18 MAY 1981

FINAL DECISION: OASD(HA) Case File 13-80
Appeal (Minor Child)
Appealing Party

The Hearing File of Record, the tape of the oral testimony presented at the Administrative Hearing, the Hearing Officer's RECOMMENDED DECISION and the Memorandum of Concurrence from the Director, OCHAMPUS, on OASD(HA) Appeal Case No. 13-80 have been reviewed. The amount in dispute is $20,296.00 (hospital costs, $13,311.00; professional fees, $2,500.00; neuroaugmentative device, $4,485.00). It was the Hearing Officer's recommendation that the initial determination to deny CHAMPUS benefits for the surgical implantation of a Cerebellar Stimulator, performed as a treatment for Cerebral Palsy should be upheld. It was the Hearing Officer's finding that the surgical implantation of the neuroaugmentative device (Cerebellar Stimulator) was essentially investigatory--i.e. experimental--and not in accordance with the generally accepted standards of usual medical practice. The Director, OCHAMPUS, concurred with the Hearing Officer's recommendation.

After due consideration and careful review of the evidence presented, the Principal Deputy Assistant Secretary of Defense (Health Affairs), acting as the designee for the Assistant Secretary, also concurs with the Hearing Officer's recommendation and accepts it as the FINAL DECISION.

PRIMARY ISSUE IN DISPUTE

The primary issue in dispute in this case is whether the surgical implantation of a Cerebellar Stimulator rendered as a treatment for Cerebral Palsy constituted care that can be considered as being provided in accordance with accepted professional medical standards or whether the procedure and device are still investigational (i.e. experimental) with respect to the treatment of Cerebral Palsy. Another issue is whether the device itself is still at the investigational stage of development particularly with respect to this procedure and whether it had received full marketing approval from the responsible Federal agency.

The applicable regulation in effect at the time the disputed services were rendered defined "experimental" [in part] as "... medical care that is essentially investigatory or an unproven procedure or treatment regimen ... does not meet the generally accepted standards of usual professional medical practice in the general medical community ..." (Reference: CHAMPUS Regulation DoD 6010.8-R, Chapter II, Subsection B, 67.) The Regulation further speaks to experimental services and supplies under the section describing exclusions and limitations, stating ... "[excluded are] Services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens." (Reference: CHAMPUS Regulation DoD 6010.8-R, Chapter IV, Subsection G. 16.)

Also under the section on exclusions and limitations the Regulation further states [in part] ... "[excluded are] all services and supplies (including inpatient institutional costs) related to a non-covered condition or treatment ..." (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER IV, Subsection G. 69.)

The appealing party, acting on behalf of his minor dependent daughter, and his spouse submitted statements and/or testimony which, in their view, supported the position that the surgical implantation of the Cerebellar Stimulator was a recognized accepted treatment for Cerebral Palsy and medically necessary for the child's well being. In addition, statements and published documents endorsing the procedure and device in the treatment of Cerebral Palsy from proponent physicians were submitted (although these physicians were not directly involved in the care of the beneficiary). Nonetheless, it is the finding of the Principal Deputy Secretary of Defense (Health Affairs) that the facts presented in this case do not support the appealing party's position.

In order to assure that the appealing party and all others concerned fully understand the bases upon which the CHAMPUS initial denial is being reaffirmed and upheld, each of the points at issue is addressed in this FINAL DECISION.

1. Presence of Cerebral Palsy: Treatment Medically Necessary. The appealing party strongly asserted that the surgical implantation of the Cerebellar Stimulator for the treatment of his daughter's Cerebral Palsy was appropriate and medically necessary to prevent progressive deterioration of her motor function due to continuous spasticity in all four extremities. The Hearing File of Record contains information which establishes that the beneficiary was diagnosed as having Cerebral Palsy when she was nine (9) months of age and that, at that

