



ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

27 JUN 1983

HEALTH AFFAIRS

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

Appeal of)
Sponsor:) OASD(HA) File No 83-09
SSN:) FINAL DECISION

This is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) File No. 83-09. 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 (the sponsor), a retired officer of the United States Navy. The appeal involves claims for the implantation of an intraocular lens in the beneficiary's right eye. 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 have been reviewed. It is the Hearing Officer's recommendation that the CHAMPUS First Level Review Determination be upheld. That determination denied CHAMPUS coverage of three claims in the amount of \$2,582.04 for the intraocular lens implantation which the beneficiary received in 1980. The Hearing Officer's recommendation is based upon a finding that the implantation of the intraocular lens is specifically excluded as a CHAMPUS benefit under the provisions of DoD 6010.8-R and the actions of the U.S. Food and Drug Administration (FDA) in classifying the intraocular lens involved as an investigational device. The Director, OCHAMPUS concurs in this Recommended Decision and recommends that it be adopted as the FINAL DECISION. The Acting Assistant Secretary of Defense (Health Affairs) after due consideration of the appeal record accepts the Hearing Officer's Recommended Decision.

The FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs), therefore, is to deny the three CHAMPUS claims in the amount of \$2,582.04 for the implantation of an intraocular lens in the beneficiary's right eye in 1980 as having involved an investigational prosthetic implant which is specifically excluded from CHAMPUS coverage. This FINAL DECISION is based upon the appeal record as stated above.

FACTUAL BACKGROUND

The beneficiary underwent the surgical implantation of an intraocular lens in her right eye at the Medical Center, . She was hospitalized from July 28 to August 1, 1980. The diagnosed condition for which this procedure was performed was surgical aphakia; i.e., absence of the lens of the eye as the result of previous surgery.

Three CHAMPUS claims were submitted for the episode of care: A claim for the attending surgeon's services in the amount of \$825.00; a claim for the anesthesiologist's services in the amount of \$160.00; and a claim for the inpatient hospital stay in the amount of \$1,597.04. The two physicians' claims were denied by the fiscal intermediary. The hospital claim initially was erroneously allowed and a payment of \$1193.85 issued to the hospital. This erroneous payment was subsequently refunded by the hospital. The stated basis for the denials of the claims was the classification of the intraocular lens as an investigational device. There was no partial allowance on these claims because the procedure involved only the implantation of a prosthetic lens and not the concomitant removal of a cataract. The total of the billed charges in this case is \$2,582.04 and the potential amount in dispute is \$1,936.53 which represents the 75% CHAMPUS cost-share.

On appeal, the fiscal intermediary sustained the denial of CHAMPUS benefits for the procedure in question on October 28, 1980. The beneficiary was advised that because the intraocular lens had not received premarket approval from the U.S. Food and Drug Administration's Bureau of Medical Devices, its implantation was specifically excluded as a CHAMPUS benefit and the claims denial was thus not appealable. However, an appeal was requested and on December 30, 1980 OCHAMPUS accepted the sponsor's appeal on behalf of his wife for review. In the appeal request the sponsor pointed out that an earlier intraocular implantation performed on his wife's left eye had been cost-shared by CHAMPUS in 1976. He also noted that other third-party payors, including Medicare, were then extending benefits for the procedure. He argued that the term "experimental" as used in the CHAMPUS regulation applies only to animal studies and that, obviously, the intraocular lens was in relatively wide use in humans. Finally, he noted that the intraocular lens had been approved by the U.S. Food and Drug Administration for use in human investigational studies and argued that this meets the CHAMPUS requirement for FDA approval.

The OCHAMPUS First Level Appeal Determination sustained the denial of coverage on April 6, 1981, because the intraocular lens was found to be a non-covered prosthetic device and because the surgical implantation of such devices is considered to be experimental (investigational) under CHAMPUS. The beneficiary requested a hearing which was held on December 10, 1981.

