ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

SEP 29 1983

Appeal of :	)	
	)	
Sponsor:	)	OASD(HA) Case File 83-25
	)	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. 83-25. 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, an officer of the United States Navy. The appeal involves claims for TERRAP therapy provided to the beneficiary for the treatment of agoraphobia in July, 1979. The billed charge for this therapy was $950.00. The amount in dispute is $710.00 ($950.00 less the 80% beneficiary cost-share for outpatient services, less a $50.00 deductible for calendar year 1979).

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, including the professional report by the OCHAMPUS Medical Director, have been reviewed. It is the Hearing Officer's recommendation that the CHAMPUS First Level Review determination which upheld a full denial of benefits, be reversed, and that benefits be partially allowed. The Hearing Officer's recommendation is based upon a finding that the First Level Review determination was erroneous in denying benefits on the basis that TERRAP therapy is specifically excluded as an educational, self-help program. He found that the TERRAP program employed therapeutic techniques and should be considered psychotherapy for the purposes of CHAMPUS. The Hearing Officer also recognized the specific limitations of DoD 6010.8-R relating to the duration and number of psychotherapy sessions and recommended that benefits be allowed for the maximum of two sessions per week. The Director, OCHAMPUS, nonconcurs in this Recommended Decision and recommends that it not be adopted as the FINAL DECISION.

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 Acting 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 Acting Assistant Secretary of Defense (Health Affairs), therefore, is to deny CHAMPUS claims for TERRAP therapy services provided to the beneficiary in 1979. This FINAL DECISION is based upon the appeal record as stated above.

FACTUAL BACKGROUND

The beneficiary was enrolled in a TERRAP treatment program from July 2, 1979 to July 13, 1979 in . "TERRAP," contraction of the phrase "Territorial Apprehensiveness," is a program created and sponsored by Dr. , M.D. for the treatment of phobic illnesses, particularly agoraphobia. The evidence of record establishes that TERRAP is organized and promoted on three levels. First, TERRAP, Inc. is a non-profit educational corporation which promotes information and public awareness concerning the recognition, cause and treatment of anxieties and phobic illnesses, especially agoraphobia. Second, TSC Management Corporation is involved in the establishment of TERRAP Service Centers. Both TERRAP, Inc. and TSC Management Corporation are described as educational organizations with a specific disclaimer stating that they do not provide therapy. Finally, TERRAP Service Centers are described as for-profit centers which "run self-help, education and training programs ... and can supply field instruction."

The beneficiary began exhibiting symptoms later diagnosed as agoraphobia during a pregnancy which followed some time after her 1975 marriage to the sponsor. These symptoms progressed to the point that she was afraid to leave her home or to go to a public place without her husband. She was unable to stay home alone after dark and became extremely dependent upon her husband. She testified that she exhibited all of the symptoms of panic including tremor, sweating hands, dizziness and fainting spells and "total terror." Her symptoms were so severe that she was virtually incapacitated, and her dependence on her husband was having a negative effect upon his military career.

The beneficiary stated that she had consulted several physicians and had attempted other psychiatric or psychological therapies with poor results. She learned of agoraphobia and TERRAP therapy from a story done on the television program "60 Minutes." She also learned of Dr. , M.D., the proponent of TERRAP. The beneficiary contacted Dr. organization and completed a questionnaire which they sent her. Her questionnaire was evaluated by , Ph.D., who responded that she appeared to be suffering from a "fairly severe case of

agoraphobia." He also expressed an opinion that TERRAP could help her. Consequently, the beneficiary enrolled in the TERRAP clinic nearest her home, in

At the time of the beneficiary's treatment there were at least two treatment programs offered at the TERRAP Service Center. The first was a sixteen-week course that met once each week. The second, a more concentrated program met for several hours each day for two weeks. The beneficiary chose the concentrated course because of the center's distance from her home. The content of both courses is similar and is described by TERRAP as providing "the fundamentals needed for learning and understanding the procedures to overcome ... phobias." The course is also described as providing "general information and demonstrating relaxation and desensitization techniques, assertiveness training, disinhibition and field work." The Hearing Officer summarized the beneficiary's testimony concerning the treatment she received as follows:

> The beneficiary stated that she was in a therapeutic group of five agoraphobics and their spouses which met several hours each day. She stated that Dr. attended the group from two to four hours a day and the balance of the program was run by assistants who were ex-agoraphobics who had received special training and served as role models. Various behavior modification techniques were employed during the treatment, including individual and group psychotherapy, peer pressure, support groups, educational material, etc.

Also testifying at the hearing was Dr. , a clinical psychologist. Dr. treated the beneficiary subsequent to her TERRAP program. He stated that while not personally involved with TERRAP therapy, he believed TERRAP employed sound therapeutic approaches and techniques which meet the generally accepted standards of practice in the United States. He stated that the intensive nature of the TERRAP program provided an important benefit because patients were able to make significant progress over a relatively short period of time and were thereafter better able to benefit from more traditional therapeutic approaches.