time, a regimen of physical therapy for relief of the spasticity was prescribed. These records indicate that the child was the product of a pregnancy complicated by the mother's suspected prediabetic state and amniotic fluid loss during the seventh month, at which time it was discovered that she had retained a contraceptive interuterine device (IUD). Shortly after the leakage of the amniotic fluid, the female child was delivered and described as premature, weighing three (3) pounds, nine (9) ounces. At the time the services in dispute were rendered, the beneficiary/patient was described as eight and one half (8½) years old, confined to a wheelchair with spasticity of all four extremities, with malformation of the feet, alert and without any distinct mental dysfunction. It was the appealing party's testimony that, although physical therapy had been helpful to some degree, it had not produced the type of results which would allow the beneficiary much motor function and that he was desperate to find some alternative which might reverse or retard the condition. It was not revealed as to how he became aware of the Cerebellar Stimulator surgical implantation procedure for Cerebral Palsy but the appealing party indicated that he first submitted his daughter as a candidate for the surgery when she was approximately age four. It was the physician's opinion at that time that she was too young and a delay was suggested. The procedure was not intended to treat the Cerebral Palsey condition itself, only to reduce the spasticity of the muscles associated with the disorder. According to the testimony of the appealing party, Cerebral Palsy is an incurable illness which is progressive at least in the areas of increased spasticity and loss of motor function and that the neuroaugmentative procedure was the only available alternative to retard further deterioration and [it was implied] that therefore CHAMPUS benefits should be available regardless of any other consideration. That the child suffered from Cerebral Palsy associated with severe spasticity and the fact that at present there is no known cure for the condition, were never at issue in the case. Nor was the basis of the CHAMPUS denial related to whether or not it was medically necessary to reduce the spasticity--that obviously was a worthwhile goal. Rather, denial was based on the finding that the surgical procedure (implantation of the Cerebellar Stimulator) and the related neuroaugmentative device are experimental--i.e. still investigational and unproven as to safety and efficacy and therefore excluded under CHAMPUS. (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.67.; CHAPTER IV, Subsection G.16.)

2. General Acceptance of Surgical Procedure in Professional Community: Weight of Evidence. The appealing party, the

attending physician and the Deputy Surgeon General of the appealing party's Military Service endorsed the surgical implantation of the Cerebellar Stimulator to control spasticity associated with Cerebral Palsy and asserted that the procedure was routine rather than experimental. Nonetheless the weight of evidence in the Hearing File of Record establishes that those professional groups and Federal agencies having special professional expertise and/or responsibility for public policy in this area were unanimous in their opinions that the disputed surgical procedure and device were still generally investigational and unproven. Despite espousal by certain individual proponent physicians, expert professional opinion is strongly to the contrary.

- o American Association of Neurological Surgeons. Statements received from the President of this Association confirmed that as late as February 1980, the procedure and the device were still considered to be at the investigational stage of development and that conclusions regarding safety and efficacy had not yet been drawn. The neurological specialists did not confirm that the procedure was standard practice within their specialty.

- o Department of Health and Human Services (DH&HS). This Federal Agency (formerly the Department of Health, Education and Welfare) reported that the National Institutes of Health and the Food and Drug Administration did not currently support the use of Cerebellar Stimulators as being safe and effective in the treatment of spasticity or movement disorders. These agencies did not indicate that the procedure or the device were generally accepted by the medical community or that development had progressed beyond the investigational stage.

- o Health Care Financing Administration (HCFA): Medicare. It was confirmed that Medicare, currently the largest Federal medical benefits program, considers the Cerebellar Stimulator implantation an investigational procedure. Benefits are not provided for this procedure under the Medicare Program on the basis that the Social Security Act prohibits expenditures of funds for experimental services.

- o Subcommittee of Neuroaugmentation Devices of the Joint Materials and Devices Committee. The chairman of this committee reported that implantation of Cerebellar Stimlator devices had not been proven to be effective

and that the committee did not recommend that it be included as a standard procedure in neurological surgery.

The professional associations of neurologists and neurosurgeons, as well as the National Institutes of Health[1/], the Department of Health and Human Services, the Food and Drug Administration and the Health Care Financing Administration were in agreement that the safety and efficacy have not been conclusively established for the implantation of the Cerebellar Stimulator at this time. Statements submitted by individual physicians in support of the procedure and the device generally reported only the results of their experiences with the procedure and did not provide evidence of scientifically controlled studies. The letter providing the position of the Surgeon General cited personal opinion only. Evidence of general acceptance within the medical community was not presented or substantiated. CHAMPUS does not unilaterally determine that a surgical procedure or treatment regimen falls within the definition of "experimental." Before such a Program decision is made, there is extensive research and consultation. In reaching its conclusion on the specific surgery and device at issue in this case, it is the CHAMPUS position that support for the procedure

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1/ To assure there has been no change in the status of the procedure since the time of the Administrative Hearing, the National Institutes of Health was contacted during March 1981. It was again confirmed that while there are those individual physicians who espouse the procedure and there is some anecdotal indication that the implantation procedure may be helpful, it is still considered investigational--i.e., it is still unproven as to the efficacy and safety. The scientific community has initiated controlled studies, but it will be at least another three years before sufficient scientific data will be available on which to base any conclusions. It is repeatedly pointed out by the scientific community that because the procedure (if eventually accepted) can be expected to be performed to a great extent on children and young adults, safety, particularly in relation to long term use, is of paramount importance.

coming from physician advocates cannot carry the same weight or credibility as the professional opinions expressed by the leadership of the neurological specialists' professional association or the Federal agencies charged with the responsibility of determining the efficacy and safety of medical procedures and devices. (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER IV, Subsection G.16.)

