

Response to Payer Coverage for Patients Enrolled Onto Clinical Trials

TO THE EDITORS:

This letter is written by leaders of the ASCO committee that developed the ASCO Provider-Payer Initiative (PPI), to provide additional background and comments on an article published in the May 2012 special joint issue of *The American Journal of Managed Care* and the *Journal of Oncology Practice* entitled, “Payer Coverage for Patients Enrolled Onto Clinical Trials: Making the Process Easy and Transparent for Everyone.”¹ We appreciate the authors’ support for the ASCO PPI and the discussion regarding coverage for clinical research which the meeting helped focus; however, we felt it important to provide feedback on a few points.

Characterization of the PPI

ASCO created the PPI as a forum where ASCO members and private insurance payers could share their perspectives on issues related to improving the delivery of high-quality cancer care. To remain compliant with US antitrust laws, an independent anti-trust monitor is also involved.

In 2012, the PPI established a Clinical Trials Subgroup to focus on clinical trials coverage requirement of the Affordable Care Act (ACA), which became effective in January 2014.² By engaging in a constructive dialogue, we hope to foster clear and consistent implementation of this important option for patients with cancer. The subgroup identified oncology-specific needs surrounding the statute, suggested potential resources to address them, and developed a framework for these tools. We understand the authors’ concerns about reimbursement and coverage, but antitrust rules prevented specific conversation about these topics and, as such, were beyond the scope of this meeting.

Clinical Trials Coverage Determination

The authors propose requiring an extensive list of information as part of the approval process for patient participation in an approved clinical trial. However, qualifying trials are explicitly defined in the ACA, and meeting these standards should be sufficient assurance that the trial is of high quality; has undergone extensive peer and ethical review; includes appropriate consent requirements; and is appropriate for participation when a patient meets eligibility criteria—criteria that are highly selective under any circumstances.

Information collection proposed by the authors is far more detailed than necessary to make a determination, and in many cases, is redundant to information already reported or available. As such, it may serve to delay or discourage both patients and practitioners from participation. For example, providers initiating therapy outside of a clinical trial are not required to provide medical reference citations supporting standard therapy. In addition, whether a patient meets a trial’s eligibility criteria is a decision best made by the clinical investigator who is most familiar with the patient

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and who has been trained by the trial sponsor on study procedures, including determining eligibility.

Palackdharry et al¹ express concern about cost and that payers are being expected to cover research-related items or services. Under the ACA requirements, payers are only obligated to cover costs associated with routine clinical care. Many payers already use mechanisms to determine care appropriateness, including preauthorization for certain services. The same tools can be used when a patient enrolls onto a clinical trial, as the “costs of routine clinical care” will be billed to and reviewed by payers in the usual manner. Although we share concern about the rising cost of health care, we note that the routine care associated with clinical trials participation is not only appropriate to be covered, but should not increase the financial responsibility of insurers.

We encourage the authors to continue this dialogue and to share with us data that will help providers better understand any additional burden payers face in covering patients treated on clinical trials. We commit to including such a discussion at the next PPI. This kind of exchange can highlight opportunities for improvement as investigators and sponsors work together in designing studies. Our primary goal is to make implementation of the ACA coverage requirement as easy as possible for our patients. It is for this reason that we express concern about the adoption of excessive and unnecessary administrative requirements that could delay care and further limit the number of patients who choose to enroll onto clinical trials. We want to ensure that more people with cancer are able to participate in clinical trials and have the opportunity

to help improve outcomes for all people facing cancer in the future.

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Acknowledgement

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Author's Disclosures of Potential Conflicts of Interest

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