

Private Insurance Reimbursement for Routine Clinical Trial Costs

By Stephanie B. Vasconcellos

This article should not be construed as legal advice or a legal opinion on any specific facts or circumstances. The contents of this article are intended solely for general purposes, and you are urged to consult a lawyer concerning your own situation and any specific legal questions you may have.

Routine clinical trial costs not covered by sponsors? Private insurance reimbursement may be available. To find out, ask the health insurance companies that are likely to make decisions on coverage. You will need to address the issues you will encounter along the way, which will likely include working with the subject to review his or her health insurance policy language and having pre-approval conversations with health insurers. By dealing with these issues up front, you may save yourself dollars — and headaches — down the line.

Issues Affecting Coverage

Private insurance companies consider many issues when approving or denying coverage for certain clinical trial costs, such as state laws, policy language, costs of coverage, and specific insured situations. As a result, insurance companies may review requests for clinical trial coverage on a case-by-case basis.

A number of factors affect whether participation in a clinical trial will be covered by an individual's health insurance. The first and most important factor is the language in the individual's health insurance policy. Each insurance company has many policy forms, so the best first step is to obtain a copy of the applicable policy directly from the subject. Look for exclusions in the individual's policy. These exclusions are most often found in provisions discussing medical necessity or investigational services, or in the definitions of those terms. The policy may prohibit coverage for clinical trials, permit coverage for clinical trials, identify types of trials for which coverage may be permitted, or not address clinical trials at all.

If the policy does not address clinical trials, is ambiguous, or even appears to prohibit reimbursement for clinical trials, reimbursement may still be possible. Various factors may weigh in favor of reimbursement. First, determine whether the applicable state mandates coverage for your type of clinical trial. State laws generally apply to insurance policies issued in the state, so a state's clinical trial coverage law would apply to any person with an insurance policy issued in that state. In addition to state laws, five states (Florida, Georgia, Michigan, New Jersey, and Ohio) have private agreements in place with many insurance companies under which the insurance companies have agreed to cover certain types of clinical trials. Second, consider whether any other approved types of treatment are available. If approved treatments are available for an individual's disease or condition, the insurance company is less likely to reimburse costs. However, if no other treatment is available for the individual's disease or condition, an insurance company is more likely to reimburse clinical trial costs.

Other factors may weigh in favor of coverage. Insurance companies are more likely to reimburse later-phase trials because the treatment is less likely to be considered

“experimental” and data proving treatment efficacy is more likely to exist. For example, all costs may be fully reimbursable for a Phase IV clinical trial comparing an existing FDA approved test article to the current standard therapy. Insurance companies are also more likely to reimburse costs for trials sponsored by well-known, reputable companies or government entities. Additionally, the more severe an individual’s disease or condition, the more likely an insurance company is to reimburse certain costs.

Lastly, the types of costs being requested may affect reimbursement. Costs that are similar to the costs incurred by an individual receiving a standard course of treatment are more likely to be reimbursed than costs that are significantly different or more expensive. Generally, when insurance companies agree to cover costs, they will follow Medicare guidelines for “routine patient care costs.” Routine costs generally include costs for items or services that are: (a) usually provided outside of a clinical trial for an individual’s disease or condition; (b) required solely for the provision of the investigational item or service, monitoring the effects of the item or service, or the prevention of complications; or (c) needed for diagnosing or treating complications. Items or services not typically covered include: (x) the investigational item or service itself (unless otherwise covered by the plan); (y) items or services provided solely for data collection and analysis; and (z) items usually provided to any trial subject for free by research sponsors.

State Law Examples

The majority of states have a law or private agreement requiring that health insurance companies cover certain types of clinical trials. States often require coverage for only cancer clinical trials, though a handful of states have broader laws. Accordingly, careful review is required to determine precisely what is covered and what is excluded. The following is a sampling of five very different laws and agreements in five states.

Illinois’s Basic Protection

Illinois formerly required that all health insurance companies offer coverage for certain types of clinical trials. That law, however, has been replaced with a much milder version, which merely states that a health insurance company may not cancel a person’s individual or group health insurance policy based on that person’s participation in a clinical trial. See 215 Ill. Comp. Stat. 5/364.01.

