ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS) 6 JUN 1984

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 84-13
	)	FINAL DECISION
SSN:	)	

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-13 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the CHAMPUS beneficiary, the spouse of a retired member of the United States Navy. The appeal involves the denial of CHAMPUS cost-sharing of a percutaneous transluminal coronary angioplasty (PTCA) and related institutional and professional care provided November 29 to December 4, 1981. The amount in dispute is $5,334.92.

The hearing file of record, 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 CHAMPUS cost-sharing of the PTCA be denied. The Hearing Officer found the care was experimental/ investigational when performed and was not medically necessary/ appropriate medical care. The Hearing Officer did recommend cost-sharing of the professional charges for interpretation of the cardiac catheterization data, affirming the OCHAMPUS Formal Review Decision.

The Director, OCHAMPUS, concurs with the Hearing Officer's Recommended Decision and recommends its adoption by the Assistant Secretary of Defense (Health Affairs) as the FINAL DECISION with the following modifications: the amount in dispute as stated in the Recommended Decision be corrected; the Hearing Officer's discussion of the secondary issue of equitable estoppel be modified for consistency with previous FINAL DECISIONS; and a discussion on the scope of exclusion of experimental procedures be added as a secondary issue.

The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, adopts and incorporates by reference the Hearing Officer's Recommended Decision, as modified in accordance with the recommendations of the Director, OCHAMPUS, to deny CHAMPUS cost-sharing of the PTCA and related

institutional and professional care based on findings the care was experimental/investigational when performed and was not medically necessary/appropriate medical care.

In my review, I find the Recommended Decision adequately states and analyzes the primary issues, applicable authorities, and evidence, including authoritative medical opinions, in this appeal. The findings are fully supported by the Recommended Decision and the appeal record. Additional factual and regulation analysis of the primary issues is not required. The Recommended Decision is acceptable for adoption as the FINAL DECISION by this office with minor modifications.

The Hearing Officer stated the amount in dispute to be $4,857.22. Review of the appeal record reveals this amount to be the allowable charges for the hospitalization of which $3,642.92 was paid. CHAMPUS claims for professional charges of $400.00 for consultations and hospital care and $1,500.00 for the PTCA were also submitted. The professional charges for the PTCA were denied and the $400.00 charge for consultation and hospital care was allowed in the amount of $256.00, including $88.00 for the interpretation of the cardiac catheterization data. Of the $356.00 in allowed charges, $192.00 was paid to the beneficiary. Therefore, the correct amount in dispute is the payment of the hospital care ($3,642.92) plus the denied PTCA ($1,500.00) plus the $192.00 payment for the consultation and hospital care for a total of $5,334.92.

Further, the Hearing Officer, in her discussion of erroneous payments, stated that the Federal Government is not bound by the doctrine of equitable estoppel in the absence of affirmative misconduct and that there is no evidence of affirmative misconduct by the fiscal intermediary in this appeal. In numerous FINAL DECISIONS, this office has stated that the Government is not estopped to deny erroneous acts of its agents, including its fiscal intermediaries, in violation of law or regulation. E.g., OASD(HA) File Numbers 84-03, 83-03, 80-15, and 80-10. To the extent the Hearing Officer's decision regarding the doctrine of estoppel is inconsistent with prior decisions of this office, I must reject it. Rejection of the Hearing Officer's discussion of the issue of estoppel does not materially affect the Hearing Officer's Recommended Decision in this case, however, because the Hearing Officer found that the appealing party failed to qualify for relief under the estoppel criteria most favorable to the appealing party.

Finally, the appealing party's attorney, in his closing argument, challenged the CHAMPUS definition of experimental as not in accordance with, and unduly restrictive of, the Appropriations Act provision limiting CHAMPUS cost-sharing to medically necessary services. The attorney also disputed the inclusion of the PTCA in the experimental category arguing the PTCA was not essentially investigatory or performed under controlled medicolegal conditions. Regarding the first argument, the Department of Defense Regulation governing CHAMPUS, DoD 6010.8-R,

clearly provides that a dispute regarding a requirement of law or regulation is not an appealable issue under the CHAMPUS appeal procedures (DoD 6010.8-R, chapter IX, A.5.). A challenge to the regulation exclusion of experimental procedures is a dispute regarding a requirement of regulation and is not cognizable under the appeals procedures.

Regarding the scope of the experimental exclusion, in OASD(HA) 83-09, this office made no distinction between "experimental" and "investigational" for purposes of CHAMPUS and determined the regulation definition of "experimental" is broad and includes investigatory or unproven procedures or treatment regimens. The attorney's attempt to distinguish the PTCA from the experimental category in arguing the procedure is not essentially investigatory or performed under controlled medicolegal conditions is ineffectual. The inclusion of essentially investigatory is designed to allow the Department of Defense to consider medical opinions in order to reach a determination on whether the procedures have made the transition from investigational to generally accepted. Additionally, the reference to "usually performed under controlled medicolegal conditions" is not a limitation in the definition but intended as a clear sign of an experimental procedure. The absence of discussion of this argument in the Recommended Decision does not affect the evidentiary discussion and findings that the care was experimental/investigational within the regulation definition. This argument is considered a secondary issue.

SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS cost-sharing of the percutaneous transluminal coronary angioplasty and related services provided to the appealing party November 29 to December 4, 1981, as this care was experimental/investigational when performed and was not medically necessary/appropriate medical care. The professional charges for interpretation of the cardiac catheterization data are approved for cost-sharing in the amount of $66.00 as I concur in the Hearing Officer's finding that the services were diagnostic and not related to the PTCA. As CHAMPUS payments of $3,642.42 for hospital charges and $126.00 for professional charges were issued erroneously, the matter of potential recoupment is referred to the Director, OCHAMPUS, for consideration under the Federal Claims Collection Act. Issuance of this FINAL DECISION completes the administrative appeal process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

William Mayer, M.D.

June 6, 1984

RECOMMENDED DECISION
Claim for CHAMPUS Benefits
Civilian Health and Medical Program of the
Uniformed Services (CHAMPUS)

Appeal of	)	
	)	
Sponsor:	)	RECOMMENDED DECISION
	)	
	)	
Social Security Number:	)	

This is the Recommended Decision of CHAMPUS Hearing Officer Hanna M. Warren in the appeal of , and is authorized pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, Chapter X. The appeal involves the denial of CHAMPUS cost sharing for a percutaneous transluminal coronary angioplasty, hospitalization to perform said procedure and related medical care from November 29, 1981, through December 3, 1981. The amount in dispute is approximately $4,857.22.

The hearing file of record and the testimony given at the hearing has been reviewed. It is the OCHAMPUS position that the formal review determination dated September 17, 1982, denying CHAMPUS cost sharing of the inpatient hospitalization for the procedure described as transluminal coronary angioplasty and related medical care be upheld on the basis that at the time the procedure was performed on Mrs. it was considered experimental and/or investigational for the treatment of coronary artery disease, not rendered in accordance with generally accepted professional medical standards and therefore not appropriate medical care under the CHAMPUS Law and Regulation.

