ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFIARS)

UNITED STATES DEPARTMENT OF DEFENSE

MAR 29 1983

Appeal of	)	
	)	OASD(HA) File 83-04
Sponsor:	)	
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) File 83-04. It is issued pursuant to the authority of 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, who was represented by her spouse, a retired E7 from the United States Navy. The appeal involves claims for psoralen-ultraviolet (PUVA) therapy for psoriasis from September 16, 1978 to March 13, 1979. The amount in dispute involves $391.13, which was initially paid by the fiscal intermediary before the fiscal intermediary determined the treatment was experimental.

The Hearing File of Record, the recorded 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 denying cost-sharing because the treatment was considered experimental be reversed. The Hearing Officer concluded OCHAMPUS was correct in its finding that PUVA therapy was an experimental/investigatory treatment. The Hearing Officer also concluded that PUVA therapy was appropriate medical care and was medically necessary even though experimental. The Director, OCHAMPUS did not concur in this Recommended Decision and recommends that the CHAMPUS denial of coverage be upheld.

The Acting Assistant Secretary of Defense (Health Affairs) after due consideration of the appeal record declines to accept the Hearing Officer's Recommended Decision for the reason that the Hearing Officer's Recommended Decision is not supported by law and regulation.

The FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) therefore is to deny CHAMPUS cost-sharing for PUVA therapy for psoriasis provided to the beneficiary from

September 16, 1978 through March 13, 1979. The decision is based on the finding that the treatment was considered experimental or investigational at the time it was given.

FACTUAL BACKGROUND

Initially, the CHAMPUS fiscal intermediary for Utah cost-shared claims for PUVA therapy submitted by the beneficiary. The sponsor questioned the use of different procedure codes by the fiscal intermediary and the differing amounts allowed, since each office visit and treatment was identical. In reviewing the matter, the fiscal intermediary determined the treatment was experimental and therefore not a covered CHAMPUS benefit and sought reimbursement for the claims previously paid.

PUVA therapy, the treament modality involved in this appeal, is a regimen in which the drug methoxsalen, which is the specific psoralen compound used, is administered to the patient prior to exposure to high intensity ultraviolet light. 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.

By letter dated April 17, 1979, the fiscal intermediary advised the sponsor that, "At the present time this treatment [PUVA] is considered investigational. Approval by the Food and Drug Administration has not been granted. Therefore, no CHAMPUS benefits are payable for this treatment or related services." The letter also requested repayment of $337.13. No appeal rights were offered to the sponsor. The beneficiary was later advised that the the correct refund total should have been $391.13. When the fiscal intermediary made this recalculation $173.71 had been reimbursed by the sponsor leaving a balance of $217.42. Recoupment action was suspended pending the outcome of this appeal.

As a result of inquiries initiated by the sponsor, the Principal Deputy Assistant Secretary of Defense (Health Affairs) reviewed the matter and advised the beneficiary of her appeal rights. He also advised:

> "The treatment rendered in your case was photochemotherapy (also known as PUVA), which employs the drug methoxsalen and a high intensity ultraviolet light. Use of ultraviolet light without the drug methoxsalen is an accepted treatment for generalized intractable psoriasis. And while tropical medications, such as coal tar creams, are often applied prior to the ultraviolet light exposure, use of the drug methoxsalen has not been approved by the U.S. Food and Drug Administration. Thus this therapy (PUVA) is considered an investigational treatment regimen."

OCHAMPUS also advised the fiscal intermediary that:

> "The exclusion of experimental procedures is a matter of Regulation and is not appealable. However, the Program's classification of a specific procedure as experimental is appealable. As a rule, all Program interpretations are appealable."

As a result of being advised of her appeal rights, the beneficiary, in a letter dated November 8, 1979 to OCHAMPUS, requested a reconsideration of the denial. OCHAMPUS by letter dated June 12, 1980 issued its First Level Appeal denying CHAMPUS coverage for PUVA treatment. The beneficiary was advised she could appeal the determination that PUVA therapy was an experimental procedure or treatment regimen and have a hearing on this issue.