At the hearing the beneficiary contended that the CHAMPUS regulation provisions excluding investigational procedures and prosthetic implants not approved by FDA, is unreasonable as applied to the intraocular lens because it denies a benefit to CHAMPUS beneficiaries which is paid by Medicare and which was previously paid by CHAMPUS. It was noted that most CHAMPUS beneficiaries eventually become eligible for Medicare benefits. The beneficiary argued that this situation discriminates against those CHAMPUS beneficiaries not eligible for Medicare.

In its hearing presentation OCHAMPUS introduced a number of exhibits illuminating the then current state of intraocular lens development and the initiatives undertaken by the Department of Defense with respect to the intraocular lens procedure. These documents establish that in 1977, when the FDA took action to classify intraocular lenses as investigational, there were substantial concerns about their safety and effectiveness. It was noted by OCHAMPUS that the FDA action was unusual in two respects. First, intraocular lenses were the first medical devices to have a regulation promulgated restricting their use to investigational studies. (The statutory basis for this classification is contained in the Medical Devices Amendments of 1976, Pub. L. 94-295.) Second, this action was taken in spite of a relatively long history of use and acceptance by the medical community. It was explained that the action of the FDA with respect to these devices was the cause of their being removed as a CHAMPUS benefit.

The OCHAMPUS submission also contained information relating to certain initiatives which were then underway within the Department of Defense regarding intraocular lenses. OCHAMPUS was then in the process of reviewing a recommendation which would have authorized a regulatory exception to the exclusion of investigative devices for intraocular lenses. This initiative was taken in recognition of the unique history relating to intraocular lenses, their acknowledged widespread use and the fact that a number of other third party payers, including Medicare, were authorizing the lenses as benefits.

The Hearing Officer has submitted his Recommended Decision in this case, finding that "the intraocular lens is specifically excluded from CHAMPUS cost-sharing coverage by DoD regulations and the action of the Food and Drug Administration in designating the intraocular lens as an investigational device." He recommended, therefore, that the OCHAMPUS formal review decision be affirmed. All prior administrative levels of appeal have been exhausted and issuance of a FINAL DECISION is proper.

ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the services provided to the beneficiary in July and August 1980 for the implantation of an intraocular lens were excluded from the CHAMPUS Basic

Program because the lens was an investigational device which is specifically excluded as a prosthetic implant which had not been approved for use in humans by the U.S. Food and Drug Administration.

The Department of Defense Appropriations Act for 1980, Public Law 96-154, prohibited the use of CHAMPUS funds to pay, among other matters:

"Any ... 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.

The current CHAMPUS regulation, DoD 6010.8-R, was implemented in June 1977. Paragraph II.B.104., defines medically necessary as:

"... the level of services and supplies (that is, frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury, ... Medically necessary includes concept of appropriate medical care."

Paragraph II.B.14., defines appropriate medical care, in part, as:

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

In further explanation, DoD 6010.8-R lists in chapter IV.G. those services and supplies which are specifically excluded under the CHAMPUS Basic Program. Specifically cited are services which are:

Not in Accordance with Accepted Standards:
Experimental. Services and supplies not provided in accordance with the accepted professional medical standards; or related to essentially experimental procedures or treatment regimens." (Paragraph IV.G.15.)

The term "experimental" is defined in DoD 6010.8-R, paragraph II. B.68., as:

"Experimental. 'Experimental' means medical care that is essentially investigatory or an unproved procedure or treatment regimen (usually performed under controlled medical

legal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community Use of drugs and medicines not approved by the Food and Drug Administration for general use by humans (even though approved for testing on human beings) is also considered to be experimental. However, if a drug or medicine is listed in the U.S. Pharmacopoeia and/or the National Formulary, and requires a prescription, it is not considered experimental even if it is under investigation by the U.S. Food and Drug Administration as to its effectiveness."

The regulation generally excludes benefits for prosthetic devices, except artificial limbs and eyes and items which are surgically implanted into the body as an integral part of a surgical procedure (See paragraph D.3.g. and G.51, chapter IV, DoD 6010.8-R). A "prosthetic device" by definition, is considered to be an artificial substitute for a missing body part. (See paragraph B.145, chapter II, DoD 6010.8-R.) Under these provisions the intraocular lens is a prosthetic device which is implanted into the body as an integral part of a surgical procedure, and its medically necessary implantation can qualify for CHAMPUS benefits. However such devices must also meet the following condition:

In order for CHAMPUS benefits to be extended, any surgical implant must be approved for use in humans by the U.S. Food and Drug Administration. (Note to paragraph D.3.g., chapter IV, DoD 6010.8-R.)