The Hearing Officer after due consideration of the record and the testimony concurs in the recommendation of OCHAMPUS denying CHAMPUS cost sharing. The recommended decision of the Hearing Officer is therefore to deny cost sharing for the beneficiary's hospitalization at St. Luke's Hospital from November 29 through December 4, 1981, and the medical care provided in connection therewith including the percutaneous transluminal coronary angioplasty. The consulation on November 29th to interpret the catheterization data was a diagnostic procedure and should be cost shared by CHAMPUS. The beneficiary was admitted to St. Luke's Hospital, Houston, Texas on November 29, 1981, with a diagnosis of coronary artery disease after having suffered angina since July 1980. A consultation was held for interpretation of catheterization films submitted by the referring physician. On December 1, 1981, a percutaneous transluminal coronary angioplasty (PTCA) was performed along with a second angiogram which was used to visualize the area for the PTCA. She was discharged from the hospital on December 4, 1981. A claim for $4,882.22 for inpatient hospitalization was submitted to the CHAMPUS Fiscal Intermediary, Wisconsin Physician's Services (Exhibit 3, p.1). The Fiscal Intermediary allowed all of the billed hospital charges except for $25.00 for personal comfort items which were denied (Exhibit 7). Payment was made to the hospital of $3,642.92 (patient's cost share $1,214.30). A claim was submitted for professional services in the amount of $400.00 by Leachman Cardiology Associates. It included a $100.00 charge for the hospital admission and $200.00 for consultation for interpretation of

catheterization data; both on November 29, 1981. In addition it included medical care from November 30 through December 3 in the amount of $25.00 per day for a total of $100.00. A statement was also submitted by Leachman Cardiology Associates for $1,500.00 for the percutaneous transluminal coronary angioplasty (Exhibits 4 and 6). The Fiscal Intermediary allowed $88.00 for the hospital admission, $88.00 for the interpretation of catheterization data and $80.00 for the 4 hospital visits together but denied benefits for the $1,500.00 charge for the PTCA. This denial was upheld on informal review and reconsideration. The beneficiary then requested an OCHAMPUS formal review and a formal review decision was issued by OCHAMPUS which affirmed the Fiscal Intermediary's denial of benefits for the PTCA and also denied benefits for the related inpatient hospitalization and professional services provided from November 29, 1981, through December 4, 1981, with the exception of the interpretation of the catheterization data on November 29, 1981, which was allowed as a diagnostic procedure. The beneficiary requested a hearing which was held February 9, 1984, before OCHAMPUS Hearing Officer Hanna M. Warren; the beneficiary; her attorney, John Rank; and the beneficiary's husband. Steven G. Plichta attended the hearing representing OCHAMPUS.

ISSUES AND FINDING OF FACT

The primary issue in dispute is whether the percutaneous transluminal coronary angioplasty (PTCA) provided the appealing party was experimental for the treatment of coronary artery disease and therefore not rendered in accordance with generally accepted professional medical standards under the CHAMPUS Regulation, DoD 6010.8-R. Secondary issues that will be addressed include whether related hospital and medical care is a CHAMPUS benefit, coverage by other insurance programs, retroactive denial of care, and burden of proof.

EXPERIMENTAL MEDICAL CARE

The Civilian Health and Medical Program of the Uniform Services (CHAMPUS) is a health benefits program authorized under law as set forth in Chapter 55, Title 10, United States Code. The Department of Defense Appropriation Act of 1979, Public Law 95-457, in appropriating funds for CHAMPUS prohibited the use of such funds for "...any service or supply which is not medically or psychologically necessary to prevent, diagnose or treat a mental or physical illness, injury, or body malfunction as assessed or diagnosed by a physician, dentist, or clinical psychologist...". This prohibition has consistently appeared in each subsequent Department of Defense Appropriation Act.

The Department of Defense Regulation DoD 6010.8-R was issued under authority of statute to establish policy and procedures for the administration of CHAMPUS. The Regulation describes CHAMPUS benefits in DoD 6010.8-R Chapter IV A.1., as follows:

> "Scope of Benefits: subject to any and all applicable definitions, conditions, limitations, and/or exclusions specified or enumerated in this regulation, the CHAMPUS basic program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury including maternity care. Benefits include specified medical services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals, other authorized institutional providers, physicians and other authorized indi-

vidual professional providers as well as professional ambulance service, prescription drugs, authorized medical supplies and rental of durable equipment".

Medically necessary is defined in the Regulation as "the level of services and supplies (that is, frequency, extent and kind) adequate for the diagnosis and treatment of illness or injury (including maternity care). Medically necessary includes concept of appropriate medical care". In this same chapter of the Regulation appropriate medical care is defined as "a. that medical care where the medical services performed in the treatment of disease or injury...are in keeping with the generally acceptable norm for medical practice in the United States" (DoD 6010.8-R, Chapter II B.14).

Chapter IV of the Regulation in paragraph G provides as follows:

> Exclusions and Limitations: In addition to any definitions, requirements, conditions and/or limitations enumerated and described in other chapters of this Regulation, the following are specifically excluded from the CHAMPUS basic program. (Emphasis theirs).
>
> 15. Not in accordance with accepted standards: experimental. Services and supplies not supplied in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens.
>
> NOTE: The fact that a physician may prescribe, order, 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.

Experimental is defined in Chapter II B.68 as "medical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medical legal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community".

The CHAMPUS policy manual DoD 6010.47-M, Volume 1, Chapter IV, Section 2, p.75972.1 describes percutaneous transluminal coronary angioplasty as a procedure of inserting a balloon catheter into a narrow or occluded artery in order to canalize and dilate the artery by inflating the balloon. PTCA in the treatment of arteriosclerotic obstruction in the lower extremities, i.e., the ileac, femoral, and popliteal arteries, is a covered procedure but the procedure involving other arteries, including coronary arteries, was considered investigational until December 29, 1982. For services after that date the angioplasty may be covered for treatment of stenotic lesions of a single coronary artery for patients when the likely alternative is coronary bypass surgery and the patients have the following characteristics: intractable angina inadequately controlled with maximal medical therapy; objective evidence of myocardial ischemia; and normal ventricular function.

In order to effectively administer world wide programs such as CHAMPUS, policy guidelines are established to interpret the Law and Regulation. These guidelines are constantly being reviewed by OCHAMPUS. This case is an example of

the evolution of a new medical procedure. Attachement A to Exhibit 32 is titled "Public Health Service Assessment of Percutaneous Transluminal Coronary Angioplasty for Treatment of Stenotic Lesions of a Single Coronary Artery-1982". This report was issued by the Office of Health Research, Statistics, and Technology (OHRST) which is a division of the Department of Health and Human Services. In describing its assessment activities it states as follows: "OHRST widely publicizes its plans to conduct evaluations so that all with information and viewpoints to contribute may do so. The involvement of other PHS agencies and experts from the private sector in gathering information, performing analysis, reviewing results, and reaching recommendations, provides access to wide experience and expertise and also fosters credibility and acceptance of the conclusions reached. The activities of OHRST are not aimed at affecting the practice of medicine nor does OHRST have regulatory authority on matters pertaining to health insurance coverage. Rather, its goal is to provide the Health Care Financing Administation (HCFA) with the best current evaluations of health care technology, so as to facilitate their policy and decision making processes". It goes on to state that the issues are generally raised by Medicare contactors when they concern new or unusual procedures or policy. A notice is then placed in the Federal Register stating that OHRST is beginning an evaluation; it then collects information, and evaluates it to develop a PHS recommendation. This PHS assessment which resulted from this OHRST study was submitted to Health Care Financing Administration regarding PTCA for treatment of stenotic lesions of the coronary arteries.