The beneficiary requested a hearing and appointed her husband to be her representative. The request included the statement that:

> "Thank you for your letter of June 12, 1980. In my original letter I was not questioning whether or not that PUVA treatment was or wasn't 'an investigational treatment regimen.' What I was questioning was that it took your Seattle office seven months to realize that they were making a mistake.
>
> I am enclosing a magazine article relative to the efficacy of PUVA which will hopefully enlighten you. I don't know what field of medicine you specialize in but if you are in to Dermatology you can appreciate what effect PUVA has had on people who have suffered from psoriasis and can finally get relief."

The medical article enclosed with the letter is entitled "Photochemotherapy for Psoriasis." The article summarizes the results of a clinical cooperative study of PUVA and states:

> "This study confirms the results of the first cooperative study reported in 1977. These results are very similar to those of the original cooperative study of photochemotherapy of psoriasis.
>
> The effectiveness and short-term safety of photochemotherapy for psoriasis has now been confirmed by two cooperative studies in a large number of psoriatic patients. Strict adherence to a rational treatment approach and weighing the risks and benefits of PUVA are essential. Close long-term follow-up

> observations are essential for determining the safety of this modality.

The record also includes a 1977 statement by the Psoriasis and Photobiology Task Forces of the American Academy of Dermatology concerning PUVA therapy for psoriasis. The statement comments that, "Because of initial success of PUVA therapy, its use may become widespread before completion of investigative evaluation." After noting five unanswered considerations in the use of the treatment, the task force stated that, "Therefore, this form of photochemotherapy cannot be recommended until the above questions have been evaluated by controlled analytical procedures."

In a 1979 article in the American Academy of Dermatology entitled "Current Status of Oral PUVA Therapy for Psoriasis" the following comments are made:

> "... the compilers of this report cannot at this time endorse PUVA therapy as an acceptable safe treatment except for Investigational New Drug (IND) use. Short-term safety and effectiveness of PUVA therapy for psoriasis have been established. However, PUVA needs to be investigated further because of long-term concerns....
>
> Since the first report of the efficacy of PUVA in 1974, thousands of psoriatics have been treated. Efficacy has been established and with careful dosimetry short-term risks are minimal.
>
> Currently, PUVA is an investigational treatment that should be carried out only under the auspices of FDA approval."

The article includes a sample "patient consent and release form" that states, "This procedure is experimental because it has not yet been approved by the U.S. Federal [sic] Food and Drug Administration."

Another medical article in the record entitled "Photochemotherapy of Psoriasis (PUVA) Without Specialized Equipment" states:

> "One of the most impressive therapeutic advances in the history of dermatology has been the development of PUVA photochemotherapy for psoriasis."
>
> "...PUVA therapy presents certain problems of its own and its long-term consequences are still unknown."

The Article concludes:

> "Clearly, PUVA is not for every patient with psoriasis. The potential long-term side effects are still unknown...."

The authors of the medical article entitled "Essentials of PUVA Therapy, Guidelines for Photochemotherapy" describe the treatment as follows:

> "Photochemotherapy (PUVA) has emerged as one of the more promissing advances in dermatologic therapy in recent years. The evidence of its effectiveness in treating psoriasis is impressive.... Despite the lack of FDA approval of this modality, its usage is spreading worldwide."

This article also includes a sample "patient consent and release form," which states:

> "This procedure is experimental because it has not yet been approved by the US Federal [sic] Food and Drug Administration."

The article concludes:

> "PUVA therapy is a promising new entity for treatment of a number of dermatologic diseases including psoriasis...."

In a October 6, 1980 letter, the treating physician states:

> "The use of the PUVA box has not been approved by the FDA.
>
> The reason for FDA's failure to approve the apparatus is not that it is ineffective, there is no question about that, it does work. It has not been approved because there is a question about skin cancer caused by strong forms of sunlight. There will undoubtedly be cancers resolving from the treatment. The apparatus will continue to be used, not only by private practice, but by large University Centers."

In a November 21, 1980 letter to the Hearing Officer, OCHAMPUS stated its position that:

> "... OCHAMPUS does not challenge the effectiveness of PUVA therapy. However, it does present a treatment modality for which there is substantial concern about its long-term safety. For this reason, those who

> have reported on its use have almost universally endorsed its classification as an investigational modality at the present time.
>
> CHAMPUS also does not assert that Psoralen, when used for approved purposes, would not be payable as a CHAMPUS benefit. Likewise, the use of ultraviolet light alone in the treatment of psoriasis is an acceptable treatment. However, it is the use of the drug in combination with high intensity ultraviolet light (PUVA) which is of concern in this appeal."