There is no substantial dispute of the facts in this case. The beneficiary suffered from surgical aphakia and an appropriate treatment of that condition was medically necessary. The treatment chosen, implantation of an intraocular lens, involved the surgical implantation of a prosthetic device. At the time the procedure was performed intraocular lenses were restricted to investigational uses by the U.S. Food and Drug Administration, i.e. none had received the required premarket approval for general use in humans.

Based upon the foregoing regulatory provisions and undisputed facts, I find that the implantation of the intraocular lens in this case was specifically excluded as an experimental procedure involving the surgical implantation of a non approved prosthetic device.

The beneficiary has argued that the exclusion of experimental procedures should not apply to this case because the term "experimental" refers only to animal studies and not to

"investigational" studies in humans. However, this is clearly not the meaning intended by the use of the term "experimental" in DoD 6010.8-R. The regulatory definition makes clear that the CHAMPUS definition is broader and includes "medical care that is essentially investigatory or an unproven procedure or treatment regimen." (emphasis added) The definition also makes it clear that "experimental" includes "drugs and medicines not approved for general use by humans (even though approved for testing on human beings)." This provision does not specifically use the term "devices" but the intent expressed therein is clear. CHAMPUS does not provide coverage for services which are investigational, including those which are involved in human testing programs. While we recognize that in some minds there is a distinction between "experimental" and "investigational" along the lines of animal versus human studies, that distinction is not made in the CHAMPUS definition. It is this specific regulatory definition which we must apply in CHAMPUS appeals, and that definition clearly encompasses human investigative studies such as those pertaining to intraocular lenses.

The beneficiary also argued that the regulatory exclusion pertaining to non FDA approved prosthetic implants should not be applied in this case. She argues that the exclusion should apply only to implants which have not received any FDA approval for use in humans, i.e. those which are presumably restricted to animal studies. This argument is based upon the specific language of the exclusion which requires surgical implants to "be approved for use in humans." Obviously, FDA had given limited approval to the use of intraocular lenses in humans, albeit in connection with investigational studies only. I find the reading urged by the beneficiary too broad, especially when considered in the context of the Regulation as a whole. The kind of "approval" contemplated by the CHAMPUS provision is that which is involved in FDA premarket approvals. These allow the distribution and sale of medicine and devices for general use. This reading is consistent with the other provisions of the Regulation excluding experimental or investigatory procedures and with the requirements that CHAMPUS benefits be extended only for medically necessary treatments and those which are generally accepted and provided in accordance with good medical practice and established standards of quality.

The beneficiary also expressed concern that the CHAMPUS exclusion of intraocular lenses operates to discriminate against our beneficiaries vis-a-vis Medicare beneficiaries and those who obtain benefits from other third party payors who cover intraocular lenses. We recognize that this difference may appear inconsistent and may be regarded as unfair. However, we note that the Medicare program does not contain a specific exclusion of experimental procedure as does CHAMPUS. Rather, Medicare exclusions of experimental or investigatory services and items is based upon an interpretation of statutory provisions relating to the reasonableness and necessity of such items or services. I recognize that an anomalous situation may exist in the case of

intraocular lenses because some third party payors provide benefits for them and they are in relatively widespread use while still under investigation. This situation has arisen at least in part because of their general use before being classified as investigational by FDA. However, such historical anomalies do not warrant CHAMPUS authorizing intraocular lenses for CHAMPUS coverage in derogation of specific regulatory requirements.