PTCA was first used to dilate the coronary artery of a patient suffering from ischemic heart disease in 1977. In 1979 the National Heart, Lung, and Blood Institute (NHLBI) established an international registry to collect baseline information as well as follow-up data on treated patients. A workshop was held in June 1981 to re-evaluate PTCA and data was presented at that time on 1500 patients who had been registered by April 1981 from 73 sites. The report states that the data "supported the technical feasibility and safety of the procedure in experienced hands. Unfortunately because the follow-up data were incomplete and scanty, a meaningful assessment of overall efficacy was not possible". A discussion followed of the complications and success rates reported by different physicians performing the procedure. It states on page 11 that the complications with PTCA appear to be the leading major concern of this procedure and one reviewer of Registry Information concluded that PTCA had been unsuccessful in approximately forty per cent (40%) of the patients. At the time of the report the position of following professional societies on PTCA is given on page 15. The American College of Physicians found it to be an investigational procedure: "the immediate efficacy and safety of the procedure is not established". The Cardiovascular Procedures and Cardiovascular Surgery Committees of the American College of Cardiology find that "rather than being considered experimental at this time, the ACC committees describe PTCA as investigative; that is a technique which has progressed to limited human applications, but one which as yet cannot be considered as a standard procedure in clinical medicine". The Society of Thorasic Surgeons finds it to be still in a clinical investigatory stage with its application limited to a small highly selected patient population. The American Roentgen Ray Society concluded in March, 1981, that there was insufficient clinical and experimental data to make a judgment regarding PTCA and that the entire procedure needed further study. The Joint Council for the International Cardiovascular Society and the Society for Vascular Surgery had concerns regarding the safety and clinical effectiveness of the technology and recommended that the federal government conduct a survey. The Society of Cardiovascular Radiology found it experimental only for

those lesions involving the left main stem coronary artery and the American Heart Association concluded that the procedure was safe and effective in experienced hands.

The OHRST report concluded that in carefully selected patients experienced cardiologists could obtain a success rate in excess of eighty per cent (80%) with a mortality rate of approximately one per cent (1%). In a memorandum from the Public Health Service to Health Care Financing dated August 5, 1982, it states that although the Public Health Service recognizes that the utility of PTCA has been demonstrated only on a short term basis they do take the position of recommending PTCA "for treatment of stenotic lesions of a single coronary artery limited to the group of patients described above". The Public Health Service recommends re-evaluation of PTCA in two years (Exhibit 32, attachment B). On the basis of this report, Medicare extended coverage for PTCA on November 15, 1982. OCHAMPUS utilized this report to evaluate the efficacy of this treatment and the decision was made to provide CHAMPUS benefits for coronary artery angioplasty provided the patients fell into the select patient group as outlined above, and coverage was extended as of December 29. 1982. The record, including a report by the OCHAMPUS Medical Director (Exhibit 18), indicates that the beneficiary in this hearing did qualify and meet the criteria for CHAMPUS coverage as of December 29, 1982.

At the hearing the beneficiary testified she became aware in October 1981 that "something needed to be done". She had been going to an internist, Lieutenant Commander Waack at the Naval Hospital and about that time she asked him what he would think about her going to a cardiologist because of her angina and he said he thought that was a good idea. He referred her to Dr. William David Jack, II who was a cardiologist at Spohn Hospital, Corpus Christi, Texas. She went to him in October, 1981, and he told her she had seventy-five per cent (75%) blockage and that something needed to be done. He said he would set up an appointment for her in Houston for angioplasty or it might be she would need bypass surgery.

Exhibit 33 is a letter written by Dr. Jack to Lieutenant Commander Waack after he had seen the beneficiary in a consultation and attached to it is the catheterization data and summary which was performed on her on November 13, 1981, by Dr. Jack. It was his opinion that a lesion in the anterior descending coronary artery was responsible for her angina and he stated "the location of this lesion is particularly dangerous. Should a total occlusion occur at that point the very extensive antero-septal infarction might result with greater than usual short term and long term morbidity-mortality. She is an ideal candidate for coronary angioplasty, and should that not be a successful procedure, she should probably have a single bypass through the left anterior descending coronary artery. Although we are making plans to do so, we have not set up a protocol for coronary angioplasty yet in Corpus Christi, and we are currently referring patients of this type to Houston". He continued by saying that he was going to start her on Beta Blockers "probably a small dose of Inderal, since she did not tolerate Lo Pressor previously".

The beneficiary testified that she did go to Houston and was seen by Doctor's Leachman and Angelini of Leachman Cardiology Associates who recommended that an angioplasty be performed. She testified at the hearing that none of the physicians she had seen ever told her that the procedure was experimental or investigational or that CHAMPUS might not pay. She was not certain that she asked as to whether payment would be made because she had a very severe heart

problem and "assumed would pay - saw no reason to doubt that it would not be paid". There was some discussion among the doctors in Houston as to whether a coronary bypass or the PTCA would be the recommended treatment, but once the decision was made, the beneficiary testified she did not sign any forms that said the procedure was experimental or investigational. No consent forms, even for the standby bypass surgery, are included in the hearing file.

Dr. Leachman wrote a letter dated September 16, 1983 (Exhibit 34) in which he stated "we had first applied this technique in the treatment of patients in December 1979 and by 1981 had sufficient experience with the technique to consider it a feasible therapeutic modality. Since there was a year of experience, it seems to me that limiting payment or at least partial payment for this procedure to those angioplasties done after November, 1982, is a rather arbitrary decision". (NOTE: This is the date Medicare approved payment, not CHAMPUS).

After the beneficiary found that CHAMPUS was denying coverage she spoke with Dr. Jack and he has written a letter for her regarding this issue which is Exhibit 35. He describes his care of her and then states that PTCA has been performed in this country "since about 1979. At the time of my recommendation (late 1981) it was becoming an increasingly accepted alternative to coronary bypass surgery. I certainly did not consider this as being experimental although it was only being performed in a relatively limited number of centers at that time. PTCA has continued to gain in popularity and now is much more widely available including many community hospitals".

After the denial the beneficiary also requested a letter from Kenneth M. Kent, M.D., Director of Cardiac Catheterization Laboratory, Georgetown University Hospital, Washington D.C. which was admitted as Exhibit 36. In this letter Dr. Kent reports the first transluminal coronary angioplasty was performed in September 1977 and a preliminary report of its use was presented at the workshop in June 1979 held by the National Institute of Health. "At that time, the procedure was considered a clinical investigation. The following year, the Federal Drug Administration approved the coronary angioplasty catheter under the Medical Devices Act. Certainly, by December 1, 1981, transluminal coronary angioplasty was performed at Georgetown University Hospital and hundreds of hospitals around the country as a routine procedure for selected patients with coronary artery disease. At that time in my own practice, I was being reimbursed for performing transluminal coronary angioplasty by most of the third party providers that we billed". Dr. Kent goes on to state that the alternative would have been a coronary bypass operation which would have cost considerably more money. This alternative and its cost was also pointed out by Dr. Jack (Exhibit 35) and the beneficiary and her counsel.

