy for psoriasis with its restrictive labeling." (FDA Drug Bulletin, Volume 8, No. 4 (August - September 1978)).

At the time the care in this case was provided the risk - benefit analysis weighed against the approval of PUVA for general use. We do not believe CHAMPUS should encourage more widespread use by approving it retroactively as an exception to established Department of Defense policy.

The Department of Defense recognizes individual perference 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 (August 1976 through May 1979), PUVA therapy was an investigational procedure and was recognized as such by the Food and Drug Administration as well as the patient's attending physician,

The beneficiary's representative asserted that PUVA has been accepted and in widespread use in Europe and noted criticism of the Food and Drug Administration that it is too slow to approve proven therapies in this country. I am convinced that the concerns over the long-term safety of PUVA therapy were substantial and genuine. Admittedly, medical regulatory authorities 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. Based upon the foregoing analysis of this case, I concur with and hereby adopt the Hearing Officer's recommendation on this issue. Therefore, I find that the PUVA therapy treatments provided to the beneficiary from August of 1976 through May 1979, including 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

The Hearing File of Record contains documents relating to three claims for PUVA therapy from October of 1978 through May of 1979. Although the beneficiary received PUVA therapy commencing in August of 1976, the Record is imcomplete regarding CHAMPUS claims prior to October of 1978. In addition, one of three claims, appearing in the Record was erroneously paid by the CHAMPUS fiscal intermediary. In view of this, the Director, OCHAMPUS is required to review the claims file to determine if additional PUVA therapy claims were received and properly

processed. Appropriate action under the Federal Claims Collection Act shall be taken in regards to payments for any claims for PUVA therapy.

SECONDARY ISSUES

Discretionary Authority. The beneficiary's representative urged that DoD 6010.8-R, chapter 1, o., be exercised in this case to allow payment of the beneficiary's PUVA therapy claims. That provision grants to the Director, OCHAMPUS, discretionary authority to waive specific provisions of the Regulation as follows:

> When it is determined to be in the best interest of the CHAMPUS Program, the Director, OCHAMPUS (or a designee) is granted discretionary authority to waive a requirement(s) of this Regulation, except that any requirement specifically set forth in chapter 55, Title 10, United States Code, or otherwise imposed by law, may not be waived. It is the intent that such discretionary authority be used only under very unusual and limited circumstances and not to deny any individual any right, benefit or privilege provided to him or her by statute of this Regulation. Any such exception granted by the Director, OCHAMPUS (or a designee) shall apply only to the individual circumstance and/or case involved and will in no way be construed to be precedent setting.

To preclude the ad hoc change of regulatory provisions in a manner which would circumvent the rule making procedures of the Administrative Procedures Act, guidelines have been established for the exercise of the Director's discretionary authority. These require that discretionary authority be exercised only when the waiver of a regulation provision would affect an individual case rather than a class of cases; and, the individual case should be so unique that application of the regulation provision would be contrary to the intent of the law or regulation, or, the individual case is so unique as not to have been adequately considered during the rule making process.

The Director, OCHAMPUS has advised that this case does not fall within the guidelines. This case is not unique and cannot be distinguished from the numerous other cases in which CHAMPUS beneficiaries have received PUVA therapy. If a waiver were granted in this case, waivers would be appropriate in other similar cases to avoid an apperance of arbitrary or capricious action. I concur with the Director's determination.

Periodic Review of the Regulation. The beneficiary's representative also urged that under the provisions of DoD 6010.8-R, chapter I., G., which requires the establishment of procedures for the receipt and processing of recommendations for changes to the Regulation from interested parties, consideration be given to amending the Regulation to allow for the payment of claims for properly supervised PUVA therapy. OCHAMPUS has monitored and reviewed the progress in the investigation of PUVA therapy for several years. PUVA holds promise as a potential treatment modality. However, I remain convinced that, at the time of the PUVA therpay in question, the concerns over its long-term safety were genuine, as expressed by the Food and Drug Administration and numerous investigators who have reported their findings.

