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# HCFA Rulings

Department of Health  
and Human Services

Health Care Financing  
Administration

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Ruling No. 82-1

Date: 1982

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**HCFA Rulings** are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous statutory or regulatory provisions relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

**HCFA Rulings** are binding on all HCFA components, the Provider Reimbursement Review Board and Administrative Law Judges who hear Medicare appeals. These decisions promote consistency in interpretation of policy and adjudication of disputes.

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HCFAR 82-1-1

MEDICARE PROGRAM

Hospital and Supplementary Medical Insurance Benefits (Parts A and B)

**Exclusion from Medicare Coverage of DMSO<sup>1</sup> for Conditions Other Than Interstitial Cystitis**

HCFAR 82-1

**Purpose:** This Ruling restates HCFA policy regarding Medicare coverage of DMSO.

**Citations:** Section 1862(a)(1) of the Social Security Act; 42 U.S.C. 1395y(a)(1); 42 CFR 405.310(k); 20 CFR 422.40; 47 FR 41867, September 22, 1982.

**Pertinent History:** The Medicare statute prohibits payment for any expenses incurred for items or services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" (section 1862(a)(1) of the Act). HCFA has interpreted this statutory provision to exclude from Medicare coverage medical and health care services and items that are not demonstrated to be safe and effective by acceptable clinical evidence. HCFA's source of medical advice on issues of medical safety and efficacy of services and items is the Public Health Service (PHS).

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<sup>1</sup> "DMSO" stands for dimethyl sulfoxide.

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HCFAR 82-1-2

DMSO has been used as an industrial solvent since the 1940s. In 1959, it was found to be useful in protecting biological tissues from damage when they are preserved by freezing. In 1963, DMSO was reported to have medicinal properties and an investigational new drug application for the study of its use in humans was approved by the Food and Drug Administration (FDA). Testing was halted, however, in 1965 after experiments in animals indicated that DMSO had adverse effects on the eyes. Experiments were resumed the following year in light of the lack of evidence of eye damage in humans.

In 1972, the FDA asked the National Academy of Sciences – National Research Council to evaluate all the data available to the FDA on use of DMSO in humans. A committee appointed by the Academy concluded that only a very small number of scientific reports could be used as the basis for scientific conclusions on the toxicity and effectiveness of DMSO. Further, the committee made the following conclusions:

- The evidence on DMSO does not warrant the general approval of the drug. There is suggestive evidence that DMSO may be effective in the treatment of acute traumatic injury and nontraumatic painful shoulder and in relieving the pain of rheumatoid arthritis.
- DMSO produces side effects, particularly of the skin, in many persons. In rare cases, DMSO has been linked to discolored patches of skin in humans. Also, when tested in some species of laboratory animals, DMSO altered the lens of the eye.

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HCFAR 82-1-3

- DMSO should be restricted to investigational use until it can be clearly demonstrated that its therapeutic effects are sufficient to risk the side effects it may cause.
- More reliable data are needed on the possible adverse effects and on the way DMSO works in the body.

The FDA approved DMSO for use in the symptomatic relief of chronic interstitial cystitis in 1978. HCFA consulted with PHS when preparing this ruling and again received advice that there is still insufficient evidence to establish that DMSO is safe and effective in conditions other than interstitial cystitis. The drug is currently being tested for other conditions.

**Ruling:** DMSO is not established to be safe and effective for any use other than interstitial cystitis; therefore, the use of DMSO for conditions other than interstitial cystitis is excluded from Medicare coverage under the authority of section 1862(a)(1) of the Act.

**Effective Date:** April 20, 1982