At the hearing the beneficiary submitted a letter from the Director of the American Hospital Association who stated that his association did not take a position "on any judgments as to whether medical treatment is experimental or a accepted procedure". He enclosed an article from the Council on Scientific Affairs of the American Medical Association which was admitted as Exhibit 37. The date of the report is not entirely clear. It is dated 1982 and appears to have been adopted at the 1982 interim meeting of the House of Delegates, but the record does not indicate when that meeting took place. The opening paragraph states "Because the technique of percutaneous transluminal coronary angioplasty (PTCA) has therapeutic potential and is one of increasing interest to physicians, AMA's Council on Scientific Affairs in December 1981, estab-

lished a panel to review medical knowledge about this new technique and experience with it to date. The CSA requested that the panel report on the therapeutic use of PTCA in the iliofemoral, coronary and renal artery beds".

After describing the procedure itself the report of the Council on Scientific Affairs discusses the need for "careful patient selection" and that the experience of the person performing the procedure is crucial. The report goes on to discuss the use of drugs before, during, and after the procedure and the availability of performing a second procedure. It discusses the results of PTCA in femoral and iliac arteries and then has a two-page discussion of the procedure with coronary arteries. It details the ideal candidate for the procedure and emphasizes that because of complications that may occur consultation with a cardiovascular surgeon "is mandatory before the procedure; and, during the procedure itself, there must be surgical back-up". It discusses the success rate regarding successful dilation and improvement in symptoms, warning "long term results are not yet available". PTCA can be less costly than surgery because of fewer complications and, of course, a shorter hospitalization. Page 9 contains the report's conclusions and recommendations and reiterates the advantages of experienced operators and the need to carefully choose the patients. This report concludes: "Because PTCA is a relatively new procedure it would be desirable to have a national registry that utilizes objective methods to evaluate the early and late results of PTCA in each arterial bed. PTCA offers promise in the treatment of vascular lesions. The panel emphasizes that physicians should be aware of the risk factors associated with atherosclerosis and should advise their patients in the best management of those factors".

It is my conclusion that PTCA for coronary artery disease in December 1981 was still an investigational/experimental procedure and thus not in accordance with generally accepted medical standards for medical practice in the United States and excluded from benefit under the CHAMPUS program.

The issue of medical necessity, appropriate care and experimental procedures was discussed in a previous final decision by the Assistant Secretary of Defense (Health Affairs) who held: "I am constrained by regulatory authorities to authorize 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 opinions" (OASD-HA-0181). The decision goes on to state that the care which was at issue was not medically necessary based upon "lack of medical documentation, authoritative medical literature and recognized professional opinions sufficient to establish a general acceptance and efficacy of the program at the time the care was received. The specific CHAMPUS Regulation bears repeating as appropriate care is defined as where the medical services performed 'are in keeping with the generally acceptable norm for medical practice in the United States'."

OCHAMPUS determined that percutaneous transluminal coronary angioplasty was an experimental and/or investigational procedure prior to December 29, 1982, more than one year after the beneficiary received the procedure in this hearing. This was based on extensive review and evaluation of the procedure by OHRST which was published in 1982. There is no known medical literature in the record showing the efficacy and general acceptance of PTCA in December 1981 except for the statements of the physicans who treated the beneficiary and even these show this procedure was in a stage of evolution. Dr. Jack says that in late 81 it was becoming an "increasingly accepted alternative". He did not consider this procedure to be experimental but goes on to state that it was

the American College of Physicians, and the American College of Cardiology felt the procedure was more investigational and experimental than the beneficiary's treating physicians.

Another issue raised by the beneficiary's representative is the fact that no one told her the procedure was experimental and that her doctors would not have risked malpractice exposure by performing an experimental procedure. The issue of legal malpractice is not appropriate to this decision and has no bearing whatsoever on whether CHAMPUS will extend benefits for any particular care. Mr. Rank stated in his closing argument "CHAMPUS thinks this lady should have known before she went in it was an experimental procedure" and he asks the rhetorical question of why didn't CHAMPUS put out notices to cardiologists at major medical centers that the procedure was experimental and would not be covered. I am certainly not holding that the beneficiary should have known this procedure was experimental at the time she had it done and I am making no judgment as to whether she should have been told by her physicians whether the procedure would be cost-shared by CHAMPUS. As hearing officer it is difficult for me to believe that people performing this procedure in December, 1981, would not be aware that Medicare was not extending benefits because of the age group of the potential patients, but my decision cannot be based on whether her physicians knew and/or told her, nor can it be based on the statements in the exhibits submitted by the beneficiary as to whether some third party payors were extending benefits for PTCA. With limited exceptions not applicable to this appeal CHAMPUS is an "at risk" program. Claims are filed, appropriate information is obtained, and the claim is adjudicated. This is clearly stated in the Nonavailability Statement submitted by the beneficiary (Exhibit 3, page 12). "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". CHAMPUS is a federal statutory benefits program operated pursuant to law and implementing regulations. While private insurance companies are free to contractually extend benefits without reference to enabling legislation I am bound by the CHAMPUS statutory provisions including various exclusions and limitations in the regulatory interpretation of the provisions. Different companies and governmental entities providing benefits for health care services all have different rules and regulations governing the coverage they provide. The same is true for CHAMPUS and as hearing officer I am bound by these specific provisions. What treatment is provided a particular patient is a personal choice between the patient and her doctor but a CHAMPUS claim must be allowed or denied based on the CHAMPUS laws and regulations. OCHAMPUS has not taken the position, nor do I as hearing officer in making this decision, that the beneficiary should have known that the care would not be reimbursed or that she should not seek medical care of her choice. My decision does not involve whether the actual care itself was properly provided but only whether the <u>charge</u> for the care will be cost shared by CHAMPUS.

The argument was made that this was an arbitrary decision as of December 29, 1982. I agree that it is difficult to look at the evolutionary state of this procedure in December, 1981, when subsequent studies, medical literature, and experience have shown it to be generally accepted in the medical community but that is what we must attempt to do since that is when the service was rendered. I am certain the beneficiary will agree that the CHAMPUS program must be administered in a fair and equitable manner to all participants. To insure this a Regulation has been published pursuant to the provisions of the CHAMPUS law and this Regulation, which has been extensively discussed in my decision, has

certain specific exclusions and criteria for coverage. One of these criteria for coverage is that the services provided must be generally medically accepted and not experimental/investigational. The record in this hearing regarding percutaneous transluminal coronary angioplasty shows that in December, 1981, evaluations were still being made of this treatment with respected professional societies taking the position it was still investigational. The general acceptance and efficacy of this procedure for coronary arteries is not supported by medical documentation and authoritative literature contemporaneous with the date of care.

RELATED MEDICAL CARE

The CHAMPUS regulation in Chapter IV, G, 66 excludes from CHAMPUS cost sharing "all services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment". Under this regulatory provision all related professional services and inpatient hospitalization must be denied since I have concluded that PTCA was a noncovered treatment in December 1981. OCHAMPUS has determined that the billing on November 29 for interpretation of the previous catherterization data was a diagnostic procedure to determine if angioplasty or bypass surgery would be recommended to the beneficiary. I agree with that determination and recommend that the charge for the interpretation be cost shared by CHAMPUS. A previous final decision (OASD-HA-8346) states: "When a denial of coverage is appealed to OCHAMPUS, the entire episode of care must be taken into consideration. In those instances where there has been a previous cost sharing of part of the claim, there is the possibility that previously paid claims will also be denied cost sharing. The appeal process is not limited to segments of a claim; as stated above, it must address the entire episode of care".

