Multiple Financial Barriers Impede Patient Participation in Cancer Clinical Trials, According to New ASCO Policy Statement

Recommended Path Forward Includes Steps that Will Address Payer Coverage for Clinical Trial Costs and Lack of Patient Support, Data, and Transparency

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The American Society of Clinical Oncology (ASCO) today issued a set of recommendations for overcoming financial barriers to patient participation in cancer clinical trials. ASCO's policy statement, "Addressing Financial Barriers to Patient Participation in Clinical Trials," stresses the importance of increasing participation in clinical research, especially for patients from particular ethnic/racial, geographic, age, socioeconomic, and other underserved demographic subgroups.

"Clinical trials are essential for evaluating the safety and efficacy of new cancer treatments, but cancer researchers have seen consistently low patient participation levels—especially among underserved patient populations—in part due to the financial burdens facing many patients with cancer," said ASCO President Monica M. Bertagnolli, MD, FACS, FASCO.

"Addressing financial barriers will help improve the enrollment rate and the efficiency, quality, and applicability of cancer research. By including more—and more diverse—participants in our research studies, we expand our ability to care for all patients."

ASCO outlines a series of recommendations that are designed to address multiple financial barriers that impede access to clinical trials, including patient costs that aren't covered...
consistently by health insurance; a lack of information provided to patients about clinical trial costs; and limited available research data on financial hardship that patients might incur by participating in clinical trials.

**ASCO Recommendations:**

1. **Improve payer clinical trial coverage policies.** Clinical trial cost payment policies should be revised so that they are made consistent, streamlined, and transparent to all stakeholders.
   - Payers should have clear definitions of “routine costs.”
   - Payers should streamline prior authorization processes and facilitate trial enrollment through provider reimbursement of clinical trial-related services.
   - State Medicaid programs should universally guarantee coverage of routine-care costs of clinical trials for their beneficiaries.
   - CMS should revise current policy that requires Medicare Advantage beneficiaries to revert to fee-for-service coverage during clinical trials.
   - CMS’s Innovation Center (CMMI) should explore the effectiveness of alternative payments models in support of clinical trial accrual.

2. **During the clinical trials development and enrollment process, provide patients with clear, transparent information about potential trial-related patient out-of-pocket costs, and include mechanisms to support patient financial/health literacy.**
   - Clinical trial sponsors should perform, and make available to enrolling institutions, comprehensive, prospective coverage analyses.
   - Research sites should consider offering in-house financial navigation/counseling to patients or consider partnering with organizations that provide such services.
   - Design clinical trials to minimize incremental costs, consistent with scientific objectives and participant safety.

3. **Remove impediments to ethically appropriate financial compensation for trial-related out-of-pocket costs.** Provision of such financial support should not be considered undue inducement.
   - Office for Human Research Protections should develop guidance on targeted financial support.

4. **Incentivize research that will better characterize patient costs incurred for participating in cancer clinical trials and support the longer-term development of tools to identify and mitigate the risk of trial-associated financial hardship.**

“Continued progress against cancer depends on improving patient access to participation in clinical research. The recommendations in ASCO’s statement aim to ensure that no patient is
denied access to a clinical trial for financial reasons and that patients are not harmed financially because of their contributions to advancing science,” said Dr. Bertagnolli.

“Ultimately, this is about strengthening the nation’s cancer research enterprise, as a whole.”

ASCO would like to thank the Lazarex Cancer Foundation for funding the ASCO Roundtable on Addressing Financial Barriers to Clinical Trials Participation in 2017, which contributed to the development of this statement.

Read the full policy statement.

About ASCO:

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world’s leading organization of its kind, ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter, LinkedIn, and YouTube.