ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

October 30, 1984

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 84-18
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-18 issued pursuant to the authority of 10 U.S.C. 1071-1092 and DoD 6010.8-R, chapter X. The appealing party is the beneficiary, the spouse of an active duty officer of the United States Air Force. The appeal involves the denial of CHAMPUS cost-sharing for inpatient hospitalization from May 1 through May 6, 1983, for leukopheresis treatments for multiple sclerosis. The amount in dispute for these services/supplies is $3,712.04. The record in this appeal also documents CHAMPUS claims have been submitted and cost-shared for leukopheresis treatments from July 28, 1980, through June 13, 1983, in the approximate amount of $40,000.00. As these claims involve leukopheresis as treatment for multiple sclerosis, the claims are also in issue in this appeal. The amount in dispute including institutional and professional claims for leukopheresis treatments is approximately $40,000.00 in billed charges.

The hearing file of record, the tapes 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 inpatient hospitalization provided May 1 through May 6, 1983, be cost-shared by CHAMPUS. The Hearing Officer's recommendation is based on his finding leukopheresis as treatment for multiple sclerosis became a generally accepted medical practice prior to May 1983 and was not an experimental/ investigational procedure in May 1983. The Hearing Officer concurred in the OCHAMPUS Formal Review Decision to the extent that leukopheresis was not a covered treatment from July 1980 to May 1983.

The Director, OCHAMPUS, nonconcurs with the Hearing Officer's Recommended Decision to cost-share the inpatient leukopheresis treatments provided May 1 through May 6, 1983, and recommends denial of cost-sharing of that care and the inpatient care for leukopheresis treatment provided July 28, 1980, through June 13, 1983. The Director, OCHAMPUS, bases his recommendation

on the absence of documentation in the appeal file that any nationally recognized professional organization has endorsed leukopheresis as a generally accepted medical practice in the treatment of multiple sclerosis, and the treatment should presently be classified as experimental/investigational.

Under Department of Defense Regulation 6010.8-R, chapter X, the Assistant Secretary of Defense (Health Affairs) may adopt or reject the Hearing Officer's Recommended Decision. In the case of rejection, a FINAL DECISION may be issued by the Assistant Secretary of Defense (Health Affairs) based on the appeal record. The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, accepts the recommendation of the Director, OCHAMPUS, and rejects the Hearing Officer's Recommended Decision. The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS cost-sharing of the inpatient care for leukopheresis treatments for multiple sclerosis provided July 28, 1980, through June 13, 1983, on the basis the care was experimental/investigational, provided above the appropriate level of care, and not medically necessary/appropriate medical care.

FACTUAL BACKGROUND

In August 1978, the beneficiary first exhibited symptoms of vertigo and vomiting which was diagnosed as multiple sclerosis in May 1980. The course of her disease has been characterized by severe relapses followed by brief periods of return to a functional level. She has been periodically confined to a wheelchair during acute episodes with symptoms of ataxia, vertigo, leg weakness, falling, diplopia, and incoordination. She has been treated with Imaron, Prednisone, ACTH, and leukopheresis. The multiple sclerosis was defined as moderately advanced in August 1983. In March 1982, the beneficiary was placed in the CHAMPUS Program for the Handicapped as a seriously handicapped individual, and an AMIGO motorized wheelchair was authorized by OCHAMPUS. The beneficiary became eligible for Medicare on August 1, 1983.

The beneficiary first received leukopheresis treatment from July 28, 1980, through August 9, 1980, at the El Dorado Medical Center, Tucson, Arizona. From July 28, 1980, through June 13, 1983, the appeal file reflects the beneficiary received leukopheresis treatments on an inpatient basis on 16 occasions at the El Dorado Medical Center, Tucson, Arizona; the Medical University Hospital, Myrtle Beach, South Carolina; and the Medical University Hospital, Charleston, South Carolina. CHAMPUS claims in the approximate billed amount of $2,700.00 were also submitted for physicians' services in connection to the leukopheresis treatments according to the appeal file. All institutional claims for the inpatient leukopheresis treatment were cost-shared by CHAMPUS Fiscal Intermediaries except for the May 1 through May 6, 1983, inpatient stay. The CHAMPUS Fiscal

Intermediary for Arizona, Blue Cross of Washington/Alaska, denied the May 1 through May 6, 1983, care as experimental/investigational treatment.

On September 29, 1982, the sponsor requested preauthorization of 100% coverage of outpatient lymphocytopheresis (leukopheresis) from the OCHAMPUS Benefit Authorization Branch. The sponsor stated he and the beneficiary were financially unable to pay the 20% outpatient CHAMPUS cost-share. By letter dated November 12, 1982, the OCHAMPUS Benefit Authorization Branch advised the sponsor that lymphocytopheresis could not be cost-shared by CHAMPUS as it was still considered investigational.