The hearing was held on September 23, 1980 in Pocatello, Idaho before CHAMPUS Hearing Officer, . The beneficiary did not attend the hearing but was represented by her sponsor. The Hearing Officer has issued his Recommended Decision and issuance of a FINAL DECISION is proper.

Primary Issue and Finding of Fact

The primary issue in this appeal is whether the outpatient care from September 16, 1978 through March 13, 1979 for the treatment of psoriasis with PUVA was an experimental or investigational procedure.

The Department of Defense Appropriation Act, 1976, Public Law 94-212, prohibited the use of CHAMPUS funds for, "...any service or supply which is not medically or psychologically 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 by 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).

To determine whether PUVA at the time of treatment was a covered benefit, it is necessary to determine whether the treatment was "in keeping with the generally acceptable norm for medical practice in the United States" and whether it was an experimental treatment.

The Hearing Officer concluded that, "PUVA treatments were provdided to [the beneficiary] in accordance with accepted professional medical standards; however, PUVA treatment at this time remains essentially experimental." Additionally, he found "The PUVA therapy administered by , has been in keeping with the generally acceptable norm for medical practioners in the field of Dermatology in the United States, although the services performed would still be considered investigational."

In his findings the Hearing Officer reasoned that even though the Regulation excludes experimental procedures that this exclusion "does not stand on its own; it need not and should not be given effect where the services at issue are provided in accordance accepted professional medical standards."

It is not possible to reconcile the Hearing Officer's conclusion that the care was considered experimental and still be provided in accordance with accepted professional medical standards. The Hearing Officer may have confused the concepts of a qualified provider competently providing unconventional treatment with a qualified provider incompetently providing conventional treatment. Generally, research and experimental studies, particularly those at university medical centers, are performed competently. This does not mean that experimental studies and treatment are "within the generally acceptable norm for medical

practice in the United States." To conclude otherwise would eliminate the exclusion for experimental treatment.

Absent from the record is any medical evidence that PUVA was considered a conventional treatment in the September 1978 to March 1979 period. All the medical articles submitted by the beneficiary in support of her appeal and the articles submitted by OCHAMPUS refer to PUVA as being experimental or as being considered investigational, or its long-term consequences are unknown, or as a promising new entity, or are silent on whether it was considered conventional treatment.

For example, the task force on psoriasis and photobiology of the American Academy of Dermatology stated, "this form of photochemotherapy [PUVA] can not be recommended...." The article entitled "Current Status of Oral PUVA Therapy for Psoriasis" states that, "... the compliers of this report cannot at this time endorse PUVA therapy as an acceptable safe treatment except for Investigational New Drug (IND) use." The authors conclude that, "currently, PUVA is an investigational treatment that should be carried out only under the auspices of FDA approval." Two of the articles included a "patient consent and release form" that stated the procedure was experimental.

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 was extensively used while it was 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. To determine PUVA's long-term safety, the FDA has monitored human studies since 1974.

The Department of Defense recognizes individual preference for certain services and 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 literture and recognized professional opinion.

The record in this appeal has been extensively reviewed and it is determined that the record supports the conclusion that the PUVA treatment, at the time it was rendered, was considered experimental.

A point that can be difficult for beneficiaries to accept, is that a treatment may be considered experimental and still be widely used within the medical profession. Indeed, it can appear that the treatment is on the verge of being accepted as conventional practice. 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 conerning 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.

The PUVA treatment received by the beneficiary was found by the Hearing Officer to be experimental. The record in this appeal supports a determination that it was experimental. Therefore, PUVA treatment was not a CHAMPUS benefit at the time in dispute. Later acceptance by the United States Food and Drug Administration does not change this result.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that PUVA therapy provided to the beneficiary from September 16, 1978 through March 13, 1979 was experimental and therefore not in keeping with the generally acceptable norm for medical practice in the United States at the time of treatment. Since the CHAMPUS Regulation excludes experimental treatment, the claims on the dates in issue and the appeal of the beneficiary are denied. Issuance of this FINAL DECISION completes administrative appeals process 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