



ASSISTANT SECRETARY OF DEFENSE  
WASHINGTON, D. C. 20301

MAY 31 1983

HEALTH AFFAIRS

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

Appeal of )  
Sponsor: ) OASD(HA) File 83-06  
SSN: ) FINAL DECISION

This is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 83-06 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the beneficiary, the spouse of an active duty officer in the United States Air Force.

The beneficiary was represented by her husband at the hearing. The appeal involves the questions of CHAMPUS cost-sharing of claims for the right and left radial keratotomies undergone by the beneficiary. A radial keratotomy was performed on the left eye of the beneficiary on March 11, 1980, and on March 25, 1980 the same surgery was performed on the beneficiary's right eye. Each procedure involved an overnight hospitalization. The amount in dispute involves total hospital charges of \$750.40 and physician charges of \$2,141. Initially the CHAMPUS fiscal intermediary cost-shared the first procedure and the hospital claim for the second surgery. Following receipt and denial of the claim for the physician's fee on the second surgery, the fiscal intermediary determined that the initial claims has been erroneously paid and initiated recoupment action to recover the claims payment.

The Hearing File of Record, the Hearing Officer's Recommended Decision, and the Analysis and Recommendation from the Director, OCHAMPUS have been reviewed. The hearing was taped, however, the tape mostly consists of static and therefore only the evidence from the hearing as summarized in the Hearing Officer's Recommended Decision was available for consideration.

It is the Hearing Officer's recommendation that the OCHAMPUS denial of cost-sharing be upheld on the basis that benefits were correctly denied for radial keratotomy under the experimental procedures exclusion of CHAMPUS Regulation DoD 6010.8-R, chapter IV, G.15. The Director, OCHAMPUS concurs and recommends adoption of the Recommended Decision to deny cost-sharing as the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs).

The Acting Assistant Secretary of Defense (Health Affairs) after due consideration of the appeal record, concurs in the recommendation of the Hearing Officer to deny CHAMPUS cost-sharing and hereby adopts the recommendation of the Hearing Officer as the FINAL DECISION. The FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) is therefore to deny CHAMPUS payment of all claims involving the radial keratotomy performed on the left eye on March 11, 1980 and on the right eye on March 25, 1980. This decision is based on the finding that radial keratotomy is an experimental/investigatory procedure and is not within the generally accepted norm for medical practice in the United States.

#### FACTUAL BACKGROUND

The record shows that on March 6, 1980 a nonavailability statement was issued by \_\_\_\_\_ Air Force Base for the beneficiary. The nonavailability statement includes the remark that, "the type of care required is not provided by this facility: Keratotomy-Ophthalmologic."

The nonavailability statement also includes the following disclaimers:

"If you receive medical care from civilian sources and such care is determined to be authorized care under the CHAMPUS, it will be paid for by the Government to the extent that the program permits ....

If you receive medical care from civilian sources and it is determined that all or part of the care is not authorized under the CHAMPUS, THE GOVERNMENT WILL NOT PAY for the unauthorized care.

The determination of whether medical care you may receive from civilian sources is authorized for payment cannot be made at this time because this determination depends, among other things, upon the care you actually receive. Further, no statement regarding your condition or diagnosis made herein will be considered in any way determinative as to whether care rendered for such condition is payable under the CHAMPUS."

A radial keratotomy was performed on the left eye of the beneficiary on March 11, 1980 at \_\_\_\_\_ Medical Center and on March 25, 1980 the same surgery was performed on her right eye.

The sponsor submitted claims for each procedure by the treating physician. The surgeon billed \$1,000 for each operation, in addition there were charges for protective lenses and eye exams. The total charges were \$1,081 and \$1,060, respectively, for the

two operations. There were also billed charges from the overnight hospitalizations: \$321.20 for March 11-12, 1980 and \$429.20 for March 25-26, 1980.

Initially the fiscal intermediary cost-shared the first operation. The charges by the surgeon for the operation totaled \$1060.00 (\$1000.00 for the operation and \$60.00 for an examination and lens) and CHAMPUS paid \$448.30. On January 29, 1981, the sponsor requested an explanation why he had received no word or payment for his wife's second eye surgery and appealed the non-payment. By letter dated February 26, 1981 the fiscal intermediary advised the beneficiary the "right radial keratotomy ... was disallowed on September 5, 1980 because 'surgery and purchase of glasses for correction of refractive errors is not a Program Benefit.'"