3. The Device. The status of the Cerebellar Stimulator as a medical device is also an issue in the case. The Cerebellar Stimulator was developed for implantation in human brain tissue and therefore its use and distribution is controlled under the Medical Devices Amendment enacted by Congress in 1976. This law awarded the responsibility of establishing the safety and efficacy of medical devices to the Food, Drug and Cosmetic Administration. This agency confirmed in February 1980 that, as of that date, the Cerebellar Stimulator attained Class III status which means it is still considered to be in the investigational stage of development and that approval for unlimited use will be awarded only after the safety and efficacy has been established. It is concluded, therefore, that the device as well as the procedure must be considered to fall within the CHAMPUS definition of "experimental" and thus excluded from benefits. (References: CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, Subsection B.67; CHAPTER IV, Subsections G.16. and Subsection G.69.)

SECONDARY ISSUES

The appealing party, while strongly supporting the surgery his daughter received, and describing it as beneficial for her condition, also directed substantial attention to secondary issues which he asserted supported special consideration for CHAMPUS benefits to be extended in this case.

1. Experiemental Exclusion: Terminology Vague and Nonspecific. The appealing party claimed that the CHAMPUS definition of "Experimental" was non-specific and vague. Of special concern to the appealing party was the use of the terms "experimental" and "investigatory" interchangably. It is true that in the scientific community the term "experimental" usually refers to experimentation limited to animals while investigational indicates that the procedure, device or therapeutic regimen involves human subjects. It was found, however, that in the non-scientific community that there was no such clear cut distinction and that the terms tended to

be used interchangeably but with both generally meaning unproven--i.e., without final results or conclusions. "Experimental" appeared to be in more dominant usage and thus is was used as the primary designation for the exclusion. Therefore, for the purposes of CHAMPUS the definition of "Experimental" was deliberately written to include the concept of "investigational" because it was the Program's intent to exclude both categories from benefits. Rather than being vague and nonspecific, it is our finding that the definition reflects an effort to use both terms in order to increase awareness and assure better understanding of the intent of this exclusion. In any event this assertion on the part of the appealing party must be considered inconsequental since regardless of the term used (i.e., experimental or investigatory), the available evidence clearly indicates that the neither the procedure nor the device have been approved or accepted as safe, effective or routine within the appropriate professional community or by the Federal agencies responsible for public policy. Because the Cerebellar Stimulator implant procedure was developed by a physician of some reputation, or because some of the reported results of using neuroaugmentative devices in Cerebral Palsy cases indicate possible promise, does not automatically establish the procedure and device as routine or appropriate. In the report provided by the American Association of Neurological Surgeons it is clear that this specialty group does not consider the procedure to be part of standard neurosurgical practice and views both the procedure and the device to be as in need of further assessment. Based on this report and the opinions of other authoritative sources, it can only be concluded that both the procedure and the device properly fall within the CHAMPUS definition of "experimental" (i.e. investigatory) as stated in the Regulation. (Reference: CHAMPUS Regulation DoD 6010.8-R, CHAPTER II, B., 67.)

2. No Grants or Other Funding. As part of his argument that the Cerebellar Stimulator implantation procedure was not either "experimental" or "investigational" the appealing party asserted that the attending physician and his associates were not funded by any research grants or other monies. (This information was in the form of personal testimony and not documented.) The absence of research grants or other funding [it was implied] automatically established that the procedure and the device are not experimental. Again, the fact that a physician's work has not been funded by public or private grants would indicate only that the physician either elected not to accept research or other grant money or that no money was offered or made available to him. This argument must be considered irrelevant since the lack of outside funding is unrelated to whether or not the

procedure and device have been proven to be safe and effective as a treatment for Cerebral Palsy.