The sponsor subsequently requested authorization of the leukopheresis treatments for his spouse under the CHAMPUS Program for the Handicapped. In July 1983 this request was denied by OCHAMPUS as the treatment was considered experimental/investigational.

The beneficiary appealed both the fiscal intermediary denial of cost-sharing of the May 1-6, 1983, inpatient care and the denial of request for preauthorization of outpatient care. The OCHAMPUS Formal Review Decision affirmed the fiscal intermediary's denial finding leukopheresis to be an investigational procedure and excluded from CHAMPUS coverage. The OCHAMPUS decision also directed the fiscal intermediary to recoup all previous payments for leukopheresis. The beneficiary appealed and requested a hearing. The hearing was held on April 6, 1984, at Tucson, Arizona, before Sherman R. Bendalin, OCHAMPUS Hearing Officer. The Hearing Officer has submitted 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 leukopheresis treatments are medically necessary and appropriate medical care for treatment of multiple sclerosis or related to essentially experimental/investigational treatment regimens and (2) whether the inpatient care was above the appropriate level of care for leukopheresis treatments.

Medically Necessary/Appropriate Medical Care Experimental/Investigational Treatment

Under the Department of Defense Regulation governing CHAMPUS, DoD 6010.8-R, CHAMPUS will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury. (DoD 6010.8-R, chapter IV, A.1.) Medically necessary is defined in DoD 6010.8-R, as:

> "the level of services and supplies (that is, frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury, including maternity care and

> well-baby care. Medically necessary includes concept of appropriate medical care." (DoD 6010.8-R, chapter II, B.104.)

Appropriate medical care, included in the definition of medically necessary, 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 accepted 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." (DoD 6010.8-R, chapter II, B.14.)

The concept of medically necessary/appropriate medical care is continued in the exclusion under CHAMPUS of services and supplies related to essentially experimental procedures or treatment regimens. (DoD 6010.8-R, chapter IV, G.15.) Experimental means in part:

> ". . . (M)edical 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. . . ." (DoD 6010.8-R, chapter II, B.68.)

In summary, as applicable to the facts in this appeal, to constitute CHAMPUS covered services leukopheresis treatments must be an adequate, proven treatment of multiple sclerosis and in keeping with the generally accepted standards of medical practice in the United States. The Hearing Officer found leukopheresis treatments met these requirements as of May 1983 but was an experimental/investigational treatment prior to that date. I partially disagree. From my review of the evidence presented, I cannot conclude leukopheresis treatments were generally accepted medical practice and a proven procedure either prior or

subsequent to May 1983. Based on the record, I find leukopheresis is not medically necessary/appropriate medical care and constitutes an experimental/investigational treatment of multiple sclerosis.

The Hearing Officer based his finding that leukopheresis became generally accepted medical practice in the spring of 1983 primarily on the extensive and knowledgeable testimony of the treating physician, Dr. Gerald F. Giordano. Dr. Giordano is the author of several articles and studies on leukopheresis and its effect on multiple sclerosis and is certainly a leading authority in the use of leukopheresis. Dr. Giordano testified that lymphocyte depletion (his preferred term for leukopheresis) is an effective treatment modality for selected multiple sclerosis patients and that it became a generally accepted practice of those physicians using apheresis by the spring of 1983.

That time period was chosen by Dr. Giordano and the Hearing Officer as coinciding with a meeting of a advisory panel of the American Medical Association (AMA) established to study the state of the art of apheresis. At this meeting of the advisory panel, on which Dr. Giordano served, he testified the panel had agreed to recommend that leukopheresis was an effective treatment for multiple sclerosis. Dr. Giordano also testified that the position of the advisory panel was not official until the House of Delegates of the AMA approved the report. A draft, unsigned report of the panel is included in the appeal file.

The Hearing Officer's conclusions regarding the effect of the advisory panel's findings are somewhat ambiguous. In his discussion of the issues and findings, the Hearing Officer concluded that the AMA had approved the treatment, but in his summary, he states the treatment was ". . . well on the way to becoming approved by the American Medical Society."

However, the record in this appeal does not document the AMA approved the advisory panel's recommendation either in May 1983 or as of the date of the hearing. The testimony of Dr. Giordano is clear on this point; the AMA has taken no official position on leukopheresis as treatment of multiple sclerosis.

This office in previous FINAL DECISIONS has affirmed the importance of the recognition of evolving medical procedures by national professional medical organizations. Their collective expertise is invaluable to OCHAMPUS in determining the present status of such procedures and, indirectly, coverage under CHAMPUS. Certainly, Dr. Giordano's testimony and articles are cogent evidence, but the opinion of a national professional organization must be considered of greater weight than the treating physician's opinion.

