
OPINION OF TRUSTEES

In Re

Complainant: Pensioner
Respondent: Employer
ROD Case No: 88-256 - June 29, 1990

Board of Trustees: Joseph P. Connors, Sr., Chairman; Paul R. Dean, Trustee; William Miller, Trustee; Donald E. Pierce, Jr., Trustee; Thomas H. Saggau, 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 the prescription drug interferon when used in the treatment of metastatic kidney cancer.

Background Facts

The Pensioner's spouse had a radical nephrectomy (surgical removal of a kidney) in 1980 due to renal cancer and a modified radical mastectomy in 1981. In May 1989, a chest x-ray revealed that she had multiple lesions in the right lung where the cancer had spread from the kidney. Her physician prescribed Megace because of the advanced stage of her cancer; however, that drug was discontinued because it exacerbated her previously controlled diabetic condition. She began receiving injections of interferon (a chemotherapeutic agent) in May 1989.

The Employer denied payment for the interferon to treat the Pensioner's spouse's spreading kidney cancer. The Pensioner's spouse discontinued treatment with interferon when she learned that coverage would not be provided for it. The Pensioner's spouse's physician states that there was some growth of the cancer during the period when she discontinued treatment with the interferon. Treatment with interferon was resumed when her physician gave her some samples from the manufacturer free of charge. Her physician states that since October 1989, when treatment with interferon was resumed, chest x-rays have not revealed any further enlargement of the tumors in the lung.

Dispute

Is the Employer required to provide health benefits for the treatment of the Pensioner's spouse's metastatic kidney cancer with interferon?

Positions of the Parties

Position of the Pensioner: The Employer is required to provide benefits for the treatment of the Pensioner's spouse's metastatic kidney cancer with interferon because its insurance carrier has paid for the drug in the past.

Position of the Employer: The Employer is not required to provide benefits for the treatment of the Pensioner's spouse's metastatic kidney cancer with interferon because interferon does not have the approval of the Food and Drug Administration (FDA) for treatment of kidney cancer. Therefore, the use of interferon in this instance would be considered experimental in nature and, as such, it is excluded from coverage under the Employer Benefit Plan. The fact that the Employer's insurance carrier may have 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. (3)(k) of the Employer Benefit Plan states:

(3) Physicians' Services and Other Primary Care

(k) Radiation and Chemotherapy Benefits

Benefits are provided for treatment by x-ray, radium, external radiation or radioactive isotope (including the cost of materials unless supplied by a hospital), provided in or out of a hospital, when performed and billed by a physician.

When a Beneficiary's condition requires radiation therapy services in conjunction with medical, surgical or obstetrical services, benefits will be provided for such radiation therapy in addition to the payment for such other types of covered services if the physician performing the radiation therapy services is not the same physician who performs the medical, surgical or obstetrical services.

Benefits are provided for treatment of malignant diseases by chemotherapy provided in or out of the hospital when prescribed and billed by a physician.

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

The Pensioner contends that the Employer should provide benefits for the treatment of his spouse's kidney cancer with interferon because the Employer's insurance carrier has provided coverage for interferon in the past. However, the fact that the Employer's insurance carrier may have provided benefits for the drug in the past does not make it a covered benefit under the Employer Benefit Plan.

Article III. A. (3)(k) of the Employer Benefit Plan provides benefits for treatment of malignant diseases by chemotherapy when prescribed and billed by a physician. 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 that are 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 the FDA has approved the use of interferon for the treatment of hairy cell leukemia, AIDS-related Kaposi's sarcoma and genital warts, but not for the treatment

of metastatic kidney cancer. Therefore, the Employer claims that any uses of interferon other than those approved by the FDA are experimental in nature and specifically excluded from coverage under the Plan. The Employer states that its position is supported by the Trustees decision in ROD 84-123. The Trustees concluded in that case that the use of minoxidil to treat psoriasis and hair loss was experimental and not covered under the Plan because it had not been approved by the FDA for that use. At the time ROD 84-123 was decided, minoxidil had been approved by the FDA for the treatment of hypertension, and the Physicians' Desk Reference (PDR) in use at the time, which lists FDA-approved treatment indications, included a warning that minoxidil was indicated only in the treatment of severe hypertension because of the potential for serious adverse effects. Although the FDA has not approved interferon for the treatment of metastatic kidney cancer as used in this case, it has not specified such use as non-approved.