New Jersey’s Consensus Agreement

New Jersey has a voluntary consensus agreement with many New Jersey health plans to cover routine medical costs of cancer clinical trials conducted in New Jersey that are approved by the National Institutes of Health, the U.S. Food and Drug Administration (for IND applications), the U.S. Department of Defense, or the U.S. Department Veterans Affairs. Eight health plans signed the agreement, including Horizon Blue Cross Blue Shield of New Jersey, Cigna Healthcare of New Jersey, and Aetna Healthcare New Jersey. The agreement is available at http://www.njctc.org/default.aspx?section=insure&subpage=main_01_sub_04.

Louisiana's Cancer Coverage

A Louisiana law requires that health insurance companies cover certain clinical trial costs. See La. Rev. Stat. Ann. § 22:1044. However, the clinical trial must meet a number of criteria, such as:

- The treatment provided by the trial must have a therapeutic or palliative intent for cancer patients or for early detection of cancer.
- The trial must be a Phase II-IV cancer trial.
- The trial must be approved by one of a list of acceptable entities, such as the NIH, the U.S. Department of Veterans Affairs, and the U.S. Department of Defense.
- There must be no other clearly superior, non-investigational approach.
- Available data must demonstrate a reasonable expectation that the treatment will be at least as efficacious as the non-investigational alternative. See La. Rev. Stat. Ann. § 22:1044.E.

North Carolina's Coverage for "Life-Threatening Medical Conditions"

North Carolina's law requires coverage for Phase II-IV clinical trials that involve the treatment of life-threatening medical conditions and meet numerous other qualifications. Two of the conditions are that the trial must be "preferable for that patient compared to available noninvestigational treatment alternatives" and data must demonstrate that the trial likely will be more effective for a patient than those alternatives. See N.C. Gen. Stat. § 58-3-255.

Oregon's Comprehensive Scheme

Oregon's law on clinical trial coverage, passed in 2009, is more comprehensive than that of many other states. Oregon provides coverage for routine patient care costs in any clinical trial that is:

- Funded or supported by a list of acceptable entities (including the NIH, the CDC, CMS, the U.S. Department of Veterans Affairs, and the U.S. Department of Defense), or
- Conducted as an IND application or exempt under federal law from submitting an IND application. See S.B. 316, 75th Leg. Assem., Reg. Sess. (Ore. 2009), available at <http://www.leg.state.or.us/09reg/measpdf/sb0300.dir/sb0316.en.pdf>.

Although the new law provides broad coverage in Oregon, those conducting clinical trials in Oregon should closely monitor health insurance company compliance with the law. Even health insurance companies with the best intentions may take time to get up to speed.

Recommendations

The key to obtaining private insurance reimbursement for a clinical trial is to maintain open lines of communication with the health insurance companies involved. Consider identifying the top five health insurance companies in your area and contacting them for preliminary pre-authorization. Make your case using policy language, the phase and necessity of your trial, the other treatments available (or not available), and the laws or private agreements

in your state. Expect the research coverage determination process to run at a similar pace as a medical necessity pre-authorization coverage determination involving the "off-label use" of a drug or device, which can take a couple of hours over the course of several days or a week. If pre-approval is turned down, follow the company's appeal procedures. Your dedication, persistence and communication may be the factors that obtain coverage. The process will become much more efficient as you gain experience working with health insurers.

Resources on Clinical Trial Coverage

1. American Cancer Society, Clinical Trials: State Laws Regarding Insurance Coverage, available at http://www.cancer.org/docroot/ETO/content/ETO_6_2x_State_Laws_Regarding_Clinical_Trials.asp.
2. Centers for Medicare & Medicaid Services, Overview Medicare Clinical Trial Policies, available at <http://www.cms.hhs.gov/clinicaltrialpolicies/>.
3. Centers for Medicare & Medicaid Services, Medicare Coverage – Clinical Trials, available at <http://www.cms.hhs.gov/clinicaltrialpolicies/downloads/finalnationalcoverage.pdf>.
4. National Conference of State Legislatures, Clinical Trials: What Are States Doing? August 2009 Update, available at <http://www.ncsl.org/default.aspx?tabid=14331>.

Acknowledgement

The author gratefully acknowledges contributions from LaDale K. George, a partner at Neal, Gerber & Eisenberg LLP.

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