The sponsor also testified at the hearing stating that he had participated with his wife in the TERRAP program and that his wife had received significant benefit from it.

The beneficiary's claim for services provided at the TERRAP Service Center was submitted to the CHAMPUS Fiscal Intermediary for the State of , Blue Cross and Blue Shield of . The claimed amount was $950.00. The fiscal Intermediary processed this claim and allowed $189.60 of the billed charges, making a payment of $111.58 after applying deductible and cost-share amounts. This payment, which was later

determined to be erroneous, was apparently made because of the manner in which the charges were billed by the provider, Dr. . The doctor's statement submitted with the claim showed only billings for a series of 2-hour office visits with the doctor during the beneficiary's two week stay at the TERRAP Service Center. These were processed as routine outpatient visits with the doctor and the maximum outpatient psychotherapy limitations of DoD 6010.8-R were applied.

Because of the relatively small amount allowed on the claim, the beneficiary requested that the claim be reviewed. The Fiscal Intermediary's first level review confirmed the original claim determination. The second level reconsideration resulted in additional development of the claim. Additional information was obtained from the beneficiary and guidance was solicited from OCHAMPUS. OCHAMPUS provided a 1978 policy statement which held TERRAP to be excluded as a CHAMPUS benefit as a self-help, education or training program. As a result of the additional information developed through the reconsideration process the Fiscal Intermediary reversed the original allowance on the claim and found that the original payment had been issued in error and should be refunded.

The beneficiary appealed the reconsideration determination to OCHAMPUS. The OCHAMPUS First Level Review Decision upheld the finding and rationale of the reconsideration on March 11, 1981. The beneficiary requested a hearing which was held in on October 22, 1981. The Hearing Officer has issued his Recommended Decision. All levels of administrative appeal have been completed and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the treatment received by the beneficiary at the TERRAP Service Center qualified for benefits under CHAMPUS during the period of July 2 - July 13, 1979. In addressing this issue we must consider the medical necessity and appropriateness of the care in question.

MEDICAL NECESSITY

The Department of Defense Appropriation Act of 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.

Paragraph A.1., chapter IV, DoD 6010.8-R, defines the scope of benefits for the CHAMPUS Basic Program as follows:

> "Scope of Benefits. Subject to any and all applicable definitions, conditions, limitations, and/or exclusion specified or enumerated in this Regulation, the CHAMPUS Basic Program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury . . . ."

Specifically excluded from CHAMPUS Coverage are all "services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury." (Paragraph G.1., Chapter IV, DoD 6010.8-R.) "Medically necessary" is defined as "the level of services and supplies (that is, frequency, extent and kinds) adequate for the diagnosis and treatment of illness or injury . . . Medical necessity includes the concept of appropriate medical care." (Paragraph B.104., Chapter II, DoD 6010.8-R.) "Appropriate medical care" is defined as:

> "a. That medical care where the medical services performed in the treatment of disease or injury, . . . are in keeping with the generally acceptable norm for medical practice in the United States.
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> "b. The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training or 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
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> "c. the medical environment in which the medical services are performed is at the level adequate to provide the required medical care."

The CHAMPUS Basic Program includes generous benefits for outpatient psychiatric care. There is no limit on the duration of treatment or total number of outpatient psychiatric visits allowed during a beneficiary's lifetime. There are, however, specific limitations on the frequency and duration of outpatient therapy sessions. Three provisions are implemented in paragraph C.3.i., chapter IV, DoD 6010.8-R as follows:

> "(1) Maximum Therapy per Twenty-Four-Hour Period: Inpatient and Outpatient. Generally, CHAMPUS benefits are limited to no more than one hour of individual and/or group psychotherapy in a twenty-four hour period, inpatient or outpatient. However, for the

purposes of crisis intervention only, CHAMPUS benefits may be extended for up to two hours of individual psychotherapy during a twenty-four hour period.

"(2) . . . (Deals with inpatient care.)

"(3) Review and Evaluation: Outpatient. All outpatient psychotherapy (group or individual) are (sic) subject to review and evaluation at eight session (visit) intervals. Such review and evaluation is automatic in every case at the initial eight session (visit) interval (assuming benefits are approved up to twenty-four sessions). More frequent review and evaluation may be required if indicated by the case. In any case where outpatient psychotherapy continues to be payable up to sixty outpatient psychotherapy sessions, it must be referred to peer review before any additional benefits are payable. In addition outpatient psychotherapy is generally limited to a maximum of two sessions per week. Before benefits can be extended for more than two psychotherapy sessions per week, peer review is required."