However, on March 18, 1981 the fiscal intermediary sent out a standard form requesting additional information.

By letter dated March 25, 1981, the sponsor acknowledged he could not claim corrective lenses. He went on to state:

"Your CHAMPUS office was specifically called 6 Mar 80, and asked if the procedure 'radial keratotomy' was a covered benefit with an affirmative answer, 'radial keratotomy is a covered benefit', given to Capt [redacted], AFB, CHAMPUS office. CHAMPUS has paid only \$448.30 of the \$1,000 charge on the radial keratotomy of the left eye ... and now the enclosed claim is represented [sic] for payment of this procedure that had verified coverage at the time of the procedure from CHAMPUS."

The sponsor was informed on April 15, 1981 that the claim was disallowed and advised of his right to an informal review. On the same date by separate correspondence the fiscal intermediary reiterated radial keratotomy was an experimental procedure and requested a refund for the payment to the physician for the first surgery.

On April 24, 1981, the sponsor requested an informal review of the denial. The letter included a copy of an OCHAMPUS news release (No. 81-7) dated April 2, 1981. The news release stated:

"The Department of Defense recently issued a statement of policy excluding from CHAMPUS benefits the radial keratotomy surgical procedure to correct nearsightedness on the basis it is still experimental.

The Assistant Secretary of Defense (Health Affairs) ... stated, 'The National Advisory Eye Council (NAEC), the principal advisory

body to the National Eye Institute, recently approved a resolution expressing concern about the widespread adoption of this surgical procedure. The NAEC considers the radial keratotomy to be an experimental procedure because of its lack of adequate scientific evaluation in animals and humans."

By letter dated May 28, 1981, the sponsor was informed that, upon reconsideration, the charges for the surgery on March 25, 1980 were correctly denied. Also on May 28, 1981, the fiscal intermediary sought a refund from the Medical Center for the payments made for the two hospitalizations (March 11-12, and March 25-26, 1980) that were cost-shared. The refund was made by the hospital.

The sponsor on June 8, 1981 requested a First Level Appeal from OCHAMPUS. The letter included copies of previous correspondence but did not include any new medical evidence or information. By letter dated June 18, 1981, the sponsor requested the hospital not to make any refund and added the hospital claim to his appeal.

On July 29, 1981 OCHAMPUS issued its First Level Appeal determination upholding the denial of benefits and finding that radial keratotomy is an experimental procedure. The determination went on to state:

"Although you have not disputed the issue of whether or not radial keratotomy is an experimental procedure, that is the controlling factor in this case. Your appeal appears to be based on a telephone conversation in which your hospital registrar was informed that radial keratotomy was a covered CHAMPUS benefit. It is unfortunate that you were given this erroneous information; however, CHAMPUS benefits cannot be extended for any service or supply that is not in full compliance with the applicable law and regulation."

The sponsor then requested a hearing. In his request, he asked if CHAMPUS decided in November 1980 not to cover radial keratotomy, and argued for coverage of his wife's care on the basis that CHAMPUS promised coverage of the hospital bill if his wife checked in overnight; the procedure is simple and safe; the CHAMPUS office on 29 Feb 1980 gave a positive yes when asked if radial keratotomy was covered; and stated his wife had no problems with the procedure. He also attached articles from Newsweek and the Hospital Tribune in support of the procedure.

The Hearing was held on November 18, 1981 at Air Force Base, . The recommended decision of the Hearing Officer, Ms. , has been received and issuance of a FINAL DECISION is proper.

ISSUES AND FINDING OF FACT

The primary issue in dispute is whether radial keratotomy is an experimental procedure within the meaning of the CHAMPUS Regulation and therefore excluded from CHAMPUS cost-sharing. A secondary issue is whether prior approval by an employee of OCHAMPUS or the fiscal intermediary, and partial payment by the OCHAMPUS fiscal intermediary, can overcome the exclusion for experimental procedures.

The Department of Defense Appropriation Act, 1978, Public Law 95-111, prohibits 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...." A similar restriction has appeared in each subsequent Department of Defense Appropriation Act. The CHAMPUS Regulation implements this statutory restriction by excluding from CHAMPUS coverage, "services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury."

The CHAMPUS Regulation DoD 6010.8-R, chapter IV, also includes the following exclusion:

"Services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens."

The Regulation in DoD 6010.8-R, chapter II provides:

"'Experimental' means medical 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."

