SEPTEMBER 2024 * 10 minute reading time

Spotlight: Routine Costs Related to Clinical Trial Treatment

Most Payers Are Legally Required to Cover Routine Costs Related to Clinical Trial Treatment

For most patients, routine care services related to clinical trial participation are covered by their insurance. Clinical trial coverage regulations (see Table 1) define "qualified individuals" and "routine costs" related to treatment on a clinical trial. Hospitals should familiarize themselves with the definitions within these regulations and use them to support equitable and timely access to clinical trials by holding payers accountable for covering and reimbursing the costs associated with routine care services related to clinical trial participation.

Patient access and hospital operations suffer when clinical trial coverage regulations are poorly understood by clinical trial sponsors, investigators, providers, and payers. The lack of knowledge can lead to misguided assumptions about which services should be paid for by a study sponsor and which services *must be* covered by the payer.

When providers do not fully understand coverage regulations, particularly the definitions that explain who and what is covered, several issues can arise:

- Clinical trial budgets may be set up incorrectly by diverting routine care services to clinical trial sponsors when they should be billed and covered by payers.
- Providers may improperly frame their prior authorization requests for routine care services related to the patient being treated in the clinical trial, leading to denials.
- Prior-authorization requests may be erroneously denied for administrative coverage reasons, and providers may lack the know-how to frame a successful appeal argument.
- Post-service denials may be written off before an attempted appeal, resulting in lost revenue for the institution.

Exploring Definitions

- "Qualified individuals" are generally defined as those with serious or life-threatening illness, but each major payer's coverage regulation has slightly different language with which hospitals must familiarize themselves. For example, Medicare's National Coverage Decision (NCD) for coverage of Routine Costs of Clinical Trials does not specify severity of illness or condition being treated, whereas the Affordable Care Act specifies that a "qualified individual" is a person with a diagnosis of cancer or another life-threatening condition.
- "Routine costs" are generally defined as services that are typically covered outside of clinical trial participation, are used in direct clinical management of the patient, or are needed for the provision of the investigational treatment. It is important to know that there are discrepancies in the way "routine costs" are defined across the regulations that mandate this coverage (see Table 1).

Some of the language in the regulations may be vague or difficult to interpret, further complicating the application of these regulations in practice. For example, the Affordable Care Act (ACA) provision excludes coverage of services "inconsistent with the established standards of care for the patient's diagnosis." Patients may receive new diagnoses as a result of an investigational treatment—such as hypogammaglobulinemia as a result of B cell aplasia after CAR-T cell therapy. Is the treatment of this secondary diagnosis a covered benefit? The answer to questions like this are dependent on the payer, since there are challenges in interpretation of these regulations. When seeking authorization, a provider must be explicit about how the item or service in question fits within relevant coverage regulations.

Some insurance plans require that a patient seek treatment within a defined network of health systems and providers. Clinical trials are often available only at a few sites and, often, there is no in-network provider offering treatment on a specific trial. This creates a barrier to care. Discrepancies exist in how coverage regulations directly address this challenge; as a result, patients can face network-related obstacles to necessary care. Additionally, providers may find that they must secure single case agreements for services or enroll physicians with the out-of-network health plan—both of which delay or restrict patient access and are not directly addressed by existing coverage regulations.

Table 1: Coverage Regulations By Payer Type		
	What is covered?	**What is not covered?**
Commercial Plans: Affordable Care Act, Section 2709[1]	• All items and services consistent with the coverage provided in the plan (or coverage) that are typically covered for a qualified individual who is not enrolled in a clinical trial.	• The investigational item, device, or service itself. • Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient. • A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.
Medicare: Clinical Trial NCD, 310.1[2]	• Items or services that are typically provided absent a clinical trial (e.g., conventional care). • Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent). • Clinically appropriate monitoring of the effects of the item or service, or the prevention of complications. • Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.	• The investigational item or service itself unless otherwise covered outside of the clinical trial. • Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan). • Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.
Medicaid: Clinical Treatment Act H.R. 913[3]	• Any item or service provided to the individual under the qualifying clinical trial, including: ○ Any item or service provided to prevent, diagnose, monitor, or treat complications resulting from such participation, to the extent that the provision of such an item or service to the individual outside the course of such participation would otherwise be covered under the State plan or waiver.	• An item or service that is the investigational item or service that is: ○ The subject of the qualifying clinical trial, ○ Provided to the individual solely to satisfy data-collection and analysis needs for the qualifying clinical trial and is not used in the direct clinical management of the individual.

Plan, communicate and advocate to improve patient access and ensure fair reimbursement!

Plan:

- Understand the intricacies of the regulations; doing so will help you work quickly and efficiently with payer partners to address coverage denials.
- Implement uniform clinical trial budgeting approaches by sending *only* what is non-covered by existing regulations to clinical research trial sponsors.
- Establish prior-authorization workflows and documentation that demonstrate why a patient's participation in a clinical trial is medically necessary.

Communicate:

- Be explicit with payers about what services you are seeking coverage for and what services you are not seeking coverage for; this removes any guesswork and enables the payer to quicky see that they are not being asked to cover excluded services—including the investigational item itself. Properly framing the "ask" makes it as easy as possible for the payer to get to a "yes."

Advocate:

- Use the coverage regulations to immediately appeal both administrative pre-service denials as well as any erroneous post-service claims denials.

References

[1] The Affordable Care Act, *TITLE X—STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMER15ICANS, Subtitle A—Provisions Relating to Title I*, 2019. Download the PDF here.

[2] Centers for Medicare & Medicaid Services (CMS), *National Coverage Decision: Routine Costs in Clinical Trials, Publication 100-3, Section 310.1*, Baltimore(MD) CMS, 2024. Download the PDF here.

[3] US House of Representatives, *HR 913: To amend title XIX of the Social Security Act to promote access to lifesaving therapies for Medicaid enrollees by ensuring coverage of routine patient costs for items and services furnished in connection with participation in qualifying clinical trials, and for other purposes*, Washington (DC), 2019. Download the PDF here.