OPINION OF TRUSTEES

In Re

Complainant: Employee
Respondent: Employer
ROD Case No: 88-445 - May 29, 1992

Board of Trustees: Joseph P. Connors, Sr., Chairman; Paul R. Dean, Trustee; William Miller, Trustee; Donald E. Pierce, Jr., Trustee; Elliot A. Segal, Trustee.

Pursuant to Article IX of the United Mine Workers of America ("UMWA") 1950 Benefit Plan and Trust, and under the authority of an exemption granted by the United States Department of Labor, the Trustees have reviewed the facts and circumstances of this dispute concerning the provision of health benefits for progesterone therapy for premenstrual syndrome under the terms of the Employer Benefit Plan.

Background Facts

The Employee's spouse has been diagnosed by her physician as suffering from premenstrual syndrome (PMS). In October 1986, after more conservative treatment methods (restricted diet and multiple vitamins with B-Complex) had failed, her physician initiated a progesterone replacement therapy using prescribed progesterone suppositories. The Employee's spouse's physician, in a letter dated February 20, 1991, stated that progesterone suppositories are not approved by the Food and Drug Administration (FDA) for treatment of premenstrual syndrome. He also stated that this therapy is well known and widely used by obstetricians. A licensed pharmacist dispenses the drug in accordance with the physician's prescription. The Employer provided benefits for this drug therapy up until the fall of 1990 when a determination was made to discontinue benefits.

The Employer has denied payment for the progesterone suppositories, stating the drug is not FDA-approved, and is experimental for the treatment of premenstrual syndrome and, as such, is not covered under the Plan. The Employer has also stated that the past benefits provided for this drug were paid in error; however, they are not requesting a refund.

Dispute

Is the Employer required to provide health benefits for the treatment of the Employee's spouse's premenstrual-syndrome using progesterone suppositories?

Positions of the Parties

Position of the Employee: The Employer is required to provide benefits for the treatment of the Employee's spouse's premenstrual syndrome using progesterone suppositories because they appropriately provided benefits for the drug in the past. Article III. A. (4) of the Employer Benefit Plan provides benefits for drugs dispensed by a licensed pharmacist and prescribed by a physician. The Plan does not state that the drug requires FDA approval.

Position of the Employer: The Employer is not required to provide benefits for the treatment of the Employee's spouse's premenstrual syndrome using progesterone suppositories because it is not approved by the FDA for treatment of premenstrual syndrome. The use of progesterone suppositories in this instance would be considered experimental in nature, and, as such, excluded from coverage under the Employer Benefit Plan. The fact that the Employer paid benefits for the drug in the past is irrelevant in this instance.

Pertinent Provisions

The Introduction to Article III of the Employer Benefit Plan states:

Article III - Benefits

Covered services shall be limited to those services which are reasonable and necessary for the diagnosis or treatment of an illness or injury and which are given at the appropriate level of care, or are otherwise provided for in the Plan. The fact that a procedure or level of care is prescribed by a physician does not mean that it is medically reasonable or necessary or that it is covered under this Plan. In determining questions of reasonableness and necessity, due consideration will be given to the customary practices of physicians in the community where the service is provided. Services which are not reasonable and necessary shall include, but are not limited to the following: procedures which are of unproven value or of questionable current usefulness; procedures which tend to be redundant when performed in combination with other procedures; diagnostic procedures which are unlikely to provide a physician with additional information when they are used repeatedly; procedures which are not ordered by a physician or which are not documented in timely fashion in the patient's medical records; procedures which can be performed with equal efficiency at a lower level of care. Covered services that are medically necessary will continue to be provided, and accordingly this paragraph shall not be construed to detract from plan coverage or eligibility as described in this Article III.

Article III. A. (4) (a) of the Employer Benefit Plan states in pertinent part:

(4) Prescription Drugs

(a) Benefits Provided

Benefits are provided for insulin and prescription drugs (only those drugs which by Federal or State law require a prescription) dispensed by a licensed pharmacist and prescribed by a (I) physician for treatment or control of an illness or a nonoccupational accident or (ii) licensed dentist

for treatment following the performance of those oral surgical services set forth in (3)(e)....

Article III. A. (11) (a) 24. of the Employer Benefit Plan states:

(11) General Exclusions

(a) In addition to the specific exclusions otherwise contained in the Plan, benefits are also not provided for the following:

24. Charges for treatment with new technological medical devices and therapy which are experimental in nature.

Discussion

Article III. A. (4) (a) of the Employer Benefit Plan provides benefits for insulin and prescription drugs (only those drugs which by Federal or State law require a doctor's written prescription) dispensed by a licensed pharmacist, and prescribed by a physician for treatment or control of an illness or a non-occupational accident. The Introduction to Article III of the Employer Benefit Plan limits covered services to those that are reasonable and necessary for the diagnosis or treatment of an illness or injury and that are given at the appropriate level of care or are otherwise provided for in the Plan. The Introduction further states that services that are not reasonable and necessary shall include procedures of unproven value or of questionable current usefulness. In addition, Article III. A. (11) (a) 24. of the Plan excludes benefits for treatment with new technological medical devices, and therapy that are experimental in nature.

The Employer has stated that progesterone suppositories are not FDA-approved for treatment of premenstrual syndrome. Therefore, the Employer claims that any uses of progesterone suppositories other than those approved by the FDA are experimental in nature and specifically excluded from the Plan. The Employer cites ROD #84-123 in support of its opinion. The Trustees concluded in this ROD that the use of Minoxidil to treat psoriasis and hair loss was experimental and, therefore, not covered under the Plan. At the time of that ruling, the FDA had approved Minoxidil for the treatment of hypertension, and the Physician's Desk Reference (PDR) in use at the time included a warning that Minoxidil was indicated only in the treatment of severe hypertension due to the potential for serious side effects. In this case, the FDA has not approved progesterone suppositories for the treatment of premenstrual syndrome, but, they have not specified this use as non-approved or issued any adverse warnings concerning alternative uses.

Funds' staff have reviewed a number of articles in well-known medical periodicals and texts regarding the use of progesterone suppositories to treat PMS. These articles included a recent study-published in the Journal of the American Medical Association (JAMA), that was provided by the American Medical Association, as well as a Committee Opinion provided by the American College of Obstetricians and Gynecologists. The consensus is that while there appears to be widespread use of this treatment protocol, there is a lack of empirical evidence of its effectiveness. The common conclusion of the articles reviewed is that scientific trials have

rendered strong statistical evidence that this method of progesterone therapy lacks sufficient effect to be clinically useful. In fact, in the 1990 JAMA study there was no statistically significant difference in outcome between the groups using progesterone suppositories and the groups being given a placebo.

A Funds' medical consultant has reviewed this file along with the articles and advisories collected by Funds' staff and has advised that progesterone suppositories have not been approved by the FDA for the treatment of PMS and, that, such therapy should be considered experimental in nature. Since Article III. A. (11) (a) 24. of the Employer Benefit Plan excludes coverage for charges which are experimental in nature, the Trustees find that the charges for the progesterone suppositories would be ineligible for benefits under the terms of the Employer Benefit Plan.

Opinion of the Trustees

The Employer is not required to provide benefits for the treatment of the Employee's spouse's premenstrual syndrome using progesterone suppositories.