ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

JUN 12 1985

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of)
)
Sponsor:) OASD(HA) File 85-11
) FINAL DECISION
SSN:)

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 85-11 pursuant to 10 U.S.C. 1071-1092, and DoD 6010.8-R, chapter X. The appealing party is the provider, H. Thomas Ballantine, Jr., M.D., who was represented by counsel. The beneficiary is the wife of an active duty enlisted member of the U.S. Army.

The appeal involves the issue of CHAMPUS cost-sharing of two bilateral stereotactic cingulotomies, and related inpatient services and hospitalization, received in October 1982 and September 1983. The physician's billed charges of $2,000.00 for the October 1982 procedure were denied by the CHAMPUS fiscal intermediary; however, related services in a billed amount of $159.00 were allowed and paid in full by the fiscal intermediary. A claim for the beneficiary's hospitalization from October 28, 1982, through November 19, 1982, in a billed amount of $9,206.00 was allowed in full by the fiscal intermediary and a payment of $9,062.16 was issued to the hospital after deducting a beneficiary cost-share of $144.10. Related radiology services in a billed amount of $95.58 were also allowed and a payment of $76.40 was made. The total amount in dispute for the 1982 episode of care is approximately $11,316.60. Following appeal to OCHAMPUS, the entire episode of care was denied CHAMPUS cost-sharing as the care was considered an investigational procedure.

Preauthorization for CHAMPUS coverage of the second procedure was requested on August 8, 1983. OCHAMPUS denied the preauthorization request on September 17, 1983, on the basis that psychosurgery is not a CHAMPUS benefit. The evidence of record indicates that because of the OCHAMPUS preauthorization denial no CHAMPUS payments were issued for the second procedure.

The hearing file of record, the tape of oral testimony and the arguments 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 previous determinations of OCHAMPUS which denied the preauthorization request and the claims of the provider and the facility be upheld. The Hearing Officer found that the cingulotomy procedures performed on the beneficiary presently do not meet the generally accepted standard of practice in the United States, and are, therefore, not a benefit of CHAMPUS.

The Director, OCHAMPUS, concurs in the Recommended Decision and recommends its adoption as the FINAL DECISION. The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, concurs in the recommendation of the Hearing Officer and hereby adopts the recommendation of the Hearing Officer as the FINAL DECISION.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS cost-sharing of the cingulotomy procedures and all related services performed on the beneficiary in 1982 and 1983. This determination is based upon a finding that at the time the services were provided, cingulotomy did not meet the generally accepted standard of medical practice in the United States.

FACTUAL BACKGROUND

The beneficiary had a long history of recurring depression. Antidepressant medication was first attempted in 1979 after her depression became severe. Since then she has had several hospital admissions, treatment with medications, individual psychotherapy, and electroshock therapy. Only moderate and short-lived improvement was ever noted with any of these therapies. During the three years preceding the treatment at issue herein, she reported a severe depression with profound anbedonia, daily suicidal thoughts, and chronic anxiety to the point of panic. The diagnosis was severe endogenous unipolar depression. In October of 1982 the beneficiary was referred by her attending physician to Dr. Thomas Ballantine at Massachusetts General Hospital for evaluation and consideration of anterior cingulotomy surgery. Following an extensive work-up and consultation at Massachusetts General Hospital, the beneficiary consented to the bilateral stereotactic cingulotomy which was performed in October 1982. For a short time following this procedure the beneficiary was nearly free of symptoms of depression. However, her symptoms gradually returned and in August of 1983 her attending physician recommended that she be evaluated for a second cingulotomy for extension of the lesion. The beneficiary's request for preauthorization of the second procedure was denied by OCHAMPUS on September 17, 1983. The neurosurgeon, Dr. Ballantine, has appealed from this preauthorization denial and the fiscal intermediary's denial of his claim for the 1982 services. The second cingulotomy was performed on September 15, 1983.

The OCHAMPUS Formal Review Decision upheld denials of CHAMPUS coverage of these procedures on February 7, 1984. A hearing was subsequently requested by the doctor.

