

BOTTOM LINE



Complete a formal coverage analysis.



Engage in proactive communication with payers.



Be aware of current coverage rules and guidelines.



Download the ASCO Insurance Coverage of Clinical Trials Toolkit.

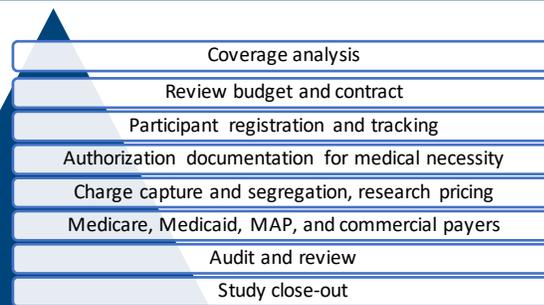
Clinical trial billing compliance is a major challenge faced by clinical trials sites, and current requirements exacerbate the financial risk that institutions and research sites may experience.¹ A clinical trials billing compliance process can uncover system wide redundancies, inconsistencies, trial delays, and potential loss of revenue. However, this process requires a high level of attention and can also be costly and decrease already-low accrual rates to cancer clinical trials.¹ Further, clinical trial sites report a need for consultation, training, and resources related to billing, compliance, and coverage analyses.²

KEY CONSIDERATIONS, TIPS, AND BEST PRACTICES



Coverage analysis is a key tool in the billing compliance process and can be used before opening a clinical trial to mitigate risks and demonstrate due diligence in the event the site undergoes a billing compliance audit.¹ Centralized coverage analysis by trials sponsors is a viable solution to site burdens and delays in trial start-up.¹

Elements of the billing process for clinical trials.²



Key Areas for Success in Insurance Coverage Analysis

There are five key areas for success in clinical trial insurance coverage analysis²:



- Coverage analysis:** A formal coverage analysis, with principal investigator input and approval, to identify covered and noncovered items for Medicare or other third-party payers and items that require coverage by the sponsor. Coverage analyses are generally completed using Medicare rules; coverage may differ with other health plans.³ Medicare rules and coverage are subject to change; be sure to reference the most current regulations. [American Society of Clinical Oncology](#) and [National Comprehensive Cancer Network](#) guidelines may also be valuable resources in supporting the rationale for coverage.
- Network verification:** An insurance verification process that includes network verification and covered benefits with potential clinical trial participants before starting on the trial.
- Benefits verification:** Routine costs in clinical trials do *not* include services, treatment, or supplies not otherwise covered under the benefit plan.
- Financial counseling:** A financial review in the coverage process can equip sites to answer participants' reimbursement questions.
- Pre-authorization:** Pre-authorization is *not* a promise of coverage. Best practices of pre-authorization include:
 - Using "scripting," such as template language or talking points for authorization of staff and a dedicated resource for clinical trials authorization (e.g., a template request form)
 - Ensuring compliance with institutional processes for insurance verification and pre-authorization
 - Implementing two levels of pre-authorization with the payer: patient – plan benefit – clinical trial level and specific items – services level.

Effectively Conducting Insurance Coverage Analysis

- Advocate and facilitate proactive communication with payers (e.g., communication prior to initial coverage submission, physician to physician communication in seeking out-of-network benefits, request and review payer policies, etc.).²
- Review the [ASCO Insurance Coverage of Clinical Trials Toolkit](#), which contains sample checklists, templates, and forms, to learn about effectively determining insurance coverage of clinical trials, dealing with coverage denials, and navigating the appeals process.⁴ Refer to the references section below for additional resources on how to implement centralized coverage analyses.

REFERENCES

1. Szczepanek CM, Hurley P, Good MJ et al: [Feasibility of a centralized clinical trials coverage analysis: A joint initiative of the American Society of Clinical Oncology and the National Cancer Institute](#). *J Oncol Pract* 13(6):395-400, 2017.
2. Willenberg K. How to Succeed with Payers for Patients on Clinical Trials: Understanding Barriers, Dealing with Denials, and Navigating the Appeals Process. ASCO Research Community Forum 2017 Annual Meeting. Contact ASCO staff for access: researchcommunityforum@asco.org.
3. Clinical Trial Resources on ASCO.org: [Insurance Coverage of Clinical Trials](#).
4. *American Society of Clinical Oncology Research Community Forum Toolkit: [ASCO Clinical Trials Insurance Coverage Toolkit](#)*. Alexandria, VA; American Society of Clinical Oncology; 2018.

OTHER RESOURCES

- Denicoff A, Mishkin G, Good M, et al. [National Coverage Analyses for NCI Clinical Trials: A Pilot Project to Reduce Participation Barriers](#). *J Clin Oncol* 35(15 suppl): 6542-6542. 2017.
- Centers for Medicare and Medicaid Services. [National Coverage Determination \(NCD\) for Routine Costs in Clinical Trials \(310.1\)](#). 2007.
- Centers for Medicare and Medicaid Services. [Medicare National Coverage Determination](#).
- Cancer.Net. Patient Resources for [Health Insurance Coverage and Clinical Trials](#). 2018.
- *American Society of Clinical Oncology Research Community Forum Toolkit: [The Business of Clinical Trials - Optimizing Clinical Trial Sites and Implementing Best Practices](#)*. Alexandria, VA; American Society of Clinical Oncology; 2018.
- ASCO Research Community Forum Online Forum. Access: myconnection.asco.org/rcf.
- Search "Research Community Forum" on asco.org for more information and to access more resources.



Email researchcommunityforum@asco.org with ideas and suggestions for content revisions, additional and/or new topics summaries.



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