On April 16, 1981 OCHAMPUS issued an instruction, OCI 6010.34, classifying radial keratotomy as experimental. The instruction stated radial keratotomy is defined as "a surgical procedure used in the treatment of myopia (nearsightedness) in which sixteen (16) radial incisions are made into the corneal tissue." The OCHAMPUS instruction specifically noted that, "Any denial decision is appealable since Program determination of what constitutes experimental (investigational) surgery is judgemental, and thus an appealable issue." The OCHAMPUS instruction in its background discussion noted that:

"Studies were conducted by the National Advisory Eye Counsel (NAEC), the principal advisory body to the Eye Institute,

concerning the efficacy and safety of radial keratotomy. As a result of these studies, a resolution was passed May 29, 1980, by the NAEC classifying radial keratotomy as an experimental procedure.... The widespread presence of nearsightedness in the CHAMPUS beneficiary population, however, makes this particular situation somewhat unique. It therefore became important to issue a statement of policy on this issue, which appeared in the Federal Register on April 1, 1981."

The sponsor has presented no medical evidence to contradict the resolution by the National Advisory Eye Counsel that radial keratotomy is experimental. The sponsor did place two articles in the record. One was from Newsweek Magazine (March 31, 1980), and includes the statement that, "The few U.S. ophthalmologists who use Fyodorov's procedure [radial keratotomy] agreed that it is still largely experimental." Although the Hearing Officer found the other article from Hospital Tribune (May 1980) did not specifically refer to the procedure as experimental, the tenor of the article is one of collecting scientific data regarding long term followup. This article quotes the executive vice president of the American Academy of Ophthalmology as saying:

"Radial keratotomy has come into the public eye before adequate trials. We are trying to obtain the information we can, and it will be reported at our annual meeting.... The academy has no official position."

It is noted that the treating physician submitted no statement and so is not on record as claiming the procedure was not considered experimental in the United States as of March 1980 when the surgery occurred. The article in the Hospital Tribune did refer to the physician who performed the surgery on the beneficiary and indicated that he is the Secretary of the Kerato-Refractive Society, an international group formed to evaluate cornea surgery and that he encourages doctors doing the operation to send data to the society.

It must be concluded the evidence in the record is that radial keratotomy was considered an experimental procedure in March, 1980 and that there was no medical evidence to the contrary. Experimental procedures are specifically excluded from coverage by CHAMPUS regulation. The OCHAMPUS Instruction issued April 16, 1981 did not change the rules; rather it simply furnished information regarding the latest evaluation of radial keratotomy which continued to categorize it as an experimental procedure.

#### Secondary Issue

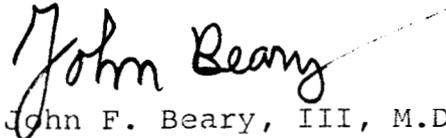
The sponsor also appealed on the basis that he received information prior to the surgical procedure that CHAMPUS had

agreed that it was a covered procedure. He states that the Health Benefit Advisor received this confirmation from the OCHAMPUS Liaison Office in Colorado. OCHAMPUS had no records to confirm the allegation and the Hearing Officer did not conclude that erroneous information was given. Rather, it was found that OCHAMPUS is not bound by any representation regarding coverage which may have been made by a Uniformed Services liaison officer.

Whether or not CHAMPUS benefits are payable cannot be ascertained until a fully completed claim is submitted and adjudicated. It is truly unfortunate when an advisor provides misleading, incomplete, or incorrect information to a sponsor or beneficiary. However, as has been repeatedly decided by this office in other appeals, CHAMPUS cost-sharing must be based on the merits of the case, in compliance with the law and applicable regulations. Prior FINAL DECISIONS have held that even assuming erroneous information was received, that fact would not overcome the law or regulation that prohibited or excluded the treatment. The patient is free to seek that medical care received which she believes to be necessary. I am constrained by law and regulation in determining what care is authorized for payment under CHAMPUS.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that the inpatient care and radial keratotomy surgery performed on the left eye of the beneficiary on March 11, 1980 and on the right eye of the beneficiary on March 25, 1980 were experimental procedures and therefore specifically excluded from CHAMPUS coverage and that any erroneous information that may have been received by the sponsor cannot alter the result. The claims for CHAMPUS cost-sharing of the two surgical procedures and the related hospital stays are denied and the Director, OCHAMPUS (or his designee) is directed to take appropriate action under the Federal Claims Collection Act to complete recovery of any erroneous payments of claims. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

  
John F. Beary, III, M.D.  
Acting Assistant Secretary