The Hearing Officer's Recommended Decision describes in much detail the beneficiary's condition, the events leading to the two psychosurgeries, and the reasons for them. Because the Hearing Officer has adequately summarized the factual record, it would be unduly repetitive to further summarize it here. Accordingly, the Hearing Officer's factual summary is accepted and incorporated into this FINAL DECISION.

The hearing was held on June 11, 1984, at Massachusetts General Hospital, before CHAMPUS Hearing Officer, Valentino D. Lombardi. Present at the hearing were the appealing party, Dr. Ballantine, and his counsel, and the OCHAMPUS representative from the Office of Appeals and Hearings. The Hearing Officer has issued his Recommended Decision and the issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the stereotactic cingulotomy surgeries performed on the beneficiary in October 1982 and September 1983 meet the CHAMPUS requirement of having been provided in accordance with the generally accepted norm for medical practice in the United States.

Essentially, two provisions of the CHAMPUS regulation are involved in resolving the primary issue. The provisions are an implementation of the statutory limitations imposed by the Department of Defense Appropriations Act for Fiscal Year 1977 (and all subsequent Appropriation Acts) restricting CHAMPUS coverage of any service which, in general, is not medically necessary to treat a mental or physical illness. The first Regulation provision restates the CHAMPUS limitation on cost-sharing to those services which are determined to be "medically necessary." (See paragraph A.1., chapter IV, DoD 6010.8-R.) "Medically necessary" is defined by the Regulation 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 the concept of Appropriate Medical Care." (Paragraph B. 104, chapter II, DoD 6010.8-R. Emphasis added.) "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."

The second regulatory provision primarily involved relates to the exclusion by CHAMPUS of what are determined to be essentially experimental procedures or treatment regimens. (See paragraph G.15, chapter IV, DoD 6010.8-R.) "Experimental" is defined in part under CHAMPUS as, "medical care that is essentially investigatory or an unproved 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." (Paragraph B.68., chapter II, DoD 6010.8-R.) In addition, precedential decisions previously issued by this office have held that while individual providers may endorse programs they believe may assist patients, CHAMPUS is constrained to authorize benefits only for services which are generally accepted in the treatment of disease or illness and are documented by authoritative literature, medical literature, and recognized professional opinion sufficient to establish the general acceptance and efficacy of the services at the time the care was received. (See OASD(HA) File 84-49 and cases cited therein.)

The issue, as presented through the factual development and evaluation of this case deals with the portions of the foregoing regulatory provisions relating to the extent to which the cingulotomy procedure has found acceptance within the general medical community. The provider has submitted a significant body of evidence that the cingulotomy procedure was appropriate for the beneficiary and that it was performed fully in keeping with professional standards of medical practice. The resolution of the issue presented does not involve questions relating to the professional qualification or competence, or the ethical standards of the provider. What is involved is the question of whether cingulotomy, as a psychosurgical procedure is reliably appropriate for the evaluation and treatment of certain mental disorders and whether it can be generally provided as a "standard of practice" with equivalent expertise and specificity of indication by neurosurgical providers of care throughout the United States.

The Hearing Officer, in his Recommended Decision, correctly identified the issues and correctly referenced applicable authorities, including those cited above.

The Hearing Officer found that:

> "In order for a medical service to be allowable under the CHAMPUS Basic Program, it must be proven to be safe and efficacious and well accepted by a majority of the medical community. In the present case, the efficacy of psychosurgical procedures has been questioned and a review of all of the evidence would indicate that there is a tendency for polarization of opinion between those who support it and those who do not, and although there has (sic) been great attempts to minimize the complications, there still exists a strong medical opinion that this procedure is investigatory and/or experimental and not keeping with the generally acceptable norm for medical practice in the United States. The evidence

> did show that there are very few institutions and physicians who provide this medical service. There is no question that it has improved over the years, but to indicate that it is generally acceptable by the medical community is not possible.

The Hearing Officer recommended that the previous determinations of OCHAMPUS as set forth in the Formal Review Decision be upheld and the claims of the provider and the inpatient facility be denied. The Hearing Officer also recommended a finding that any services or supplies related to the stereotactic cingulotomy surgery be denied cost-sharing under the CHAMPUS basic program.

