ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301

MAR 3 1983

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT

SECRETARY OF DEFENSE (HEALTH AFFAIRS)

UNITED STATES DEPARTMENT OF DEFENSE

Appeal of	)	
	)	
Sponsor:	)	OASD(HA) File 82-11
	)	
SSN:	)	FINAL DECISION
	)	

This is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 82-11 pursuant to 10 U.S.C. Sections 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is a retired officer in the United States Air Force. The appeal involves the denial of CHAMPUS coverage for the treatment of erosive osteoarthritis with dimethyl sulfoxide (DMSO) at the Clinica De Especialistas, Piedras Negras, Mexico on November 15-17, 1978. The amount in dispute involves a $648.90 charge for the inpatient care.

The hearing file of record, the tape of oral testimony and the argument presented at the hearing, the Hearing Officer's Recommended Decision and the Analysis and Recommendation of the Director, OCHAMPUS have been reviewed. It is the Hearing Officer's recommendation that the OCHAMPUS denial of cost-sharing be upheld. The Director, OCHAMPUS concurs in the Recommended Decision and further recommends that certain clarifications as to secondary issues in the Recommended Decision be addressed in this FINAL DECISION.

The Acting Assistant Secretary of Defense (Health Affairs) after due consideration of the appeal record, concurs in the recommendation of the Hearing Officer to deny CHAMPUS cost-sharing and hereby adopts the recommendation of the Hearing Officer as the FINAL DECISION, with certain modifications involving the issue whether the treatment was an emergency inpatient admission.

The FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) is therefore to deny CHAMPUS cost-sharing of inpatient treatment at the Clinica De Especialistas of erosive osteoarthritis with DMSO. This decision is based on the finding that treatment of osteoarthritis with DMSO is not generally accepted medical practice, is not medically necessary nor appropriate medical care pursuant to CHAMPUS regulations, is

considered an investigative procedure, and DMSO is not medically approved by the United States Food and Drug Administration for treating osteoarthritis.

FACTUAL BACKGROUND

The record reflects that the beneficiary received medical care in the United States for several years for a deteriorating condition finally diagnosed as erosive osteoarthritis. The testimony at the hearing indicated that the treatment received by the beneficiary in the United States provided little or no relief and that some of the medical care undergone by the beneficiary may have been counterproductive in that her condition worsened. The record further reflects that the beneficiary sought medical care at the Clinica De Especialistas in order to obtain DMSO treatment and that she was aware that it may not be covered by CHAMPUS. The treatment was obtained on November 15-17, 1978 and the beneficiary believes the DMSO treatment to be successful and her condition improved.

A claim in the amount of $648.90 for the treatment at Clinica De Especialistas was filed with the CHAMPUS fiscal intermediary in January of 1980. The fiscal intermediary denied the claim on February 4, 1980, because the treatment has not been fully documented to be safe and effective for arthritis. The beneficiary appealed the decision and the following additional information was furnished by the clinic:

- Laboratory tests included "Blood count (red and white), Uric Acid, R A Test, Glucose, Urine (general), CBS, BUN, EKG, Thyroid Perfil Test."

- Treatment consisted of the following drugs - "(I.V. Fluids) for 3 days, T.L.C., S.S.A., Pyrazolone, Estrogen, Dyazepan, Mecoten, Bonadoxina, Glucose, (Dymety [sic] Sulphoxide)."

The fiscal intermediary continued to deny the claim on appeal because the care was determined to be experimental and the drugs could not be determined to be approved by the Food and Drug Administration.

Following an appeal to OCHAMPUS, medical consultants with the Colorado Foundation for Medical Care reviewed the file. These consultants, opined that the treatment received by the patient was not the standard treatment for osteoarthritis. They further opined that dimethyl sulfoxide (DMSO) is "an investigational drug with limited approved indication for use in the United States [treatment of interstitial cystitis]... it is not currently approved for treatment of osteoarthritis and therefore it is not considered medically appropriate for clinical use at this time." In consideration of the medical consultants' opinions, OCHAMPUS denied the appeal.