The payment by the CHAMPUS Fiscal Intermediary of the hospitalization and some related medical charges was erroneous. It is unfortunate that this erroneous determination was made and the argument made by the beneficiary and her representative is one of estoppel. The fact that erroneous payments were made (whether or not subsequently identifed and recouped) is not in any way binding upon the program in connection with future benefit payments. The error cannot be used as the basis for making further erroneous payments; to do otherwise would result in perpetrating a mistake instead of correcting it. The federal government is not bound by the equitable doctrine of estoppel in the absence of affirmative misconduct and there is no evidence in the record to indicate affirmative misconduct on the part of the Fiscal Intermediary.

BURDEN OF EVIDENCE

A decision on a CHAMPUS claim on appeal must be based on evidence in the hearing filed of record. Under the CHAMPUS regulation the burden is on the appealing party to present whatever evidence she can to overcome this initial adverse decision (Chapter X, 16, (h and i). It is my decision that the beneficiary has not met this burden and the OCHAMPUS denial of benefits is amply supported by evidence in the record.

SUMMARY

In summary, it is the recommended decision of the hearing officer that the percutaneous transluminal coronary angioplasty provided to the beneficiary on December 1, 1981, be denied CHAMPUS cost-sharing because the care was ex-

periental/investigational at the time rendered for the treatment of coronary artery lesions and therefore not appropriate and medically necessary care under the CHAMPUS law and regulation. In addition, the hospitalization from November 29 through December 4, 1981, and attendant medical care should be denied as related to a noncovered treatment. However, the consultation for the interpretation of catherterization data on November 29, 1981, was a diagnostic procedure and should be cost-shared by CHAMPUS.

HANNA M. WARREN,
Hearing Officer

REC DEC

24-13

RECOMMENDED DECISION
Claim for CHAMPUS Benefits
Civilian Health and Medical Program of the
Uniformed Services (CHAMPUS)

Appeal of	)	
	)	
Sponsor:	)	RECOMMENDED DECISION
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Social Security Number:	)	

This is the Recommended Decision of CHAMPUS Hearing Officer Hanna M. Warren in the appeal of , and is authorized pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, Chapter X. The appeal involves the denial of CHAMPUS cost sharing for a percutaneous transluminal coronary angioplasty, hospitalization to perform said procedure and related medical care from November 29, 1981, through December 3, 1981. The amount in dispute is approximately $4,857.22.

The hearing file of record and the testimony given at the hearing has been reviewed. It is the OCHAMPUS position that the formal review determination dated September 17, 1982, denying CHAMPUS cost sharing of the inpatient hospitalization for the procedure described as transluminal coronary angioplasty and related medical care be upheld on the basis that at the time the procedure was performed on , it was considered experimental and/or investigational for the treatment of coronary artery disease, not rendered in accordance with generally accepted professional medical standards and therefore not appropriate medical care under the CHAMPUS Law and Regulation.

The Hearing Officer after due consideration of the record and the testimony concurs in the recommendation of OCHAMPUS denying CHAMPUS cost sharing. The recommended decision of the Hearing Officer is therefore to deny cost sharing for the beneficiary's hospitalization at St. Luke's Hospital from November 29 through December 4, 1981, and the medical care provided in connection therewith including the percutaneous transluminal coronary angioplasty. The consulation on November 29th to interpret the catheterization data was a diagnostic procedure and should be cost shared by CHAMPUS. The beneficiary was admitted to St. Luke's Hospital, Houston, Texas on November 29, 1981, with a diagnosis of coronary artery disease after having suffered angina since July 1980. A consultation was held for interpretation of catheterization films submitted by the referring physician. On December 1, 1981, a percutaneous transluminal coronary angioplasty (PTCA) was performed along with a second angiogram which was used to visualize the area for the PTCA. She was discharged from the hospital on December 4, 1981. A claim for $4,882.22 for inpatient hospitalization was submitted to the CHAMPUS Fiscal Intermediary, Wisconsin Physician's Services (Exhibit 3, p.1). The Fiscal Intermediary allowed all of the billed hospital charges except for $25.00 for personal comfort items which were denied (Exhibit 7). Payment was made to the hospital of $3,642.92 (patient's cost share $1,214.30). A claim was submitted for professional services in the amount of $400.00 by Leachman Cardiology Associates. It included a $100.00 charge for the hospital admission and $200.00 for consultation for interpretation of

catheterization data; both on November 29, 1981. In addition it included medical care from November 30 through December 3 in the amount of $25.00 per day for a total of $100.00. A statement was also submitted by Leachman Cardiology Associates for $1,500.00 for the percutaneous transluminal coronary angioplasty (Exhibits 4 and 6). The Fiscal Intermediary allowed $88.00 for the hospital admission, $88.00 for the interpretation of catheterization data and $80.00 for the 4 hospital visits together but denied benefits for the $1,500.00 charge for the PTCA. This denial was upheld on informal review and reconsideration. The beneficiary then requested an OCHAMPUS formal review and a formal review decision was issued by OCHAMPUS which affirmed the Fiscal Intermediary's denial of benefits for the PTCA and also denied benefits for the related inpatient hospitalization and professional services provided from November 29, 1981, through December 4, 1981, with the exception of the interpretation of the catheterization data on November 29, 1981, which was allowed as a diagnostic procedure. The beneficiary requested a hearing which was held February 9, 1984, before OCHAMPUS Hearing Officer Hanna M. Warren; the beneficiary; her attorney, John Rank; and the beneficiary's husband. Steven G. Plichta attended the hearing representing OCHAMPUS.

ISSUES AND FINDING OF FACT

The primary issue in dispute is whether the percutaneous transluminal coronary angioplasty (PTCA) provided the appealing party was experimental for the treatment of coronary artery disease and therefore not rendered in accordance with generally accepted professional medical standards under the CHAMPUS Regulation, DoD 6010.8-R. Secondary issues that will be addressed include whether related hospital and medical care is a CHAMPUS benefit, coverage by other insurance programs, retroactive denial of care, and burden of proof.

EXPERIMENTAL MEDICAL CARE

The Civilian Health and Medical Program of the Uniform Services (CHAMPUS) is a health benefits program authorized under law as set forth in Chapter 55, Title 10, United States Code. The Department of Defense Appropriation Act of 1979, Public Law 95-457, in appropriating funds for CHAMPUS prohibited the use of such funds for "...any service or supply which is not medically or psychologically necessary to prevent, diagnose or treat a mental or physical illness, injury, or body malfunction as assessed or diagnosed by a physician, dentist, or clinical psychologist...". This prohibition has consistently appeared in each subsequent Department of Defense Appropriation Act.

The Department of Defense Regulation DoD 6010.8-R was issued under authority of statute to establish policy and procedures for the administration of CHAMPUS. The Regulation describes CHAMPUS benefits in DoD 6010.8-R Chapter IV A.1., as follows:

> "Scope of Benefits: subject to any and all applicable definitions, conditions, limitations, and/or exclusions specified or enumerated in this regulation, the CHAMPUS basic program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury including maternity care. Benefits include specified medical services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals, other authorized institutional providers, physicians and other authorized indi-

vidual professional providers as well as professional ambulance service, prescription drugs, authorized medical supplies and rental of durable equipment".