I concur with the Hearing Officer's findings and recommendations. I hereby adopt the Hearing Officer's Recommended Decision, including the findings and recommendations, as the FINAL DECISION in this appeal.

The provider in this appeal has submitted a well presented and thoroughly documented case in support of his position that the cingulotomy procedure should be a benefit of CHAMPUS. A number of authorities were cited in support of this position, including a number of specialty professional associations. This, on the surface, appears to establish a strong case in support of the provider's position. However, at the same time, the provider acknowledges that psychosurgical procedures have been the subject of what he terms "gross misunderstanding." It is not accidental that they are so controversial--they not only stimulate strong reactions in those he would consider misinformed, but also they have failed to convince a consensus of national medical policy bodies that there is adequate evidence of generally reliable scientific efficacy and safety. The core position taken by OCHAMPUS and adopted by the Hearing Officer is based upon the failure of established national consensus development entities to endorse psychosurgical procedures (including cingulotomy) as standard medical care. The public positions taken by the Health Care Financing Administration and Blue Cross/Blue Shield Association are simply not avoidable by CHAMPUS, particularly given the traditional legislative and administrative ties to those programs. Their positions were not developed, as has been suggested, because of a paramount concern about costs, but because the procedures are not generally reliably provided by neurosurgeons in the United States. They are provided only by a small number of neurosurgeons and, therefore, are not standard or generally accepted care in the sense that they are not common or normative services, even though they may be acceptable medical practice to individual providers, patients, state licensing authorities, and some specialty professional associations.

<u>SUMMARY</u>

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS cost-sharing of the

October 1982 and September 1983 bilateral stereotactic cingulotomies and any related services because these procedures did not meet CHAMPUS standards for medically necessary care and did not meet the generally accepted standards of usual professional medical practice in the general medical community. Because there is evidence in the record that some payments may have been made for the procedure performed in 1982, the Director, OCHAMPUS, is directed to review the case for appropriate recoupment action in accordance with the Federal Claims Collection Act. Issuance of this Final Decision completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

William Mayer, M.D.

William Mayer, M.D.

REC DEC

85-11

RECOMMENDED DECISION

CIVILIAN HEALTH AND MEDICAL PROGRAM FOR UNIFORMED SERVICES

(CHAMPUS)

IN THE APPEAL OF BENEFICIARY:

SPONSOR:

SPONSOR'S SOCIAL SECURITY NO:

PROVIDER/CLAIMANT: H. THOMAS BALLANTINE, JR., M.

This case is before the undersigned Hearing Officer pursuant to a request for a hearing by the above-named provider/claimant dated March 30, 1984. The Office of Civilian Health and Medical Program for the Uniformed Services has granted this request for hearing. This hearing was conducted pursuant to Regulation DOD 6010.8-R Civilian Health and Medical Programs for the Uniformed Services (CHAMPUS), Chapter X, Section F, Paragraph 4 and Section H, Paragraph 2B.

A hearing was conducted by the undersigned on June 11, 1984, in the ACC Building of the Massachusetts General Hospital, 15 Parkman Street, Boston, Massachusetts pursuant to notices sent by the undersigned on May 17, 1984. The provider/claimant was present at the hearing and represented by Ira S. Yanowitz, Esq. of Choate, Hall & Stewart, 60 State Street, Boston, Massachusetts 02109. OCHAMPUS was represented by Barbara S. Udelhofen, Esq. All of the evidence has been submitted both at the time of the hearing and subsequent thereto in the form of exhibits, testimonial evidence and the Position Papers submitted on behalf of the parties.