During the pendancy of this appeal, the Food and Drug Administration approved PUVA therapy recommending the treatment only for severe, recalitrant, 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 will authorize 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, safety and efficacy of a treatment at the time of care determines CHAMPUS coverage.

Cost Effectiveness of PUVA. It was argued that PUVA, which is most frequently accomplished on an outpatient basis, represents a much more cost-effective means of treating psoriasis than many traditional therapies which require quite lengthly periods of hospitalization. It was also suggested that for this reason a number of private health insurance carriers had determined to cover this therapy. We are urged to approve PUVA therapy as a CHAMPUS benefit to likewise take advantage of the cost-saving which this therapy may provide. While the Department of Defense is fully committed to cost-containment to preserve the public monies entrusted to it, economic considerations alone are not determinative of the questions presented by CHAMPUS appeals. Questions regarding the general acceptance and efficacy of procedures are of primary concern in these cases.

In a similar vein, it was urged that questions of risk-benefit analysis are best left to the physician and his or her patient. While this is undoubtedly true where traditional therapies are concerned, investigational treatment regimens often represent serious threats to the public health which should not be encouraged by the infusion of public monies which have not been specifically designated for research or grant purposes. While a

patient may seek out treatment which is a personal choice, CHAMPUS coverage cannot be authorized unless the general acceptance and efficacy at the time of care is established.

Discrimination against Psoriasis Patients. The beneficiary's representative asserted that the denial of PUVA therapy as a CHAMPUS benefit is unjust and discriminates against psoriatics who are thereby denied an effective and less costly treatment. It is urged that this is true especially in light of the fact that the Government spends money to support experimental cancer research and subsidize the tobacco industry. This argument is rejected because it fails to recognize the fundamental differences between the Government agencies and programs involved. CHAMPUS is a statutory health benefits program which is intended to provide medically necessary services to the dependents of active duty military personnel, and retired military personnel and their dependents. CHAMPUS does not engage in or directly support original medical research. Experimental cancer treatments are not allowed as CHAMPUS benefits. Further, while certain Federal programs and policies may appear contradictory, it must be remembered that they are frequently undertaken by virtually independent Federal agencies in the face of overriding economic or policy considerations.

Hearing Record and Exhibit Index. My review of documents received subsequent to this hearing reveals that certain corrective action is required with respect to the Hearing Record and the Exhibit Index. In his Recommended Decision, the Hearing Officer included an index of hearing exhibits. That index, however, did not coincide exactly with the index prepared by OCHAMPUS. Specifically in preparing the Position Statement OCHAMPUS submitted a compilation of PUVA related articles. These articles were originally listed as Exhibit 28 and the Position Statement was shown as Exhibit 29. However, the Hearing Officer's index lists the OCHAMPUS Position Statement as Exhibit 28 and does not separately identify the compilation of articles submitted by OCHAMPUS. Exhibit 29 is shown as the Hearing Officer's Opening Statement in his listing. Therefore, to better reflect the Record's exhibit continuity, I have caused to be renumbered these three exhibits as follows:

Exhibit 28:	OCHAMPUS Interpretation 28-78-I and a compilation of PUVA therapy related literature (40 pages)
Exhibit 28A:	OCHAMPUS Position Statement
Exhibit 29:	Hearing Officer's Opening Statement

In making this correction, no documents have been added to or deleted from the Record, the Exhibit Index has simply been clarified.

One additional problem with the Hearing Record arose subsequent to the hearing. The Hearing Officer returned his Recommended Decision and his copy of the Hearing Record in separate packages. The Recommended Decision was duly received at OCHAMPUS; the Hearing Record was not. A search by the Hearing Officer, OCHAMPUS and the United States Postal Service has failed to locate this copy of the record. Because this copy is the one upon which the Hearing Officer's Recommended Decision was based, OCHAMPUS felt it necessary to provide the Hearing Officer with a duplicate Hearing Record and obtain the Hearing Officer's certification of that record. This has been accomplished and I concur with that action. Documents relating to this matter have been added to the Record as Exhibit 16 by OCHAMPUS.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that the PUVA therapy provided to the beneficiary from August of 1976 through May of 1979, 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 had 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