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Of Language and Reimbursement

by John S. Hoff

Major issues of coverage and reimbursement are often obscured by the use of language of indeterminate meaning, or of no meaning at all. What care is *appropriate* or *necessary?* What is *reasonable cost?* What is *proven safe and effective?*

Of particular relevance to oncologists is the meaning of *investigational.* When is a treatment not reimbursable because it is investigational? This issue often comes up in connection with high dose chemotherapy and autologous bone marrow transplants (HDC-ABMT).

An interesting case was recently decided by the United States Court of Appeals for the Eighth Circuit.[1] It demonstrates the vagueness of the word investigational and details the issues that must be addressed in deciding what the term means. Most importantly and most disturbingly, the case demonstrates the extent to which reimbursement decisions become the subject of difficult, lengthy, and expensive court proceedings and, consequently, the need for reimbursement rules to be articulated more precisely.

The patient was diagnosed with mediastinal germ cell carcinoma with pulmonary metastases. HDC-ABMT was recommended after the standard dose of chemotherapy had proved unsuccessful. Coverage was provided by an ERISA plan. The administrator of the plan denied coverage for the treatment on the ground that the procedure was investigational. It based its decision on the informed consent form, the protocol document of the medical school, and the literature.

The patient brought an action in District Court. He submitted affidavits from experts that the HDC-ABMT was the standard of care and the best available therapy, and that it was not experimental or investigative. As is usual in these cases, the District Court found for the patient. It did so on the ground that the plan administrator had not provided an adequate explanation for its denial of coverage. The Court then conducted its own review of the procedure and found that it was not investigational. The plan appealed.

The Court of Appeals agreed with the District Court that the plan administrator did not provide a sufficient explanation for its denial of coverage, but said that the District Court erred in looking into the evidence concerning the nature of the treatment on its own. Instead, it should have required the plan administrator to conduct a better analysis. The Court detailed the issues this analysis should entail. They are instructive. It asked:

- Does the use of a treatment for one type of germ cell cancer make it noninvestigative for other types?
- Does the fact that the treatment was in phase II study make it investigative?
- Is the standard of care to use investigative treatment for patients who do not respond to regular chemotherapy?

To this list should be added the ultimate question: If the standard of care is to use investigative treatment, is it standard care or investigational?

Until the definitions used to delineate insurance coverage are given flesh, either by law if part of a federal basic insurance plan or by more detailed contractual language in private insurance, these issues will continue to bedevil practitioners and patients and require attention by the courts. This case, moreover, demonstrates that even after court review, where an ERISA plan is involved, the decision may ultimately be made by the plan itself—if it goes through the right hoops. ■

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[1] Bernards v. United of Omaha Life Insurance Company, 987 F.2nd 486 (8th Cir. 1993)