OVERVIEW

The record indicates that . . the wife of a United States Army Active-Duty Service member, was suffering from major depression, recurrent, severe, together with possible boaderline personality disorder when first referred to Dr. Ballantine by Frank Winston, M.D., on October 15, 1982. She was 28 years old at the time and had had recurring depression since her teenage years which became quite severe in 1979. From that time until her referral to Dr. Ballantine, she was hospitalized at various times, underwent a multitude of treatments with medication and psychotherapy and eventually even electroshock therapy. None of the treatment seemed to have a lasting effect. In October 1982, she was seen by Dr. Ballantine and admitted to the Massachusetts General Hospital where it was recommended, after testing and consultation, that the patient undergo surgery for bilateral frontal bur holes and bilateral stereo-

tactic cingulotomy which was performed on October 29, 1982. After her discharge on November 19, 1982, she was followed by Dr. Winston who noted that although Mrs. ras quite better she still sustained serious depression quite often; therefore, he recommended a second cingulotomy for her.

Dr. Ballantine agreed with the recommendations of Mrs. treating physician and performed a second cingulotomy on September 15, 1983, at the Massachusetts General Hospital. The beneficiary tolerated this second procedure and was discharged from the hospital in a virtual symptom-free condition.

Dr. Ballentine had on December 2, 1982, filed claims for which he accepted assignment for the medical services rendered Mrs. between October 27, 1982 and November 19, 1982. The latter portion of the claim involving the surgical procedure was denied by the CHAMPUS Fiscal Intermediary, Blue Shield of California, as services not approved per OCHAMPUS Policy. Claims were also filed by the Massachusetts General Hospital for the hospital cost and related services provided during that initial hospital stay; these claims were approved for payment by the said Fiscal Intermediary. Upon receiving notice of the denial, the claimant requested a review of the claim by letter dated July 20, 1983. The Fiscal Intermediary had its medical advisors conduct a review, but determined that the pyschosurgery was not provided in accordance with accepted professional medical standards or related to essentially investigational procedures or treatment regimens and therefore upheld the initial denial. The claimant subsequently requested a Formal Review by OCHAMPUS on November 14, 1983. On February 7, 1984, the results of the Formal Review were forwarded to the claimant which indicated that the CHAMPUS cost sharing for the cingulotomy must be denied as this is considered to be an experimental/investigational procedure which is not generally accepted among the medical community in the United States; consequently, CHAMPUS coverage is specifically excluded. The claimant upon receipt of this decision requested a hearing.

Meanwhile, when Dr. Winston recommeded Dr. Ballentine perform a second cingulotomy on Dr. Winston requested a preauthorization for CHAMPUS coverage of said surgery by letter dated August 8, 1983. This request was denied by OCHAMPUS who indicated that psychosurgery is not a CHAMPUS benefit and no part of care associated with such procedure may be paid by the program. There is nothing in the record to indicate when claims for this second cingulotomy were filed by Dr. Ballentine or by the Massachusetts General Hospital and if they were allowed for the latter as had been done previously.

FACTUAL BACKGROUND

The exhibits which comprise the CHAMPUS Record facutally set forth the background regarding Mrs. s long history of pyschiatric problems. The history, physical examination and psychological summaries and discharge summary which reflect the most recent hospitalization just prior to the initial admission to the Massachusetts General Hospital indicate the beneficiary's

long-standing depression and also a very poor prognosis. (Exhibits 6, 7, and 8) Even Dr. Winston's letter of October 15, 1982, establishes a pattern of treatment which would indicate that Mrs. had reached a point when conventional type treatments would not be of any further value to the beneficiary. (Exhibit 9) The Psychiatric Evaluation performed by Anthony Bouckoms, M.D. at Massachusetts General Hospital in conjunction with Mrs. initial admission indicates that the doctor supported her plans for cingulotomy since there is little else that can be offered her either with ECT or psychopharmacology. (Exhibit 4) Dr. Bouckoms also testified at the hearing in this regard indicating that he had evaluated Mrs. twice prior to each surgery and also had seen her additional times during her inpatient hospital stays. He higly recommended the surgery for this beneficiary and stated that after the second surgery she was symptom free.