The Employer has further stated that a letter from the manufacturer of the drug to the Pensioner's spouse's physician specifically states that the drug should be used in the treatment of hairy cell leukemia and AIDS-related Kaposi's sarcoma; it does not mention its ability to treat renal cell carcinoma. A practicing oncologist has advised Funds' staff that there are numerous articles and studies citing the efficacy of interferon in treating kidney cancer and that interferon is now widely used and accepted by the medical community as a treatment for kidney cancer. Information obtained from the American Cancer Society, a recognized authority on the diagnosis and treatment of cancer, indicates that kidney cancer is a common indication for interferon treatments. The American Medical Association, professional association of physicians, published an article on tumor immunology in a 1987 edition of the Journal of the American Medical Association indicating that renal cell carcinoma has responded to treatment with interferon.

A Funds' medical consultant has reviewed this case and advises that the standard of care accepted by the medical community is to use interferon to treat metastatic kidney cancer. The consultant states that in 1989, The Medical Letter on Drugs and Therapeutics, an authoritative pharmaceutical treatment guide, did not list interferon as an experimental chemotherapy, but listed it as the preferred agent for the treatment of renal cell carcinoma. He also states that, according to the medical literature reviewed, interferon is most effective in treating metastatic renal cell carcinoma when there is involvement of the lung parenchyma (functional parts) or mediastinal nodes (those located in the mass of tissues and organs separating the lungs). The consultant advises that this was the case with the Pensioner's spouse's metastatic lesions; her chest x-ray report dated February 13, 1990 indicates that the interferon treatment caused a minimal decrease in the size of the lesion in the region of the upper right lung and a resolving of nodular densities in the lower right lung. The medical consultant is therefore of the opinion that the use of interferon in this instance is not experimental, but is medically reasonable and necessary for the treatment of the Pensioner's spouse's metastatic renal cell carcinoma.

The Employer has stated that Medicare would not cover interferon for treatment of kidney cancer because such use has not been approved by the FDA, and that this is also the general policy of the Employer's insurance carrier. However, Medicare allows coverage for use of an FDA-approved drug for indications other than those specifically approved by the FDA, when the FDA has not specified such use as non-approved, and subject to the Medicare carrier's determination that use of the drug in a particular case is medically reasonable and necessary for the treatment of

an illness or injury and that such use is a generally accepted practice in the area serviced by the Medicare carrier. As noted above, the FDA has approved the use of interferon for the treatment of hairy cell leukemia, AIDS-related Kaposi's sarcoma and genital warts. The FDA has not specified the use of interferon for the treatment of kidney cancer as non-approved. Thus, Medicare would cover the use of interferon for the treatment of kidney cancer if it determines that such use is medically reasonable and necessary in a particular case and consistent with accepted standards of medical practice. Contacts with four major insurance carriers indicate that two of the carriers routinely provide coverage for the treatment of kidney cancer with interferon; the other two carriers make coverage determinations for such treatment on the basis of a medical consultant's review of each individual case.

In this case, the Pensioner's spouse's physician has prescribed interferon for the treatment of metastatic kidney cancer. Although the FDA has not approved interferon for this specific use, the FDA has not specified such use as non-approved. The evidence indicates that interferon is widely used and accepted as an effective treatment for kidney cancer and a Funds' medical consultant has advised that its use in this particular case is medically reasonable and necessary for the treatment of the Pensioner's spouse's metastatic kidney cancer. Accordingly, the Trustees find that the use of interferon in this case is not experimental and the Employer is required to provide benefits for its use, consistent with Article III. A. (3)(k) of the Employer Benefit Plan.

Opinion of the Trustees

The Employer is required to provide benefits for the treatment of the Pensioner's spouse's metastatic kidney cancer with interferon.