Medically necessary is defined in the Regulation as "the level of services and supplies (that is, frequency, extent and kind) adequate for the diagnosis and treatment of illness or injury (including maternity care). Medically necessary includes concept of appropriate medical care". In this same chapter of the Regulation appropriate medical care is defined as "a. that medical care where the medical services performed in the treatment of disease or injury...are in keeping with the generally acceptable norm for medical practice in the United States" (DoD 6010.8-R, Chapter II B.14).

Chapter IV of the Regulation in paragraph G provides as follows:

> Exclusions and Limitations: In addition to any definitions, requirements, conditions and/or limitations enumerated and described in other chapters of this Regulation, the following are specifically excluded from the CHAMPUS basic program. (Empnasis theirs).
>
> 15. Not in accordance with accepted standards; experimental. Services and supplies not supplied in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens.
>
> NOTE: The fact that a physician may prescribe, order, 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.

Experimental is defined in Chapter II B.68 as "medical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medical legal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community".

The CHAMPUS policy manual DoD 6010.47-M, Volume 1, Chapter IV, Section 2, p.75972.1 describes percutaneous transluminal coronary angioplasty as a procedure of inserting a balloon catheter into a narrow or occluded artery in order to canalize and dilate the artery by inflating the balloon. PTCA in the treatment of arteriosclerotic obstruction in the lower extremities, i.e., the ileac, femoral, and popliteal arteries, is a covered procedure but the procedure involving other arteries, including coronary arteries, was considered investigational until December 29, 1982. For services after that date the angioplasty may be covered for treatment of stenotic lesions of a single coronary artery for patients when the likely alternative is coronary bypass surgery and the patients have the following characteristics: intractable angina inadequately controlled with maximal medical therapy; objective evidence of myocardial ischemia; and normal ventricular function.

In order to effectively administer world wide programs such as CHAMPUS, policy guidelines are established to interpret the Law and Regulation. These guidelines are constantly being reviewed by OCHAMPUS. This case is an example of

the evolution of a new medical procedure. Attachement A to Exhibit 32 is titled "Public Health Service Assessment of Percutaneous Transluminal Coronary Angioplasty for Treatment of Stenotic Lesions of a Single Coronary Artery-1982". This report was issued by the Office of Health Research, Statistics, and Technology (OHRST) which is a division of the Department of Health and Human Services. In describing its assessment activities it states as follows: "OHRST widely publicizes its plans to conduct evaluations so that all with information and viewpoints to contribute may do so. The involvement of other PHS agencies and experts from the private sector in gathering information, performing analysis, reviewing results, and reaching recommendations, provides access to wide experience and expertise and also fosters credibility and acceptance of the conclusions reached. The activities of OHRST are not aimed at affecting the practice of medicine nor does OHRST have regulatory authority on matters pertaining to health insurance coverage. Rather, its goal is to provide the Health Care Financing Administation (HCFA) with the best current evaluations of health care technology, so as to facilitate their policy and decision making processes". It goes on to state that the issues are generally raised by Medicare contactors when they concern new or unusual procedures or policy. A notice is then placed in the Federal Register stating that OHRST is beginning an evaluation; it then collects information, and evaluates it to develop a PHS recommendation. This PHS assessment which resulted from this OHRST study was submitted to Health Care Financing Administration regarding PTCA for treatment of stenotic lesions of the coronary arteries.

PTCA was first used to dilate the coronary artery of a patient suffering from ischemic heart disease in 1977. In 1979 the National Heart, Lung, and Blood Institute (NHLBI) established an international registry to collect baseline information as well as follow-up data on treated patients. A workshop was held in June 1981 to re-evaluate PTCA and data was presented at that time on 1500 patients who had been registered by April 1981 from 73 sites. The report states that the data "supported the technical feasibility and safety of the procedure in experienced hands. Unfortunately because the follow-up data were incomplete and scanty, a meaningful assessment of overall efficacy was not possible". A discussion followed of the complications and success rates reported by different physicians performing the procedure. It states on page 11 that the complications with PTCA appear to be the leading major concern of this procedure and one reviewer of Registry Information concluded that PTCA had been unsuccessful in approximately forty per cent (40%) of the patients. At the time of the report the position of following professional societies on PTCA is given on page 15. The American College of Physicians found it to be an investigational procedure: "the immediate efficacy and safety of the procedure is not established". The Cardiovascular Procedures and Cardiovascular Surgery Committees of the American College of Cardiology find that "rather than being considered experimental at this time, the ACC committees describe PTCA as investigative; that is a technique which has progressed to limited human applications, but one which as yet cannot be considered as a standard procedure in clinical medicine". The Society of Thorasic Surgeons finds it to be still in a clinical investigatory stage with its application limited to a small highly selected patient population. The American Roentgen Ray Society concluded in March, 1981, that there was insufficient clinical and experimental data to make a judgment regarding PTCA and that the entire procedure needed further study. The Joint Council for the International Cardiovascular Society and the Society for Vascular Surgery had concerns regarding the safety and clinical effectiveness of the technology and recommended that the federal government conduct a survey. The Society of Cardiovascular Radiology found it experimental only for

those lesions involving the left main stem coronary artery and the American Heart Association concluded that the procedure was safe and effective in experienced hands.

The OHRST report concluded that in carefully selected patients experienced cardiologists could obtain a success rate in excess of eighty per cent (80%) with a mortality rate of approximately one per cent (1%). In a memorandum from the Public Health Service to Health Care Financing dated August 5, 1982, it states that although the Public Health Service recognizes that the utility of PTCA has been demonstrated only on a short term basis they do take the position of recommending PTCA "for treatment of stenotic lesions of a single coronary artery limited to the group of patients described above". The Public Health Service recommends re-evaluation of PTCA in two years (Exhibit 32, attachment B). On the basis of this report, Medicare extended coverage for PTCA on November 15, 1982. OCHAMPUS utilized this report to evaluate the efficacy of this treatment and the decision was made to provide CHAMPUS benefits for coronary artery angioplasty provided the patients fell into the select patient group as outlined above, and coverage was extended as of December 29. 1982. The record, including a report by the OCHAMPUS Medical Director (Exhibit 18), indicates that the beneficiary in this hearing did qualify and meet the criteria for CHAMPUS coverage as of December 29, 1982.

At the hearing the beneficiary testified she became aware in October 1981 that "something needed to be done". She had been going to an internist, Lieutenant Commander Waack at the Naval Hospital and about that time she asked him what he would think about her going to a cardiologist because of her angina and he said he thought that was a good idea. He referred her to Dr. William David Jack, II who was a cardiologist at Spohn Hospital, Corpus Christi, Texas. She went to him in October, 1981, and he told her she had seventy-five per cent (75%) blockage and that something needed to be done. He said he would set up an appointment for her in Houston for angioplasty or it might be she would need bypass surgery.

Exhibit 33 is a letter written by Dr. Jack to Lieutenant Commander Waack after he had seen the beneficiary in a consultation and attached to it is the catheterization data and summary which was performed on her on November 13, 1981, by Dr. Jack. It was his opinion that a lesion in the anterior descending coronary artery was responsible for her angina and he stated "the location of this lesion is particularly dangerous. Should a total occlusion occur at that point the very extensive antero-septal infarction might result with greater than usual short term and long term morbidity-mortality. She is an ideal candidate for coronary angioplasty, and should that not be a successful procedure, she should probably have a single bypass through the left anterior descending coronary artery. Although we are making plans to do so, we have not set up a protocol for coronary angioplasty yet in Corpus Christi, and we are currently referring patients of this type to Houston". He continued by saying that he was going to start her on Beta Blockers "probably a small dose of Inderal, since she did not tolerate Lo Pressor previously".