At the hearing OCHAMPUS presented its position indicating that the stereotactic cingulotomy surgeries performed on Mrs. on October 29, 1982, and September 15, 1982, were not provided in accordance with accepted professional medical standards and are therefore not appropriate medical care and as such are excluded from coverage under the CHAMPUS Basic Program. It was further stated that OCHAMPUS takes the position that these surgeries are experimental and as such excluded from said coverage. OCHAMPUS had its Medical Director, Alex Rodriguez, M.D., who is a Board-certified psychiatrist, reviewed the records involving this case. He concluded that while many in the medical community may accept this procedure (cingulotomy) as a standard of care from the medical point of view, it has not been validated by any medical policy groups to be both safe and efficacious over the longrun. He further stated that although psychosurgery is accepted under the law and within the auspices of the medical practice, when in fact it is the course of last resort for a patient who has been treated for a significant period of time and remains disabled by an emotional disease, it is only performed infrequently and in a few facilities, the major health policy review groups have not endorsed psychosurgery as safe and efficacious and neither the Diagnostic and Theraputic Technology Assement Project of the American Medical Association nor the Clinical Effectiveness Project of the American College of Physicians has reviewed psychosurgery and are not prepared to offer an opinion on the topic; that is, not to say they would find it acceptable or not acceptable. He concluded his review in stating that there is no question that this program is an excellent program and that these are gifted surgeons who are getting good results; nevertheless, psychosurgery cannot be considered the standard of care or practice in the United States when there are bonified major health policy determination groups that are finding the evidence lacking and as such cannot be considered appropriate medical care. (Exhibit 30 Attachment 1)

OCHAMPUS had also pointed out that at the 20th meeting of the Health Care and Financing Administration (HCFA) Physicians held on September 21, 1982, the issue of medical coverage of psychosurgery was discussed and the panel decided that due to a lack of new medical and scientific information, no instructions should be issued at this time and the HCFA should continue its policy of noncoverage of psychosurgery under Medicare. (Exhibit 30 Attachment 5) OCHAMPUS

has also indicated that opinions vary on this subject from purely scientific, which embraces the procedure, to the opposite end of the spectrum which considers it an unethical means of manipulating behavior. (Exhibit 30 Attachment 8) In citing the Harvard Guide to Modern Psychiatry, it stated that psychosurgery is performed infrequently in the United States and one of the many reasons for this situation is the lack of controlled prospective studies demonstrating the efficacy and safety of psychosurgery, which report also indicated, however, that it is premature to eliminate psychosurgery totally without this further research. (Exhibit 30 Attachment 4) A Psychiatric Viewpoint Report introduced into evidence concludes that the state of the art of psychosurgery is not sufficiently advanced to warrant total approval. (Exhibit 30 Attachment 3)

Based upon these above-stated opinions and conclusions, OCHAMPUS has issued, in its CHAMPUS Policy Manual, a policy involving psychosurgery which stated that said surgery is not in accordance with accepted professional medical standards and is not covered. (Exhibit 30 Attachment 7) Although the date of this policy issuance was January 23, 1983, it repeated a CHAMPUS Interpretation established on February 1, 1978, which excluded all coverage for this surgery under the CHAMPUS Basic Program. (Exhibit 38)

In his presentation, Dr. Ballantine stressed what he believed to be an important consideration that stereotactic cingulotomy is but one of a group of neurosurgical procedures to which have been applied the term psychosurgery; in citing the Canadian Journal of Psychiatry which states that the recognition of such a concept as psychosurgery promotes a global view of a group of techniques and ignores the heterogeneous nature of the component operations; therefore, he indicated that it is important to keep in mind whether statements made or introduced at the hearing containing the term psychosurgery referred to the global view or the particular operation performed on the beneficiary. (Exhibits 42 & 43) The doctor offered additional evidence which would indicate that this specific surgery performed on Mrs. was widely accepted and both safe and efficacious. Dr. Ballantine also cited various medical groups which have investigated this procedure and its effects, determining that it is a safe and efficacious method of treatment. These groups include the Massachusetts Institute of Technology, the Congress of Neurological Surgeons, the Society of BiologicalPsychiatry, and many third-party payors. (Exhibit 35 Attachments B, L, M, & O) The doctor also indicated that certain groups such as the American Medical Association, the American College of Physicians and the American Psychiatric Association have not reviewed, are not accustomed to reviewing, or have not been requested to review the cingulotomy procedure. (Exhibit 35 Attachments H, I, & J) In response to the OCHAMPUS exhibit citing the Harvard Guide to Modern Psychiatry (Exhibit 30 Attachment 4), Dr. Ballantine requested the author of the article cited, T. Corwin Fleming, M.D. to comment on said article. Dr. Fleming indicated in a letter of June 8, 1984 to the claimant that it is certainly his understanding that in suitably selected patients cingulotomy is accepted medical practices and not experimental. (Ehibit 35 Attachment F)