The beneficiary requested a hearing in this matter and the hearing was held on August 4, 1982, before CHAMPUS Hearing Officer. The Hearing Officer found, in his evaluation of the evidence including the testimony of the beneficiary and the exhibits that after the medical care in question, that is the DMSO treatment, the beneficiary's condition improved, she apparently had little or no further problems regarding the erosive osteoarthritis through the time of the hearing or at least, she had filed no additional claims that were at issue in the hearing. The Hearing Officer has issued his recommended Decision and issuance of a FINAL DECISION is proper.

PRIMARY ISSUES AND FINDINGS OF FACT

The primary issues in this appeal are whether the inpatient care on November 15-17, 1978, for the treatment of erosive osteoarthritis with DMSO was medically necessary/appropriate medical care; an investigational procedure; generally accepted medical practice; and involved drugs approved by the United States Food and Drug Administration.

The Department of Defense Appropriations Act, 1978, Public Law 95-111, prohibits the use of CHAMPUS funds for "... any service or supply which is not medically or psychologically necessary to diagnose and treat a mental or physical illness, injury or bodily malfunction...." This restriction has consistently appeared in each subsequent Department of Defense Appropriation Act.

Department of Defense Regulation 6010.8-R, chapter IV, G. implements this statutory restriction by specifically excluding from CHAMPUS coverage "Services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury." and "Services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens."

Department of Defense Regulation 6010.8-R, chapter II, defines medically necessary as:

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

In addition, DoD 6010.8-R defines appropriate medical care as:

> "That medical care where the medical services performed in the treatment of a disease or injury ... are in keeping with the generally

> accepted norm for medical practice in the United States."

Finally, DOD, 6010.8-R, chapter II, defines experimental/ investigational as:

> "[M]edical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community. The conduct of bio-medical or behavioral research involving human subjects at risk to physical, psychological, or social injury is experimental medicine. For the purposes of CHAMPUS, any medical services or supplies provided under a scientific research grant, either public or private, is classified as "experimental." (Financial grants-in-aid to an individual beneficiary are not considered grants for this purpose.) Use of drugs and medicines not approved by the Food and Drug Administration for general use by humans (even though approved for testing on human beings) is also considered to be experimental. However, if a drug or medicine is listed in the U.S. Pharmacopeia and/or the National Formulary and requires a prescription, it is not considered experimental even if it is under investigation by the U.S. Food and Drug Administration as to its effectiveness.
>
> Note: In areas outside the United States, standards comparable to those of the U.S. Food and Drug Administration is the CHAMPUS objective."

Treatment in this case was received outside the United States; however, the CHAMPUS regulation applies in all foreign countries unless specific exceptions are granted in writing by the Director, OCHAMPUS. DoD 6010.8-R, chapter I, B.1. No exemptions for Mexico have been made which are applicable to this case.

The requirements of the above cited regulation provisions are clear. The standard for determining the appropriateness of the beneficiary's treatment in Mexico is the same standard for identical treatment in the United States. Additionally, since the treatment involved a drug not approved by the Food and Drug Administration for general use, CHAMPUS coverage is prohibited within the United States and in areas outside the United States.

The treating physician did not provide a medical analysis of the treatment other than to indicate what laboratory tests were carried out and what drugs were administered. The only substantive medical evidence in the record was provided by the Colorado Foundation for Medical Care pursuant to a request by OCHAMPUS. This review was provided by two specialists, one in arthritis and rheumatic disease, the other in internal medicine.

The medical reviewers stated that erosive osteoarthritis is a localized form of osteoarthritis usually affecting the fingers. It differs from rheumatoid arthritis in that it is localized to the interphalangeal joints and is not systematic to other joints or other organ involvement as with rheumatoid disease. The medical reviewers further advised that treatment for erosive osteoarthritis mainly involves the relief of pain and reduction of inflammation. Surgical intervention is sometimes necessary in cases of advanced joint changes. Therapies may include moist heat, aspirin or sodium salicylate analgesics.

