

Should Insurance Be Responsible for the Cost of Care While a Patient Is Enrolled in a Clinical Trial?

Patricia A. Weiss, RN, MSN, OCN®, CCRP

Myth: Insurance companies are not responsible for charges if a patient is in a clinical trial. This issue continues to be a focus of debate and contention among insurance companies, sponsoring agencies, and the treating site.

Answer: Payment responsibility for patients in a clinical trial has been an ongoing source of contention between the sponsoring company and patients' health insurance. Some legislation addresses part of this issue. The Code of Federal Regulations (CFR) states, "Charging for an investigational drug in a clinical trial under an IND (investigational new drug) is not permitted without the prior written approval of FDA [U.S. Food and Drug Administration]" (Clinical Research Resources, 2004). (For simplicity, all investigational agents, biologics, and drugs will be referred to as "drug.") This regulation clearly states that if the drug under investigation is not FDA approved, the sponsoring company cannot charge for it and must provide the drug free to the patient. The regulation only addresses the cost of the drug, not the administration, technical charges, or care involved in the trial. In June 2000, President Clinton signed a law directing Medicare to pay for medical care of patients involved in clinical trials (Bennett et al., 2000). A July 9, 2007, Medicare policy permitted payment for the "investigational item, if the item is otherwise covered outside of a clinical trial" (U.S. Department of Health and Human Services, 2007). Medicare currently is working on standards related to clinical trials, and many large insurance companies will follow Medicare's billing guidelines. However, insurance companies in

some states can set their own standards for clinical trial coverage. Several states have enacted legislation or engaged in agreements related to clinical trial coverage of standard of care (SOC) costs. New Jersey, California, and Rhode Island are among the states that promote coverage of trial expenses to help recruit clinical trials participants (McBride, 2003).

Dividing the Bill

Clinical trial billing generally is divided into SOC costs, which are considered to be any activities or charges that normally would occur in the care of a patient with a specific disease diagnosis, and research charges, which are related to activities that occur only because the patient is in a clinical trial. Some activities clearly are research related, such as pharmacokinetic, pharmacodynamic, and genomic blood testing. However, because no nationally accepted SOC exist to cover all aspects of oncology care, the charges can become less defined. For example, one physician in a multiphysician practice may require a weekly complete blood count, whereas another may require it every other week. Some drugs require a weekly chemistry panel prior to administration. If this is a SOC in some circumstances and a weekly chemistry panel on an investigational drug was ordered, should the insurance company be asked to pay for the test?

Budget Issues

Institutions develop a budget detailing the costs of the testing and care prior to opening a clinical trial. The budget separates required items into SOC or research. The sponsoring agency and the site conducting the trial must agree on a budget that defines SOC versus research and sign contracts before enrollment begins. The SOC charges then become the responsibility of the insurance company or the patient.

Differing reports were published in 2000 that estimated the monetary cost of SOC being done in association with a clinical trial against the cost of SOC for the same disease with no clinical trial involvement. Original estimates from the Congressional Budgeting Office (CBO) found the cost of care to clinical trial patients was 25% higher than for nonstudy patients. The CBO then moved that average to 3%–13% after a published report from the Mayo Clinic estimated the cost of SOC participation in clinical trials. The CBO now accepts the average SOC cost to be 10% higher for clinical trial participants than those patients treated off trial. (Bennett et al., 2000).

Sponsoring agencies for oncology clinical trials include groups, such as South West Oncology Group, Eastern Conference Oncology Group, New Approaches to Brain Tumor Therapy,

Patricia A. Weiss, RN, MSN, OCN®, CCRP, is a clinical research coordinator at the Cleveland Clinic Foundation in Ohio.

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