Edwin H. Cassem, M.D. and Anthony J. Bouckomas, M.D. presented testimony on behalf of Dr. Ballantine. Dr. Cassem who is

a psychiatrist on the staff of Massachusetts General Hospital, stated his opinion that the cingulotomy procedure is not unproven; he stated that when there is disagreement in a scientific community, a procedure is determined to be unproven, however, there is no disagreement in the scientific community that this procedure is both safe and efficacious. He further stated that this is not an investigational procedure, it is a therapeutic procedure conclusively established and easily meets the standards of medical acceptance in the general medical community. He concluded that those who have tried to disprove Dr. Ballantine's procedure have failed and that this surgery is the generally acceptable norm for practicioners throughout the United States.

Dr. Bouckoms, whose psychological evaluation of the beneficiary was included in the exhibit file, testified that in his opinion cingulotomy is a proven procedure which offers long-term results. He commented on an article from the November 1977 issue of the American Journal of Psychiatry entitled "Nuclear Symptoms of Schizophrenia After Cingulotomy: A Case Report" by Javier I. Escobar, M.D. and Vijaya Chandel, M.D., indicating that it would not be typical for such symptoms to appear after the procedure but he did not know if it could be related to such procedure. (Exhibit 34) He also commented on an article entitled "Psychosurgery" by John Donnelly, M.D., and indicated that he disagrees completely with the article that it is an error since there are no valid studies and that the writer speaks of all of psychosurgery rather than this specific procedure. (Exhibit 33) It should also be noted that at the request of Dr. Ballantine, the author of the last cited article, John Donnelly, M.D., wrote a letter to the claimant indicating that there is considerable evidence that cingulotomy is a safe procedure more so than any other surgical procedures. (Exhibit 40)

A video tape was also shown at the hearing, a copy of which was made an exhibit to this file. Said tape followed the history of another patient of Dr. Ballantine who had undergone a similar procedure as Mrs. . It demonstrated the thoroughness of the valuations performed to determine the need for the surgery and also the successful results. It cited the Massachusetts Institute of Technology study and also the view of certain objectors to this type of surgical procedure. (Exhibit 39) Dr. Ballantine along with Dr. Bouckoms commented on the need for a second cingulotomy. It appears that this procedure is done very conservatively, and in some 30 to 40 percent of the cases a second treatment is necessary. They both firmly stated, however, that in no way was this procedure performed in stages. They believe that the conservative approach would lessen any possible side effects in the patients. Dr. Ballantine did say that in England it is common to use larger bur holes, therefore, possibly causing more side effects.

A cirriculum vitae of each doctor who testified was made part of the exhibit file along with the cirriculum vitae of Dr. Rodriguez. All of these exhibits indicate a well established background in his respective field. (Exhibits 30 Attachment 2, 35 Attachment A, 36 & 37)

ISSUES AND FINDINGS OF FACT

> "Whether the surgical services, more specifically, the stereotactic cingulotomy, performed on on October 29, 1982, and September 15, 1983, by H. Thomas Ballantine, Jr., M.D., at the Massachusetts General Hospital are covered benefits under the CHAMPUS Basic Program?"
>
> "Whether the medical services rendered said beneficiary during her hospital stays at the Massachusetts General Hospital when the surgeries were performed are covered benefits under the CHAMPUS Basic Program?"