In this appeal the Department of Defense has been urged to adopt such an exception to the rule on investigative or experimental treatment modalities in the case of intraocular lenses. As mentioned earlier, OCHAMPUS had under consideration, during the pendency of this appeal, a rule change which would have granted such an exception. That initiative was undertaken in recognition of the unique history pertaining to these devices. However, concomitantly the Food and Drug Administration began to grant premarket approval for individual intraocular lenses. For this reason OCHAMPUS has determined not to pursue the exception, but to rely on the approval process which is underway. To date about thirty-four intraocular lenses have received FDA premarket approval assuring a substantial choice for CHAMPUS beneficiaries and their physicians. I agree that the course taken by OCHAMPUS is the better one. I am convinced that in adopting a cautious approach and holding firm on the rules relating to investigatory procedures and devices, CHAMPUS is acting in the best interest of the Program and its beneficiaries. Investigatory treatments are by definition unproven in one or more respects. In 1977 FDA voiced substantial concern over the safety of intraocular lenses and their implantation, and to a lesser degree over their effectiveness. I do not believe it is appropriate for the Department of Defense to lend tacit encouragement to its beneficiaries to seek unproven treatments which may involve unnecessary or unwarranted complications and risks. At the time the care in this case was provided the risks associated with the implantation of intraocular lenses were considered too great for their approval for general use. In the interim a number of lenses have received premarket approval. However, CHAMPUS should not encourage more widespread use of those lenses which have not been approved by authorizing retroactive coverage beyond the date of premarket approval for a particular lens.

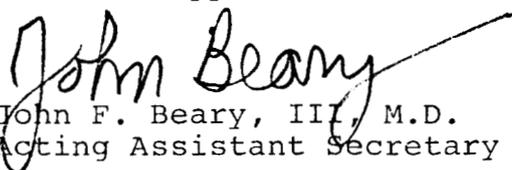
The Department of Defense recognizes individual preference for certain services and the possible improvement in a patient's condition which may be perceived as a result of such services. However, I am constrained by statutory and regulatory authorities to authorize CHAMPUS benefits only for services which are generally accepted in the treatment of disease or illness and are documented by authoritative medical literature and recognized professional opinion. The evidence in the Hearing File of Record indicates that at the time the services were rendered (July 1980), intraocular lens implantation was an investigational procedure and was recognized as such by the Food and Drug Administration.

In its initial processing of this appeal the fiscal intermediary did not offer appeal rights. The fiscal intermediary considered the intraocular lens to be specifically excluded as a CHAMPUS benefit because of the stated requirement for FDA approval. OCHAMPUS determined to allow an appeal because of a perceived need to clarify some of the issues relating to the investigational nature and history of the intraocular lens. While I agree with OCHAMPUS concerning clarification of this issue, I find that given the analysis and clarifications expressed herein, there can be no disputed issues of fact in other similar cases. Once a particular lens receives FDA premarket approval it will be allowed as a CHAMPUS benefit under existing authority. Therefore, these cases normally involve only a question upon which there can be no significant factual dispute, i.e. the FDA approval or the lack of it. CHAMPUS appeals are proper only in challenging determination in which there can be substantial factual disputes. They are not proper for challenging specific regulatory provisions and exclusions. For this reason it would not be proper to allow additional appeals on cases involving the denial of benefits for an intraocular lens which has not received FDA premarket approval at the time of its implantation.

The Hearing Officer found intraocular lens implantation to be an experimental or investigatory treatment which is excluded as a benefit of the CHAMPUS Basic Program. Based upon the foregoing analysis of this case, I concur with and hereby adopt the Hearing Officer's recommendation on this issue. Therefore, I find that the lens implantation surgery provided to the beneficiary in July and August, 1980, including related inpatient and ancillary services, was a part of an experimental treatment regimen and specifically excluded from coverage in the CHAMPUS Basic Program under the authorities cited above.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that the intraocular lens implant provided to the beneficiary in July and August of 1980 was not a covered procedure under CHAMPUS. This determination, is based on findings that, at the time of the care in question, the intraocular lens implant had not received premarket approval by the U.S. Food and Drug Administration, the safety of the implantation procedure had not been established, and the treatment was investigational. The appeal of the beneficiary is therefore denied. Issuance of this FINAL DECISION completes the administrative appeals process as provided under DoD 6010.8-R, chapter X, and no further administrative appeal is available.


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