The beneficiary testified that she did go to Houston and was seen by Doctor's Leachman and Angelini of Leachman Cardiology Associates who recommended that an angioplasty be performed. She testified at the hearing that none of the physicians she had seen ever told her that the procedure was experimental or investigational or that CHAMPUS might not pay. She was not certain that she asked as to whether payment would be made because she had a very severe heart

problem and "assumed would pay - saw no reason to doubt that it would not be paid". There was some discussion among the doctors in Houston as to whether a coronary bypass or the PTCA would be the recommended treatment, but once the decision was made, the beneficiary testified she did not sign any forms that said the procedure was experimental or investigational. No consent forms, even for the standby bypass surgery, are included in the hearing file.

Dr. Leachman wrote a letter dated September 16, 1983 (Exhibit 34) in which he stated "we had first applied this technique in the treatment of patients in December 1979 and by 1981 had sufficient experience with the technique to consider it a feasible therapeutic modality. Since there was a year of experience, it seems to me that limiting payment or at least partial payment for this procedure to those angioplasties done after November, 1982, is a rather arbitrary decision". (NOTE: This is the date Medicare approved payment, not CHAMPUS).

After the beneficiary found that CHAMPUS was denying coverage she spoke with Dr. Jack and he has written a letter for her regarding this issue which is Exhibit 35. He describes his care of her and then states that PTCA has been performed in this country "since about 1979. At the time of my recommendation (late 1981) it was becoming an increasingly accepted alternative to coronary bypass surgery. I certainly did not consider this as being experimental although it was only being performed in a relatively limited number of centers at that time. PTCA has continued to gain in popularity and now is much more widely available including many community hospitals".

After the denial the beneficiary also requested a letter from Kenneth M. Kent, M.D., Director of Cardiac Catheterization Laboratory, Georgetown University Hospital, Washington D.C. which was admitted as Exhibit 36. In this letter Dr. Kent reports the first transluminal coronary angioplasty was performed in September 1977 and a preliminary report of its use was presented at the workshop in June 1979 held by the National Institute of Health. "At that time, the procedure was considered a clinical investigation. The following year, the Federal Drug Administration approved the coronary angioplasty catheter under the Medical Devices Act. Certainly, by December 1, 1981, transluminal coronary angioplasty was performed at Georgetown University Hospital and hundreds of hospitals around the country as a routine procedure for selected patients with coronary artery disease. At that time in my own practice, I was being reimbursed for performing transluminal coronary angioplasty by most of the third party providers that we billed". Dr. Kent goes on to state that the alternative would have been a coronary bypass operation which would have cost considerably more money. This alternative and its cost was also pointed out by Dr. Jack (Exhibit 35) and the beneficiary and her counsel.

At the hearing the beneficiary submitted a letter from the Director of the American Hospital Association who stated that his association did not take a position "on any judgments as to whether medical treatment is experimental or a accepted procedure". He enclosed an article from the Council on Scientific Affairs of the American Medical Association which was admitted as Exhibit 37. The date of the report is not entirely clear. It is dated 1982 and appears to have been adopted at the 1982 interim meeting of the House of Delegates, but the record does not indicate when that meeting took place. The opening paragraph states "Because the technique of percutaneous transluminal coronary angioplasty (PTCA) has therapeutic potential and is one of increasing interest to physicians, AMA's Council on Scientific Affairs in December 1981, estab-

lished a panel to review medical knowledge about this new technique and experience with it to date. The CSA requested that the panel report on the therapeutic use of PTCA in the iliofemoral, coronary and renal artery beds".

After describing the procedure itself the report of the Council on Scientific Affairs discusses the need for "careful patient selection" and that the experience of the person performing the procedure is crucial. The report goes on to discuss the use of drugs before, during, and after the procedure and the availability of performing a second procedure. It discusses the results of PTCA in femoral and iliac arteries and then has a two-page discussion of the procedure with coronary arteries. It details the ideal candidate for the procedure and emphasizes that because of complications that may occur consultation with a cardiovascular surgeon "is mandatory before the procedure; and, during the procedure itself, there must be surgical back-up". It discusses the success rate regarding successful dilation and improvement in symptoms, warning "long term results are not yet available". PTCA can be less costly than surgery because of fewer complications and, of course, a shorter hospitalization. Page 9 contains the report's conclusions and recommendations and reiterates the advantages of experienced operators and the need to carefully choose the patients. This report concludes: "Because PTCA is a relatively new procedure it would be desirable to have a national registry that utilizes objective methods to evaluate the early and late results of PTCA in each arterial bed. PTCA offers promise in the treatment of vascular lesions. The panel emphasizes that physicians should be aware of the risk factors associated with atherosclerosis and should advise their patients in the best management of those factors".

It is my conclusion that PTCA for coronary artery disease in December 1981 was still an investigational/experimental procedure and thus not in accordance with generally accepted medical standards for medical practice in the United States and excluded from benefit under the CHAMPUS program.

The issue of medical necessity, appropriate care and experimental procedures was discussed in a previous final decision by the Assistant Secretary of Defense (Health Affairs) who held: "I am constrained by regulatory authorities to authorize 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 opinions" (OASD-HA-0181). The decision goes on to state that the care which was at issue was not medically necessary based upon "lack of medical documentation, authoritative medical literature and recognized professional opinions sufficient to establish a general acceptance and efficacy of the program at the time the care was received. The specific CHAMPUS Regulation bears repeating as appropriate care is defined as where the medical services performed 'are in keeping with the generally acceptable norm for medical practice in the United States'."

OCHAMPUS determined that percutaneous transluminal coronary angioplasty was an experimental and/or investigational procedure prior to December 29, 1982, more than one year after the beneficiary received the procedure in this hearing. This was based on extensive review and evaluation of the procedure by OHRST which was published in 1982. There is no known medical literature in the record showing the efficacy and general acceptance of PTCA in December 1981 except for the statements of the physicans who treated the beneficiary and even these show this procedure was in a stage of evolution. Dr. Jack says that in late 81 it was becoming an "increasingly accepted alternative". He did not consider this procedure to be experimental but goes on to state that it was

only being performed in a "relatively limited number of centers at that time", which was late 1981. Dr. Leachman in his letter (Exhibits 15 and 34) suggests that CHAMPUS should base payment on his experience with this procedure. Dr. Kent was the only physician who described the procedure as "routine for selected patients with coronary artery disease" and stated it was being done at "hundreds of hospitals around the country". A controlled study submitted by the beneficiary, which is the report of the Council on Scientific Affairs of the AMA, was published the year after the beneficiary received her surgery and it states that the Council established a panel in December 1981 to "review medical knowledge about this new technique and experience with it to date". The panel investigating this new technique was appointed the same month as the beneficiary had her surgery. This would indicate to me as hearing officer that in December 1981 the AMA Council on Scientific Affairs considered the procedure still experimental and/or investigatory enough to want to evaluate it, especially since in its conclusions it recommends that a national registry be established to evaluate the results of the procedure.