Department of Defense Regulation 6010.8-R

Chapter II, B, 14-Appropriate Medical Care
Chapter II, B, 68-Experimental
Chapter II, B, 104-Medically Necessary
Chapter IV, A, 1-Scope of Benefits
Chapter IV, G, 1-Not Medically Necessary
Chapter IV, G, 15- Not in Accordance with Accepted Standards: Experimental
Chapter IV, G, 75-Not Specifically Listed

Interpertation-13-78-I-Psychosurgery

CHAMPUS Policy Manual Volume 1, Chapter III, 14, 6499.1.1-Psychosurgery

The CHAMPUS Basic Program provides benefits for any and all medically necessary services and supplies required in the diagnosis and treatment of an illness or injury. This payment doctrine, however, as set forth in Chapter IV, Section A 1 of the Regulation, does indicate that said payment is:

> "Subject to any and all applicable definitions, conditions, limitations, and/or exclusions specified or enumerated in this regulation."

In Chapter II, Section B 104, medically necessary is defined as that level of services and supplies, (that is, frequentcy, extent & kinds), adequate for the diagnosis and treatment of illness or injury, and further that medically necessary includes the concept of appropriate medical care. Appropriate medical care is defined in Chapter II, Section B 14. That portion of the definition which is applicable to the within hearing reads as follows:

> "That medical care where medical services performed in the treatment of a disease or injury, or in connection with a obstetrical case, are in keeping with the generally acceptable norm for medical practice in the United States."

A certain medical service may ordinarily be determined to be medically necessary, however, the two-fold requirement that it meets the definition of "appropriate medical care" requires that each claim for medi-

cal services should be scrutinize to determine that the services are keeping with the generally acceptable norm for medical practice within the United States. If the service is not within that norm, it is determined to be not medically necessary. If that is the case, the exclusion set forth in Chapter IV, Section G 1 would apply. Said section indicates that services and supplies which are not medically necessary for the diagnosis or treatment of a covered illness or injury are specifically excluded from the CHAMPUS Basic Program. With regard to the above-mentioned guidelines, at first instance it would appear that the medical services including the surgery rendered the beneficiary by Dr. Ballantine on the dates in question, would be medically necessary considering her diagnosis. The services were performed at a well-known hospital and under the auspices of well-reknown and expert physicians. The results of the surgeries proved beneficial to Mrs. and as one physician indicated, she is now symptom-free. However, since the term "medically necessary" includes the definition of "appropriate medical care", it must be determined whether or not the surgery performed by Dr. Ballantine was in keeping with the generally acceptable norm for medical practice in the United States. In making this determination, another section of the Regulation must be viewed. Section B 68 of Chapter II Regulation defines "experimental" as medical care that is essentially investigatory or an unproven procedure or treatment regiment (usually performed under controlled medicolegal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community. If it is determined that certain medical services meet this definition, Section G 15 of Chapter IV of the Regulation indicates that services and supplies not provided in accordance with accepted professional medical standards or related to essentially experimental procedures or treatment regiments are specifically excluded from the CHAMPUS Basic Program.

The claimant has presented a multitude of opinions which support his position with regard to cingulotomy surgery. All of these opinions are from well-reknown doctors and medical organizations. He has indicated the success that he has had with the performance of these operations.

The CHAMPUS position has been that cingulotomy is a form of psychosurgery which has not been proven safe and efficacious and is not in keeping with the generally acceptable norm for medical practice in the United States and is essentially investigatory or an unproven procedure or treatment regiment which does not meet the generally accepted standards of usual professional medical practice in the general medical community. Based upon this position, CHAMPUS had issued an Interpretation on February 1, 1978, by which it defined psychosurgery; a portion of said interpretation reads as follows:

> "PSYCHOSURGERY means brain surgery on: (1) normal brain tissue of an individual who does not suffer from any physical disease, for the purpose of changing or controlling the behaivor or emotions of such individual; or (2) diseased brain tissue of an individual, if the primary object of the performance of such surgery is to control, change or affect any behavioral or emotional disturbance of such individual."

"PSYCHOSURGERY includes the implantation of electrodes destruction of or direct stimulation of brain tissue by any means (e.g., ultrasound, laser), and the direct application of substances to the brain, when the primary purpose of such intervention is to change or control behavior or emotions."