3. Incurable Illness: Discrimination. The beneficiary/patient's Cerebral Palsy, with severe spasticity of all extremities and grossly impaired motor function, was described by the appealing party as an incurable disease which is anticipated to become even more handicapping as the child grows older. It was the appealing party's position that it was discriminatory on the part of CHAMPUS to deny victims of this disease the opportunity to take advantage of any modern scientific developments and medical innovations of their choosing which might reverse or retard the progressive deterioration associated with Cerebral Palsy. The appealing party is correct that at this point in time there is no known cure for Cerebral Palsy and that the usual therapeutic regimens have been shown to have little effect in most severe cases. It is very understandable that a parent would seek out treatments to help a child so aflicted. The discussion is to some extent misleading, however. First, CHAMPUS cannot and does not deny to any beneficiary the right to choose his/her medical care. This is a matter of individual and personal choice. It is, however, the Program's prerogative to determined what medical services/supplies qualify for benefits. In this case CHAMPUS did not make its determination on the basis the type of illness involved or that alternative therapies have not been successful or that the condition is considered incurable. The CHAMPUS decision was based on its finding that both the procedure and the device fall within its regulatory definition of "experimental" treatment. We do not agree that it is discriminatory to require that procedures, medical devices or therapeutic regimens offered to any patient (including those with Cerebral Palsy) be proven to be save and effective regardless of the circumstances. The child in this case is not being treated differently from any other beneficiary and it is our position she deserves equal protection.

4. Other Health Insurers Offer Coverage. The appealing party claimed that in determining what is accepted within the general medical community, the practices and policies of commercial and non-commercial health insurers should be considered. It was his position that since many health insurers were providing coverage for the costs associated with the implantation of Cerebellar Stimulators, CHAMPUS should also extend benefits. (As a matter of fact he claimed he had been specifically advised by an CHAMPUS official that availability of coverage was THE criteria used to determine whether a procedure was still "experimental." If such a

statement was actually made, it was in error.) Some documentation relative to a group of non-commercial medical plans indicated that while some did provide benefits, many others did not. There was no information presented as to the specific contractual provisions or limitations of those that did cover the surgery as compared to those that did not. Additional information concerning commercial insurers was not submitted to the record. (As reported earlier, Medicare, the largest Federal medical benefits program, considers the surgical procedure and neuroaugmentative devices for treatment of motor function disorders to be experimental since it had not yet been established that the procedures and devices were safe and effective.) The question of what other programs, plans and/or insurers do is, however, moot. First, the fact that some health benefit plans have determined that benefits can be provided is not persuasive inasmuch as their policies or certificates may or may not specifically exclude services and supplies which are experimental, investigatory and not provided in accordance with accepted medical standards. More importantly, however, the availability of CHAMPUS benefits is not based on the definitions and/or provisions of any other insurance or benefit plan whether private or Government-sponsored. CHAMPUS benefits are determined in accordance with its authorizing statute and applicable regulations governing the Program.

5. Previous Payments for the Cerebellar Stimulator. It was claimed that the attending physician had previously received CHAMPUS benefits for similar services. This claim was in the form of a personal statement only and no evidence from the attending physician was submitted to support this claim and no specific cases were cited. If CHAMPUS benefits were, in fact, extended in the past for the Cerebellar Stimulator implantation procedure, the benefits were provided in error whether under the current or prior regulation. (The prior regulation did not address "experimental" services specifically but did require that benefits be provided only for services and supplies rendered in accordance with accepted standards of medical practice.) Again, the discussion is moot because even if such a case(s) was paid, the Program is not bound by prior errors. In the case of an appeal, each case must be considered on its own merits, on the basis of the substantive issue(s), and in accordance with its authorizing statute and applicable regulation governing the Program.

6. Financial Hardship. The appealing party requested that his case be considered one of financial hardship because the expenses related to the Cerebellar Stimulator implantation

procedure provided for his daughter had cost in excess of $20,000. He claimed that this debt had seriously limited his ability to provide education for his other children and meet their other needs. Although financial hardship is now being claimed, the Hearing File of Record indicates that while still contemplating the surgery, the appealing party was specifically advised by OCHAMPUS in writing that the Cerebellar Stimulator implantation procedure as well as the device itself were considered experimental and that CHAMPUS benefits would not be available for any of the costs, including professional fees and hospital costs. It is our finding that the appealing party made a personal decision to proceed with the surgery well aware of the financial risks involved. Further, the records showed no evidence that the appealing party encouraged the limitation of expensive inpatient hospital days inasmuch as the beneficiary was confined a full ten (10) days prior to the surgery for the diagnostic work-up. All of the diagnostic studies performed in this case could have been (and routinely are) done on an outpatient basis without adverse effect on either the patient or the results of the tests. It should also be noted that the child's condition apparently did not require an inpatient setting for any of the medical tests since during this ten day period of preoperative testing the patient was permitted to leave the institution for extended excursions with her parents. Considering the potential for financial risk which was predicted by the OCHAMPUS written notice that both the surgical procedure and the device were considered to be experimental, it would appear that the appealing party would have been more prudent and would have encouraged a less extended inpatient confinement particularly during the preoperative period. Notwithstanding the described circumstances, it is always deeply regretted whenever a Program decision adversely impacts on a beneficary and his/her family. Nonetheless, financial hardship, per se, is not a valid basis on which to consider an appeal (particularly when the financial risk was known prior to incurring the expenses). To assure uniform unbiased Program decisions, consideration must be made on substantive issues as they relate to the law and regulations.

