



New Medicare Rules for Clinical Trials

by Roberta L. Buell, M.B.A.

Q: Are all trials and related services and supplies covered under the new Medicare rules that were released September 19, 2000?

A: No, both the trial and service delivered must meet certain Medicare criteria. Medicare covers 1) routine costs of *qualifying* Medicare trials and 2) medically necessary items and services used to diagnose and treat complications arising from participation in *any* clinical trial. If the service meets either of these two criteria, Medicare will pay for it regardless of setting—physician's office, hospital inpatient or outpatient, or through the Durable Medical Equipment Regional Carrier (DMERC).

Q: What is a qualifying trial?

A: A qualifying trial must meet *all* of the following criteria:

- The trial must evaluate a covered medical benefit, such as intravenous drug therapy, radiation therapy, or a diagnostic test. Trials of oral drugs would probably not be reimbursed because oral agents are excluded by statute.
- The trial must aim towards a therapeutic benefit. Trials for quality of life or testing toxicities probably will not be reimbursed.
- The clinical trial may enroll only diagnosed beneficiaries. Beneficiaries may not be part of a control group and must have a diagnosed disease. Preventive trials would not be covered for this reason as well as that Medicare does not usually cover preventive services.
- The clinical trial must have

"desirable" characteristics, meaning Medicare approves the trial. Also approved as desirable are trials conducted under an investigational new drug application and some that are exempt.

Q: Are all items or services covered?

A: No. Items or services not part of the Medicare benefit, those that are excluded by statute, or those that fall under a national non-coverage policy are not reimbursed. In addition, one cannot bill for something received by the provider at no charge (such as the drug). Other exclusions are items and services that are necessary only to fulfill trial

data requirements (and are *not* used in clinical management of the patient) and items and services used to determine trial eligibility.

Services that *are* covered include those that are medically necessary for conventional care (such as visits with the physician) as well as items and/or services that are necessary for provision of the trial service (such as chemo administration). Items and/or services necessary for monitoring the trial item or service or for preventing complications are covered. Also covered are items or services that are medically necessary for the diagnosis or treatment of complications associated with the trial item or service. ☐

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