Since significant disagreement exists within the medical community as to the appropriateness of psychosurgery, OCHAMPUS concluded that it should be excluded under the CHAMPUS Basic Program.

This has been the position of OCHAMPUS up until the present as indicated by the recent issuance in the CHAMPUS Policy Manual Volume 1, Chapter III, Section 14, Page 64999.1.1 on January 23, 1984. Said policy concluded that psychosurgery is not in accordance with accepted professional medical standards and is not covered.

The Hearing Officer has viewed both sides of this argument. There are authorities cited by both parties which indicate opposite view points. The Hearing Officer is satisfied that Dr. Ballantine sincerely believes that his position in the rendering of these services are in the relm of proper medical practice; however, as indicated in Section G 75 of Chapter IV of the Regulation, the fact that a physician may prescribe, recommend or approve a service or supply does not of itself make it medically necessary or make the charge an allowable expense, even though it is not specifically listed as an exclusion within the Regulation. It is true that the Regulation does not specifically exclude the surgery; however, the CHAMPUS position with regard to the surgery has been well established going back to February 1, 1978.

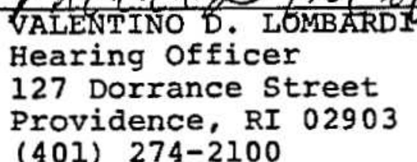
In order for a medical service to be allowable under the CHAMPUS Basic Program, it must be proven to be safe and efficacious and well accepted by a majority of the medical community. In the present case, the efficacy of psychosurgical procedures has been questioned and a review of all of the evidence would indicate that there is a tendency for polarization of opinion between those who support it and those who do not, and although there has been great attempts to minimize the complications, there still exists a strong medical opinion that this procedure is investigatory and/or experimental and not keeping with the generally acceptable norm for medical practice in the United States. The evidence did show that there are very few institutions and physicians who provide this medical service. There is no question that it has improved over the years, but to indicate that it is generally acceptable by the medical community is not possible.

CHAMPUS Regulations provide that benefits would include specified medical services and supplies provided to eligible beneficiaries from authorized sources, but subject to any and all applicable exculsions, therefore, if a specific surgery is performed on this patient is disallowed under the CHAMPUS Basic Program, all related medical services and supplies provided in conjunction with this service are also disallowed under the CHAMPUS Basic Program. The services must be rendered in connection with and dir-

ectly related to a covered diagnosis and/or definite set of symptoms requiring medically necessary treatment; if the treatment is determined to be medically unnecessary as not appropriate medical care and/or investigational/experimental, the related services are also determined to be not medically necessary and are specifically excluded from the CHAMPUS Basic Program.

SUMMARY

A Hearing Officer is authorized to conduct CHAMPUS hearings in compliance with the CHAMPUS Regulation as well as with policy statements, operating manuals, CHAMPUS handbooks, instructions, procedures and other guidelines issued by the director in effect that the time, the services and/or supply was provided. A Hearing Officer may not establish, amend, question or change, challange policy, procedures or instructions, but is to render a decision as to whether the initial determination in the case in question was made in accordance with said regulations, policies, procedures, instructions, etc. Based upon the facts as indicated by the evidence set forth in the Exhibit File and the testimony established at the hearing and in conjunction with the above-stated authority, the Hearing Officer must recommend that the determinations of OCHAMPUS as set forth in its Formal Review be upheld and the claims of Dr. Ballantine and Massachusetts General Hospital be denied. Based upon CHAMPUS policy, the inpatient medical services rendered to the beneficiary, by H. Thomas Ballantine, Jr., M.D. at the Massachusetts General Hospital, Boston, Massachusetts from October 28, 1982, through November 19, 1982, and from September 14, 1983, through September 20, 1983, are not covered benefits under the CHAMPUS Basic Program; and further, that any of these services or supplies related to the stereotactic cingulotomy surgery performed by Dr. Ballantine and provided by the hospital are also not covered benefits under the CHAMPUS Basic Program.



VALENTINO D. LOMBARDI
Hearing Officer
127 Dorrance Street
Providence, RI 02903
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Date: September 28, 1984