The situation presented in this case is a most difficult one. The evidence of record, involving Dr. Giordano's testimony, clearly establishes that leukopheresis was an investigational

procedure from July 28, 1980 (the beneficiary's first treatment), through April 1983. The appeal record also indicates additional studies of leukopheresis have been recently completed, and the results are favorable. In his Recommended Decision, the Hearing Officer recognized an important issue in appeals involving an experimental/investigational issue: When does an evolving procedure cease being investigational? In his conclusion, leukopheresis became generally accepted, i.e., noninvestigational, when the advisory panel agreed to recommend its acceptance by the AMA. I cannot accept this conclusion. I find more than a recommendation of an advisory panel is required. At the very least, the national professional organization must act upon the recommendation. CHAMPUS cannot authorize cost-sharing of a controversial procedure without the benefit of review of a number of sources, including the representative body of a national professional organization. To hold otherwise would empower informal advisory groups with the prestige and authority of a national organization. The AMA has not delegated its authority to accept or reject panel recommendations. Therefore, at present, I find the AMA has no position on the treatment of multiple sclerosis with leukopheresis.

Similarly, the appeal file does not reflect the acceptance of the treatment regimen by any national professional medical organization. Testimony indicates neither the United States Public Health Service nor the National Institute of Health has endorsed leukopheresis as treatment for multiple sclerosis. As noted by the beneficiary, Medicare does not cover leukopheresis for multiple sclerosis. (See 4 CCH Medicare and Medicaid Guide, 35-60, at 9011-B (January 31,1983).) In actuality, CHAMPUS is requested to authorize cost-sharing of leukopheresis where no national professional or government health agency has endorsed the procedure.

The Hearing Officer also supports his recommendation with two other documents in the record. One of these documents is a list of third party payors known to cover leukopheresis according to the beneficiary. As noted by the Hearing Officer, CHAMPUS is not bound by decisions or policies of any third party payors. However, he apparently was impressed by the list. I give little weight to a list of third party payors as any insurance company can write a policy covering a particular procedure if the rate covers the cost. The reasons coverage is extended would be relevant, but those have not been furnished to OCHAMPUS. The Hearing Officer also gave weight to a list of physicians using leukopheresis. Many well recognized physicians utilize procedures not generally accepted in the medical community. Use of such procedures, including leukopheresis, is a primary method of development of new procedures and treatments. I cannot conclude leukopheresis is generally accepted simply because 15 physicians presently use the technique.

While the absence of documentation of acceptance of leukopheresis by national professional organizations is central in my decision, there is other evidence of record indicating the

investigational nature of leukopheresis in 1983. The 1983 edition of Current Therapy (page 742-744) in its article on multiple sclerosis, does not list leukopheresis as a treatment modality. An article in Human Pathology, Volume 14, No. 3, page 237, March 1983, states the optimal protocols and long-term complications of lymphocytopheresis (leukopheresis) remain to be determined.

In summary, I find the testimony and articles of Dr. Giordano strongly indicate that leukopheresis as treatment for multiple sclerosis has considerable promise. However, movement from the investigational category to a status of generally accepted medical practice must await endorsement of the treatment by the majority of the medical profession as expressed by national professional organizations and by national health care organizations who review evolving medical procedures and treatments.

As I have found the leukopheresis is an experimental/ investigational treatment for multiple sclerosis, I must also deny cost-sharing for the inpatient care related to this treatment. Under DoD 6010.8-R, chapter IV, G.66, all services and supplies (including inpatient institutional costs) related to a noncovered treatment are excluded from CHAMPUS coverage. As leukopheresis (a noncovered treatment) was received during the inpatient care from July 28, 1980, through June 13, 1983, the inpatient care is excluded from cost-sharing under the above cited authority.

Appropriate Level of Care

Under DoD 6010.8-R, chapter IV, B.1.g., the level of institutional care for which CHAMPUS benefits may be extended must be at the appropriate level required to provide the medically necessary services. Services and supplies related to inpatient stays above the appropriate level are excluded from coverage. (DoD 6010.8-R, chapter IV, G.3.) As applied to this appeal, the inpatient care must have been required to provide the leukopheresis treatments. If outpatient treatment would have been sufficient, no institutional benefits are payable under CHAMPUS. The Hearing Officer did not discuss this issue although OCHAMPUS raised the question of appropriate level of care at the hearing.

In reviewing the evidence of record, I find no real dispute that outpatient care would have been appropriate for the leukopheresis treatments. The beneficiary and sponsor testified inpatient care was utilized only because CHAMPUS would cost-share the care only on an inpatient, not outpatient, basis. The beneficiary on two occasions requested preauthorization of outpatient care. Finally, the attending physician, Dr. Giordano, in a post-hearing letter, advised:

> "Her hospitalization was not medically necessary to receive apheresis treatments, as we frequently do this as an outpatient." (Exhibit 5, page 3.)