7. Service Approval. It was the appealing party's position that it was the intent of his Military Service that CHAMPUS provide benefits in this case. The Hearing File of Record does contain a letter from the Deputy Surgeon General supporting the appealing party in his appeal. The letter also indicated that the Surgeon General was familiar with the procedure, the device, and the attending physician in the case and offered the personal opinion that in the treatment of Cerebral Palsy, Cerebellar Stimulator implantation was

considered "routine." No documentation was submitted in support of these personal opinions and obervations, however. Although the Surgeon General and Deputy Surgeon General might have personally believed that Cerebellar Stimulator implantation procedures were "routine," other expert opinions indicated that these services fall with the regulatory definition of "experimental" (i.e., investigatory) and are not eligible for CHAMPUS benefits. We would point out again that the discussion is irrelevant since the individual Services do not have authority for Program policy or its application. This is the prerogative of the Office of the Assistant Secretary of Defense (Health Affairs). Any Service "intent" to pay for civilian medical care is limited to its available Supplemental funds--and cannot be extended to the use of CHAMPUS funds.

8. Determination by Non-Physicians. The Deputy Surgeon took strong exception to the CHAMPUS position in this case because [he claimed] decisions relative to what is or is not considered "experimental" are being made by non-physicians. The basis for this assumption was not explained. As is indicated by the information contained in this FINAL DECISION, no single individual in the Department of Defense, either physician or non-physician, unilaterally makes such determinations. Rather, Program policy is the result of extensive consultations with those professional groups having expertise in the field (i.e., physicians) and those agencies having responsibility for public policy (i.e., both physicians and non-physicians). It would appear the Deputy Surgeon General's reaction in this case must be attributed to misinformation.

9. Obligation to Active Duty Members. It was asserted that the financial hardship resulting from the CHAMPUS position severely limited the appealing party's ability to remain on active duty in the Air Force. He further contended that the Government was obligated to provide medical care for an active duty family and that if the needed care was not available from Uniformed Services Facilities, CHAMPUS benefits must be provided. It is agreed that, by law, the Government's obligation to provide all needed medical care to the active duty member is absolute. Based on the same statute, however, this absolute right does not extend to dependents of active duty members. It is unfortunate that many Military sponsors have this misconception. What the law does provide is that after the active duty member, their dependents have first priority for medical care at Uniformed Service medical facilities on a space available/professional capability basis, but this availability is not guaranteed. Where direct care is not available CHAMPUS benefits are provided subject to law and applicable regulations. CHAMPUS

is not now nor was, it ever, designed to be a full payment program. It has deductibles and requires cost sharing and there are benefit exclusions and limitations. Under the authority granted the Department of Defense, it has been determined that it is not appropriate for Program funds to be expended for surgical procedures or other treatment regimens which are still experimental/investigational and which have not been proven effective and safe. While this policy may adversely impact on an individual beneficiary, there is an overriding Program responsibility to protect all beneficiaries by assuring that funds are used only for safe, efficacious, appropriate and generally accepted treatment regimens.

RELATED ISSUE

Other Similar or Related Services/Supplies. While this FINAL DECISION applies specifically to the surgical implantation of the Cerebellar Stimulator (and related expenses) performed in 1978, its significance is more far reaching. The appealing party is therefore reminded that any similar services or supplies related to the care, maintenance or replacement of the implanted device continue to be excluded, including any related physician service or hospital stay.

SUMMARY

This FINAL DECISION in no way implies that the appealing party was not acting within his right as a parent when he elected to have his daughter undergo the disputed surgery or that it may not have had some beneficial effect. It simply reaffirms the Program's position that the Cerebellar Stimulator implantation procedure (as well as the device) falls under the "experimental" exclusion and therefore does not qualify for benefits.

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Our review indicates the appealing party has been afforded full due process in his appeal. Issuance of this FINAL DECISION is the concluding step in the CHAMPUS appeals process. No further administrative appeal is available.

SIGNED

Vernon McKenzie
Principal Deputy Assistant Secretary
of Defense (Health Affairs)

18 MAY 1981

FINAL DECISION
OASD(HA) 13-80

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Selby; Rewritten Carpenter/3E339/x75185/SC/11May1981

COORDINATION

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