The 1978 OCHAMPUS policy statement which excludes TERRAP as an educational, self-help program is based upon the regulatory exclusion of paragraph G.44, chapter IV, DoD 6010.8-R which states:

"Exclusions and Limitations. In addition to any definitions, requirements, conditions and/or limitations enumerated and described in other Chapters of this Regulation, the following are specifically excluded from the CHAMPUS Basic Program:

. . . .

44. Educational/Training. Educational services and supplies, training, nonmedical self-care/self-help training and any related diagnostic testing or supplies." (This exclusion includes such items as special tutoring, remedial reading and natural childbirth classes.) (Paragraph G.44, Chapter IV, DoD 6010.8-R)

Also excluded are miscellaneous ancillary therapy modalities, such as art, music, play or recreation therapies and mind expansion therapies such as Gestalt Therapy and Transactional Analysis. (See paragraphs G.48 and G.49, Chapter IV, DoD 6010.8-R.)

Finally, CHAMPUS excludes treatment modalities which are not provided in accordance with accepted professional medical standards, or related to essentially experimental, investigatory or unproven treatment regimens. These exclusions are found in paragraph G.15, chapter IV, DoD 6010.8-R. The term "experimental" is defined in part in paragraph B.68, chapter II, DoD 6010.8-R as:

> ". . . (M)edical care that is essentially investigatory or an unproven 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."

The evidence of record establishes that the TERRAP therapy provided to the beneficiary consisted of an intensive program of individual and group sessions employing various behavior modification techniques, peer interaction, the provision of general information about the condition of agoraphobia, relaxation and desensitization techniques, assertiveness training and field work. The program was under the general supervision of Dr. who attended group sessions from two to four hours per day. The remainder of the program was run by ex-agoraphobics who had received training in the TERRAP method.

Based upon the evidence of record which includes the oral evidence presented at the hearing and the written documentation which described the TERRAP treatment methods, it is clear that TERRAP is not strictly an education or self-help program. TERRAP employs a unique amalgam of psychotherapeutic approaches and methods which are either provided directly or supervised by a medical doctor. Combined with these are a number of educational aspects which are intended to increase the patient's general understanding.

Based upon the foregoing, I find that the OCHAMPUS First Level Review Decision of March 11, 1981 was erroneous in denying benefits solely on the basis that TERRAP therapy is merely an educational or self-help program. However, even when the essentially therapeutic nature of the TERRAP program is recognized, the more difficult question of its authorization as a CHAMPUS benefit must be addressed. I have concluded that TERRAP cannot presently qualify as a benefit under CHAMPUS. This finding is based upon several factors.

First, as indicated above, TERRAP employs a unique combination of therapeutic and educational approaches to the problems presented by persons suffering from phobic illnesses. While most of these approaches have been individually generally accepted, there is no evidence that the unique approach employed by TERRAP has been subjected to an independent, scientific validating study. As stated by the OCHAMPUS Medical Director, a psychiatrist, who professionally reviewed this and other TERRAP cases:

> ". . . (T)here is no significant or available body of scientific evidence or national professional consensus that these various [traditional] therapies would be more efficacious or safe when used in the combinations or intensity (duration, frequency) employed in the TERRAP approach. It is, in fact, somewhat surprising that there are no comparative studies or professional body of knowledge that can be reviewed about TERRAP program, considering its fairly wide distribution nationally.
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> . . . (W)ithout scientifically validated evidence, these services can only be considered as effective as any other "placebo effect," for which individuals interpret positive perceived outcomes resulting from a specifically applied treatment to be solely a result of the treatment. In this instance there is no evidence that a less intensive initial course of treatment would not have been equally effective." (Emphasis in original.)

In other words, without the independent scientifically validated evidence there is no way to objectively evaluate the TERRAP program to determine if it is safe and effective and if it meets the generally accepted standards for practice in the general medical community. For this reason, I find that TERRAP therapy does not qualify for CHAMPUS benefits because it is essentially an unproven treatment regimen, the safety, efficacy, medical necessity and appropriateness of which have not to date been demonstrated.

The situation involved here is analogous to that encountered in a previous FINAL DECISION issued by this office, OASD(HA) File 01-81. That decision dealt with a significantly different treatment modality, cardiac rehabilitation. However, the principles of medical necessity and appropriateness of care upon which that case was decided are essentially the same as those involved in this case. In OASD(HA) File 01-81 we determined that cardiac rehabilitation, while endorsed as a treatment regimen by a number of physicians, was not generally accepted in the treatment of disease or illness as documented by authoritative medical literature and recognized professional opinion.