While inpatient care may be required to receive leukopheresis treatments during acute exacerbations of multiple sclerosis, the beneficiary and her attending physician have not contended this situation existed at any particular time in her treatment. The treatment itself, at least during 1982-83, appears to have been provided on a regular basis and was not based on period of acute exacerbations.

Based on the above evidence, I find inpatient care was not required for the leukopheresis treatments and was above the appropriate level of care. Cost-sharing must, therefore, be denied for the inpatient charges.

As I have determined inpatient care was not required, I must also find the specific provisions of DoD 6010.8-R, chapter V, H.1., exclude coverage of the care under the CHAMPUS Basic Program subsequent to March 1982. The beneficiary became eligible for the CHAMPUS Program for the Handicapped (PFTH) in March 1982 and, under the above cited regulation provision, all services and supplies related to the handicapping condition (multiple sclerosis) shall be considered for benefits only under the PFTH. The monthly statutory cost-share limit for the PFTH is $1,000.00. The only exception to this requirement, as stated in the regulation, is a serious, acute exacerbation of the handicapping condition requiring an inpatient stay. As the record does not document the inpatient care was required for an acute exacerbation, I conclude the care is not eligible for cost-sharing under the CHAMPUS Basic Program and charges in excess of $1000.00 per month would have been excluded subsequent to March 1982, regardless of other regulatory provisions.

SECONDARY ISSUE

Estoppel/Prior Erroneous Payments

The beneficiary, sponsor, and attending physician argue that the leukopheresis treatments and treatment on an inpatient basis would not have been undertaken if CHAMPUS had not cost-shared the care beginning in July 1980. The record documents approximately $40,000.00 in inpatient and professional charges were cost-shared for leukopheresis from July 28, 1980, through June 13, 1983. The record does not reflect outpatient claims were submitted and denied.

This argument is essentially an estoppel argument. This office has held in numerous FINAL DECISIONS that the doctrine of estoppel does not apply to erroneous acts of the Government's agent (fiscal intermediary) in cost-sharing noncovered charges. The Hearing Officer recognizes this position in the Recommended

Decision. However, several salient facts in the record deserve discussion on this issue. In September 1982, the sponsor requested preauthorization of 100% coverage of outpatient leukopheresis treatments. Therein, he clearly indicated that inpatient care had been and would be utilized in the future because he and the beneficiary could not afford the outpatient cost-share (20% of the allowable charges). This statement certainly diminishes an estoppel argument based on reliance. Additionally, the sponsor and beneficiary were advised in November 1982 that CHAMPUS did not cover leukopheresis.

Subsequent to November 1982, the beneficiary continued inpatient leukopheresis treatments on 11 occasions for which billed charges were approximately $19,000. As these charges were incurred after notification that leukopheresis was not covered, the beneficiary cannot validly contend she continued to rely on the erroneous payments. Based on the above, I conclude estoppel is neither legally nor factually applicable.

The Hearing Officer, in his Recommended Decision, also discusses the potential recoupment of the erroneous CHAMPUS payments recognizing he has no authority in this area. Recoupment of erroneously paid Federal funds is governed by the Federal Claims Collection Act (31 U.S.C. 951, et seq.) and guidelines established by the Department of Justice. Whether or not recoupment will be pursued or in what manner is not cognizable under the CHAMPUS appeal procedure and is separately subject to the above cited law and regulation. To the extent applicable under recoupment procedures, the arguments of the beneficiary and sponsor and the facts herein will be considered in determining recoupment.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny cost-sharing of the inpatient and professional care provided from July 28, 1980, through June 13, 1983, for leukopheresis as treatment for multiple sclerosis. The decision is based on findings that leukopheresis is an experimental/investigational treatment and not medically necessary/appropriate medical care in the treatment of multiple sclerosis. I also find that inpatient care for leukopheresis was above the appropriate level of care, and cost-sharing of inpatient charges must be denied on that basis. As this decision results in a finding establishing previous erroneous payments by the Government in the approximate amount of $40,000, the matter of potential recoupment is referred to OCHAMPUS for consideration under the Federal Claims Collection Act.

As the evidence in this appeal indicates leukopheresis may be endorsed by the American Medical Association in the future, I direct OCHAMPUS to periodically review the status of leukopheresis and provide appropriate notice if the treatment becomes a generally accepted medical practice and CHAMPUS

coverage is extended. This FINAL DECISION completes the administrative process under 32 C.F.R. 199, and no further administrative appeal is available.

William Mayer, M.D.