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Billing for Clinical Trials

by Roberta Buell, M.B.A.

Q: *Billing for clinical trials is confusing. What are the major hazards to watch out for?*

A: When participating in a clinical trial funded by an outside partner, providers must protect themselves from double billing (i.e., the provider receives a drug free of charge and a patient management fee from the trial sponsor, then bills Medicare for the drug and evaluation and management [E&M] services). The Office of Inspector General (OIG) is making double billing its focal point this year. Therefore, it is important to clarify in writing with trial sponsors whether management fees will cover patient or data management. Patient management fees will negate billing for E&M services for clinical trials if there is double billing.

Q: *How does FDA approval of a drug affect billing for clinical trials?*

A: It depends on the type of clinical trial. In cancer care, there are two prevalent types of trials: trials with drugs that are not FDA-approved (Phase III) and trials with drugs that are FDA-approved (Phase IV). The problems differ in each scenario.

■ **Non-FDA approved drug trials (Phase III):** The drug will not be billable to most insurance companies without FDA approval. The "gray area" is whether the infusion codes, labs, and E&M services can be billed. I do not recommend billing these to Medicare unless E&M and lab services are clearly documented as being performed for reasons other than trial administration. Private insurance companies vary as to whether they pay for services secondary to experimental drug trials. While we see more and more private insurers covering services associated with trials, it is always wise to check your contract or verify coverage before treatment.

■ **FDA-approved drug trials (Phase IV):** Many attorneys do not agree as to how Phase IV trials should be handled. If the indication (diagnosis) for the drug given in the trial is unpublished and/or not included in the major compendia, from a billing standpoint this scenario mirrors that of non-FDA approved drug trials. Thus, drug and services would not be billable. However, if the indication for the drug has been published (depending on where it has been published) or is part of the drug's package insert, then the drug and services can be billed. Again, whether the expenses for the drug, labs, and E&M services will be paid by any insurance company depends on the off-label status of the trial. A state's cancer coverage laws may mandate off-label coverage for private insurance companies, depending on whether the plan is self-insured. Self-insured plans are often exempt from cancer coverage laws under ERISA.

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Q: *Can I bill the patient for Phase IV trials that will not be covered by insurance?*

A: You cannot bill patients for any drug that is provided by the trial sponsor. You can bill them for chemotherapy administration, lab tests, and E&M services that will otherwise not be paid. Medicare patients must sign an Advanced Beneficiary Notice for each service rendered in a clinical trial. For Medicare Part B, services must be billed using a–GA modifier.

Q: *What about excess inventory of a drug that expands from experimental to commercial use? Can we administer it?*

A: If you have remaining quantities of a drug left over from the trial, you can use it, but you cannot bill for it. However, you can bill for E&M and other services. If you believe that an insurance company will likely deny payment for chemotherapy administration without a drug charge, use the NDC (National Drug Code) number rather than a miscellaneous drug code (J3490 or J9999).

Have a coding question? You can e-mail your questions to Ms. Buell at codemistress@documedics.com. Or, you may submit your questions in writing to Ms. Buell c/o *Oncology Issues* at 11600 Nebel Street Suite 201, Rockville MD 20852-2557. Fax: 301-770-1949.

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