While the Department of Defense recognizes individual improvement in overcoming phobic illnesses may occur through TERRAP therapy programs, I am constrained by regulatory authorities here, as in OASD(HA) File 01-81, to authorize benefits only for services which are generally accepted in the medical community and are documented by authoritative medical literature and recognized professional opinion. The evidence herein and the professional

review opinion rendered subsequent to the hearing, disclose no evidence of the documented effectiveness of TERRAP therapy in the treatment of agoraphobia or other phobic illnesses at the time the care in question was rendered. Instead, the file clearly indicates its unproven nature. Furthermore, a search of the relevant medical literature subsequent to the time of the care provided to the beneficiary also fails to reveal any evidence to date which would document the medical necessity, effectiveness or appropriateness of TERRAP therapy. Therefore, I find that TERRAP therapy was not documented as medically necessary in 1979 when the care was provided to this beneficiary and has not been documented as medically necessary to the present time.

Second, TERRAP is a program which, particularly in its intensive, two-week format, cannot qualify under the specific CHAMPUS limitations on the frequency and duration of CHAMPUS outpatient psychotherapy. CHAMPUS does not at this time recognize any such intensive and comprehensive outpatient treatment programs which exceed the specific one-hour-per-day, two-days-per-week limitations on such benefits. A change in the current DoD regulation governing CHAMPUS would be required before CHAMPUS could allow such treatment regimens as a benefit. As stated above, the evidence compiled to date does not warrant such a change because of the lack of acknowledged national professional accreditation standards and treatment criteria.

Finally, there is also concern about the level of professional supervision given to the non-professional ex-agoraphobics who play an integral role in the TERRAP program. It is evident that these individuals play an important part in the direct counseling of patients and certainly in the field work exercises which are a significant part of TERRAP. The record does not clearly establish the degree of involvement or the level of professional supervision given to the non-professional staff. Again, this concern is a reflection of the lack of scientific validation and the lack of a means to objectively evaluate this treatment modality. It also demonstrates the need for national professional accreditation standards and treatment criteria for this and other similar approaches to mental health care.

The Hearing Officer found TERRAP therapy to be psychotherapy within the meaning of paragraph C.2(e), chapter IV, DoD 6010.8-R. Based upon the foregoing analysis of this case I do not concur with this finding. Although, TERRAP therapy involves a therapeutic approach which is more than mere education or self-help, for the reasons stated it does not qualify as psychotherapy for the purpose of extending CHAMPUS benefits. Therefore, I do not accept the Hearing Officer's recommendation in this regard. I find that the TERRAP therapy extended to the beneficiary in July 1979 was part of what is essentially an unproven treatment regimen, the scientific validity, medical necessity and appropriateness of which have not been established. Consequently, TERRAP therapy does not qualify for benefits under the CHAMPUS Basic Program because the care is not medically necessary or appropriate pursuant to the authorities cited above.

The hearing file of record establishes that the Fiscal Intermediary made a payment on the claim for TERRAP therapy services provided to the beneficiary in July, 1979. Therefore, the Director, OCHAMPUS is required to review this case based upon this FINAL DECISION and take appropriate action under the Federal Claims Collection Act in regards to this erroneous payment.

SECONDARY ISSUE

SCOPE OF BENEFITS - CRISIS INTERVENTION

CHAMPUS outpatient psychotherapy benefits are generally limited to two one-hour therapy sessions per week with each session in a different 24 hour period. However, for the purpose of crisis intervention the limitation of one hour of therapy in a 24 hour period may be expanded to a maximum of two hours.

The Hearing Officer reasoned in his Recommended Decision that because the beneficiary's agoraphobic condition was severe and incapacitating, it warranted the "crisis intervention" level of treatment as provided in paragraph C.3.i.(1), chapter IV, DoD 6010.8-R. Although this rationale is largely rendered moot by the decision herein, it should be stated that this beneficiary's condition would not likely have qualified for the level of care contemplated by the crisis intervention provision. That provision is intended only to address those situations in which a patient is in the throes of an acute psychiatric episode which demands immediate and extensive intervention. A possible example of what is contemplated by that provision would be an agoraphobic experiencing a severe acute panic attack. A higher level of care would possibly be required on a short-term basis to [illegible] patient through the acute episode. There is no indication that this beneficiary, whose condition was admittedly severe, experienced such an acute episode in association with her TERRAP program. In fact, the record confirms that she traveled a long distance from her home to attend the TERRAP clinic and was obviously not in an acute episode at the time.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that the TERRAP therapy provided to the beneficiary in July, 1979 was not a covered benefit under CHAMPUS. This determination is based upon findings that TERRAP therapy is an unproven treatment modality, the medical necessity and appropriateness of which have not been established. These findings are based on the lack of medical documentation, authoritative medical literature and recognized professional opinion sufficient to establish the general acceptance and efficacy of the program at the time the care was received. I further find that there has been no additional development of documentation in the medical literature or published professional opinion to establish the acceptance and efficacy of the therapy at the present time. The appeal of the beneficiary, therefore is denied. The Director, OCHAMPUS shall review the claims file and take appropriate action under the Federal Claims Collection Act in regards to the payment of the