I have considered the beneficiary's testimony regarding the improvement in her health and certainly the procedure appears to have been successful for her, but whether or not PTCA was successful or resulted in a lack of symptoms for this particular patient is not the issue. Payment of CHAMPUS benefits cannot be dependent upon treatment being successful in any individual case. The efficacy of a treatment regimen must be established and be recognized by national professional organizations in the medical profession, not by individual patients. Another final defense decision, OASD-HA-83-04 states: "The Department of Defense recognizes individual preference for certain services and possible improvements of the 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". Benefits are predicated on the regulatory requirements of whether the treatment is still experimental/investigatory at the time it is rendered. The record in this case establishes the investigational and/or experimental nature of PTCA in December 1981 and does not contain evidence satisfactory to overcome the policy adopted by OCHAMPUS.

There were several points raised by the beneficiary's attorney at the hearing that I would like to address. He made the point that many patients had been treated with this procedure prior to December 1981 and discussed the numbers which were given in articles submitted both by the beneficiary and by OCHAMPUS. Since this procedure can be used on only five to ten per cent of the patients with coronary artery disease, the argument was made that these were a significant number of people and shows that this procedure was no longer experimental. He stated that the beneficiary had a special problem and that we must look to major medical centers where the tough problems go. At Georgetown and Houston Medical Centers this was not an investigatory or experimental procedure but was "state of the art". I would like to point out that I am not using as the sole basis for my decision that this procedure was not being performed in smaller hospitals and only being done in major medical centers. I agree with Mr. Rank that this would be an unduly restrictive interpretation of the generally accepted norm. The problem is that the record shows that speciality societies of physicians working in this area including the Scientific Council of the AMA,

the American College of Physicians, and the American College of Cardiology felt the procedure was more investigational and experimental than the beneficiary's treating physicians.

Another issue raised by the beneficiary's representative is the fact that no one told her the procedure was experimental and that her doctors would not have risked malpractice exposure by performing an experimental procedure. The issue of legal malpractice is not appropriate to this decision and has no bearing whatsoever on whether CHAMPUS will extend benefits for any particular care. Mr. Rank stated in his closing argument "CHAMPUS thinks this lady should have known before she went in it was an experimental procedure" and he asks the rhetorical question of why didn't CHAMPUS put out notices to cardiologists at major medical centers that the procedure was experimental and would not be covered. I am certainly not holding that the beneficiary should have known this procedure was experimental at the time she had it done and I am making no judgment as to whether she should have been told by her physicians whether the procedure would be cost-shared by CHAMPUS. As hearing officer it is difficult for me to believe that people performing this procedure in December, 1981, would not be aware that Medicare was not extending benefits because of the age group of the potential patients, but my decision cannot be based on whether her physicians knew and/or told her, nor can it be based on the statements in the exhibits submitted by the beneficiary as to whether some third party payors were extending benefits for PTCA. With limited exceptions not applicable to this appeal CHAMPUS is an "at risk" program. Claims are filed, appropriate information is obtained, and the claim is adjudicated. This is clearly stated in the Nonavailability Statement submitted by the beneficiary (Exhibit 3, page 12). "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". CHAMPUS is a federal statutory benefits program operated pursuant to law and implementing regulations. While private insurance companies are free to contractually extend benefits without reference to enabling legislation I am bound by the CHAMPUS statutory provisions including various exclusions and limitations in the regulatory interpretation of the provisions. Different companies and governmental entities providing benefits for health care services all have different rules and regulations governing the coverage they provide. The same is true for CHAMPUS and as hearing officer I am bound by these specific provisions. What treatment is provided a particular patient is a personal choice between the patient and her doctor but a CHAMPUS claim must be allowed or denied based on the CHAMPUS laws and regulations. OCHAMPUS has not taken the position, nor do I as hearing officer in making this decision, that the beneficiary should have known that the care would not be reimbursed or that she should not seek medical care of her choice. My decision does not involve whether the actual care itself was properly provided but only whether the <u>charge</u> for the care will be cost shared by CHAMPUS.

The argument was made that this was an arbitrary decision as of December 29, 1982. I agree that it is difficult to look at the evolutionary state of this procedure in December, 1981, when subsequent studies, medical literature, and experience have shown it to be generally accepted in the medical community but that is what we must attempt to do since that is when the service was rendered. I am certain the beneficiary will agree that the CHAMPUS program must be administered in a fair and equitable manner to all participants. To insure this a Regulation has been published pursuant to the provisions of the CHAMPUS law and this Regulation, which has been extensively discussed in my decision, has

certain specific exclusions and criteria for coverage. One of these criteria for coverage is that the services provided must be generally medically accepted and not experimental/investigational. The record in this hearing regarding percutaneous transluminal coronary angioplasty shows that in December, 1981, evaluations were still being made of this treatment with respected professional societies taking the position it was still investigational. The general acceptance and efficacy of this procedure for coronary arteries is not supported by medical documentation and authoritative literature contemporaneous with the date of care.

RELATED MEDICAL CARE

The CHAMPUS regulation in Chapter IV, G, 66 excludes from CHAMPUS cost sharing "all services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment". Under this regulatory provision all related professional services and inpatient hospitalization must be denied since I have concluded that PTCA was a noncovered treatment in December 1981. OCHAMPUS has determined that the billing on November 29 for interpretation of the previous catherterization data was a diagnostic procedure to determine if angioplasty or bypass surgery would be recommended to the beneficiary. I agree with that determination and recommend that the charge for the interpretation be cost shared by CHAMPUS. A previous final decision (OASD-HA-8346) states: "When a denial of coverage is appealed to OCHAMPUS, the entire episode of care must be taken into consideration. In those instances where there has been a previous cost sharing of part of the claim, there is the possibility that previously paid claims will also be oenied cost sharing. The appeal process is not limited to segments of a claim; as stated above, it must address the entire episode of care".

The payment by the CHAMPUS Fiscal Intermediary of the hospitalization and some related medical charges was erroneous. It is unfortunate that this erroneous determination was made and the argument made by the beneficiary and her representative is one of estoppel. The fact that erroneous payments were made (whether or not subsequently identifed and recouped) is not in any way binding upon the program in connection with future benefit payments. The error cannot be used as the basis for making further erroneous payments; to do otherwise would result in perpetrating a mistake instead of correcting it. The federal government is not bound by the equitable doctrine of estoppel in the absence of affirmative misconduct and there is no evidence in the record to indicate affirmative misconduct on the part of the Fiscal Intermediary.

BURDEN OF EVIDENCE

A decision on a CHAMPUS claim on appeal must be based on evidence in the hearing filed of record. Under the CHAMPUS regulation the burden is on the appealing party to present whatever evidence she can to overcome this initial adverse decision (Chapter X, 16, (h and i). It is my decision that the beneficiary has not met this burden and the OCHAMPUS denial of benefits is amply supported by evidence in the record.

SUMMARY

In summary, it is the recommended decision of the hearing officer that the percutaneous transluminal coronary angioplasty provided to the beneficiary on December 1, 1981, be denied CHAMPUS cost-sharing because the care was ex-

periental/investigational at the time rendered for the treatment of coronary artery lesions and therefore not appropriate and medically necessary care under the CHAMPUS law and regulation. In addition, the hospitalization from November 29 through December 4, 1981, and attendant medical care should be denied as related to a noncovered treatment. However, the consultation for the interpretation of catherterization data on November 29, 1981, was a diagnostic procedure and should be cost-shared by CHAMPUS.

HANNA M. WARREN,
Hearing Officer