The medical reviewers also stated that dimethyl sulfoxide (DMSO) is an investigational drug with limited approved indication for use in the United States. The report indicated that DMSO has been reported to be effective in relieving pain, tenderness, swelling, muscle spasm and restoring range of motion, but is not currently approved for treatment of osteoarthritis and therefore is not considered medically appropriate for clinical use at this time. The reviewers advised DMSO is not approved by the Food and Drug Administration for treatment of osteoarthritis and that it is considered investigational for treatment for osteoarthritis.

The medical reviewers were specifially asked whether any of the nine drugs listed in the beneficiary's treatment were safe and effective in treating osteoarthritis and whether they met the generally accepted professional standards for treating this condition. The drugs and the reviewer's comments are as follows:

- T.L.C. - unknown what this is - tender loving care?
- S.S.A. - unknown what this is - perhaps ASA (aspirin)?
- Pyrazoline - Butazolidin may be used for short-term treatment only, not long-term treatment.
- Estrogen - no value
- Dyazepam - (Valium) - no value
- Mecoten - To our knowledge this is not currently being used in the United States. It is a very dangerous drug and can cause agranulocytosis.
- Bonadoxina - No value

- Glucose - No value

- Dimethyl sulfoxide - Not approved for use in the United States for osteoarthritis, and IV administration is highly questionable.

Based on the medical testimony and the record, it is concluded that the Hearing Officer's findings were well founded. His findings included the following:

o The medical care rendered by the Clinic at issue herein is not medically necessary nor appropriate medical care pursuant to CHAMPUS regulations.

o The portion of the medical treatment at issue herein, treatment of Beneficiary/Sponsor's erosive osteoarthritis with DMSO, is an experimental or investigational procedure as defined by CHAMPUS regulations.

o The medical care at issue herein was not rendered pursuant to generally accepted medical practice as set forth and prescribed by CHAMPUS regulations.

o The medical care at issue herein is medical care not approved by the United States Food and Drug Administration.

It is also apparent that the fact the beneficiary had to seek the DMSO treatment outside the United States is evidence that it was not a treatment within the generally accepted norm for medical practice in the United States.

In view of the above, I concur with the Hearing Officer and adopt his Recommended Decision as the FINAL DECISION to deny CHAMPUS coverage of the inpatient care on November 15-18, 1978, at Clinica De Especialistas.

Secondary Issues

Emergency Care

The Hearing Officer also addressed the issue whether the treatment rendered the beneficiary met the definition of a medical emergency. The hearing officer concluded it was not a medical emergency and I concur. However, had the Hearing Officer concluded it was a medical emergency the result would not be changed. Treatment that is deemed to be not medically necessary or appropriate, not rendered pursuant to generally accepted medical procedure in the United States and to be an investigational procedure is not covered by CHAMPUS whether administer in an emergency or non-emergency situtation. An emergency situation does not change the standards set forth in the DoD Regulation.

Success Of The Treatment

There is no testimony or evidence in the record to contradict the beneficiary's statement that she benefited from the DMSO treatment. Neither is there any clinical evidence submitted that substantiates the beneficiary's statement regarding the success of the DMSO. However, some credence must be given to the beneficiary's statement since she was a registered nurse with the Air Force and therefore has a medical background, though there was no showing that she had any expertise in this particular area. However, whether or not the treatment in question was or was not successful is moot. Assuming that it was, payment of CHAMPUS benefits is not dependent on a treatment being successful or a cure effected. Success of treatment is not a consideration in terms of an individual case. Benefits are predicated on an overall "effectiveness" basis, i.e., that a treatment is considered effective and appropriate by the general medical community. This showing was not made for the DMSO treatment.

The patient is free to seek that medical care which she believes to be necessary in the treatment for her medical conditions. However, I am constrained by law and regulation in determining what care is authorized for payment under CHAMPUS.

SUMMARY

In summary, it is the FINAL DECISION of the Acting Assistant Secretary of Defense (Health Affairs) that the inpatient care received on November 15-17, 1978, for treatment of erosive osteoarthritis with dimethyl sulfoxide and other drugs be denied CHAMPUS cost-sharing as the treatment is found not to be the standard treatment for osteoarthritis, that it was not medically necessary or appropriate, and that the drug DMSO is an investigational drug not currently approved for general use by the U. S. Food and Drug Administration. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X and no further administrative appeal is available.

John Beary

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