

Payer Coverage for Patients Enrolled Onto Clinical Trials: Making the Process Easy and Transparent for Everyone

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SETTING THE STAGE FOR CHANGE

Aetna was invited to participate in the 2011 American Society of Clinical Oncology (ASCO) Provider-Payer Initiative (PPI). We participated in the clinical trial subgroup, which was charged with deciphering the information contained in the related provisions of the Affordable Care Act (ACA) and exploring future opportunities for improving communication between the multiple stakeholders involved in the care of patients with cancer enrolled onto clinical trials (if the ACA is not repealed). Our goals were to (1) identify what information would help determine coverage and expected out-of-pocket expenses for individuals on clinical trials, (2) obtain comprehensive and transparent details about the treatment plan, and (3) ensure that all patient rights and responsibilities have been addressed and documented.

Between Aetna and ActiveHealth Management (AHM), we represent several payer perspectives. Aetna's current policy covers routine costs for patients enrolled onto *any* qualified clinical trial (not just for trials for cancer or terminal illness as specified in the ACA), as well as the cost of treatment-associated adverse events. Thus, for Aetna, as for many large payer organizations, compliance with the ACA will not require significant changes to current policies. However, AHM and Aetna provide utilization management services to many employer-funded plans that have excluded coverage for persons on clinical trials. For these organizations, the ACA will necessitate substantial changes.

Currently, payers are challenged on many levels when trying to obtain the information necessary to make coverage decisions. There is little or no publicly available information about the financial burdens payers and patients are expected to encounter under the auspices of a clinical trial. In addition, payer-employed physicians sometimes experience tremendous resistance from oncology providers when attempting to obtain this information. We hope our work with the PPI will help navigate the difficult journey toward a more cohesive,

team-oriented approach to the care of these patients.

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What Payers Must Cover Under the ACA

An in-depth review of the relevant provisions of the ACA pertaining to clinical trial coverage was carried out by legal experts participating in the clinical trials subgroup. In brief, all payers must cover routine costs for qualified patients who are enrolled onto an approved phase I-IV clinical trial. The definitions of "routine patient costs," "qualified individual," and "approved clinical trial" are listed in [Figure 1](#).¹

What Payers Are Not Mandated to Cover

It is important for all stakeholders, particularly patients, to understand the financial burden they may encounter when participating in a trial. In addition to containing language pertaining to patients who choose plans that do not provide any out-of-network coverage, the ACA also specifically states what payers are not required to cover, including:

- the actual investigational drugs, devices, or procedures;
- any testing or imaging done for the purposes of data collection or testing or frequency of testing not considered part of standard care; or
- data collection and analysis.

OUR CONTRIBUTION TO THE PPI

Methodology of Gathering Data

We gathered input from our organizations about what data we believe payers would like to be able to obtain when patients are on clinical trials. Our internal team was composed of physicians from different divisions of Aetna and AHM, providing expertise in the development and meaningful use of electronic health data, oncology practice, clinical investigation, payer policy, and use management.

Our internal team established goals to identify what information could be used to sort out investigational versus routine studies and therapies so all parties can estimate coverage and expected out-of-pocket expenses for individuals on clinical trials; obtain comprehensive and transparent information about the treat-

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■ **Figure 1.** The Affordable Care Act (ACA) Definitions of “Routine Patient Costs,” “Qualified Individual,” and “Approved Clinical Trial”

ACA definition of routine patient costs:

“All items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled onto a clinical trial.”

ACA definition of qualified individual with respect to a cancer diagnosis:
An individual who is a participant or beneficiary of a health plan *and*:

- The individual meets the eligibility/inclusion requirements of clinical trial
- Either
 - the referring health care professional is a plan participant and has concluded the trial is in the patient’s best interest
- or*
- the participant or beneficiary provides adequate medical and scientific information establishing that participation in the trial is appropriate (*and* the patient meets eligibility requirements)
- Limitations of coverage:
 - Insurers are not mandated to provide benefits for routine patient care expenses outside of the plan’s network of physicians, unless the individual/beneficiary has a plan that provides for out-of-network coverage

ACA definition of approved clinical trial:

- An approved trial must meet *all* of the following:
- Phase I to IV
- Conducted for prevention, detection, or treatment for cancer or another disease/condition likely to result in death unless the course is interrupted
- Either:
 - federally funded (approved and funded by NIH, CDC, AHRQ, CMS, a nongovernmental research entity identified in the NIH guidelines for center support grants, DOD, VA, or cooperative group of two or more of the listed agencies)
- or*
- Either:
 - conducted under an IND application reviewed by the US Food and Drug Administration
- or*
- IND exempt

AHRQ indicates Agency for Healthcare Research and Quality; CDC, Centers for Disease Control and Prevention; CMS, Centers for Medicare & Medicaid Services; DOD, Department of Defense; IND, Investigational New Drug; NIH, National Institute of Health; VA, US Department of Veterans Affairs.¹

ment plan to both meet our financial obligations and identify those individuals who might benefit from extra supportive services; and ensure that all patient rights and responsibilities have been addressed and documented. We subsequently discussed current AHM and Aetna policies, as well as the policies of other clients we represent; the impact of the ACA on our organizations; and the type, quality, and quantity of specific information that might be necessary for a payer or plan manager to make informed decisions regarding several issues.

Recommendations

We compiled a list of questions/data elements that we would like to be able to capture (Figure 2). Most of the items on the list are trial-specific and could be electronically transmitted with only an individual patient’s characteristics needing to be added to each request. The proof of documentation elements require only a yes or no answer and not transmission of any forms. The data sheet was first presented to the clinical

trials subgroup for review and discussion and subsequently to the full PPI committee on December 5, 2011.

COMMENTS AND ADDITIONAL PERSPECTIVES

Perhaps not surprisingly, our thoughts on what clinical trial data elements we would like to receive were not met with resounding enthusiasm from the subgroup. Many objections and concerns were voiced, including comments about the lack of qualifications of physicians who create and adjudicate payer policies. Clearly, these first steps toward a more collegial relationship between payers and providers are proving the hardest. The landscape of oncology treatment has undergone dramatic change in the past decade, with current intense focus on the particularly high costs and resource use associated with modern cancer care. We believe it is important for oncologists to understand the payer perspective and are committed to working together with ASCO to make the PPI a fruitful endeavor.

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■ **Figure 2.** List of Proposed Data Elements to Be Provided to Payers for Patients on Clinical Trials

| | |
|---|--|
| <p>Patient Identification:</p> <ul style="list-style-type: none"> • Name • Employer/plan info • Policy ID • DOB/ID verification <p>Patient Clinical Information:</p> <ul style="list-style-type: none"> • Type of cancer • Diagnosis date • Stage • Prior therapy • Major medical problems • Current documented ECOG/WHO PS: <p>Trial Registration Details:</p> <ul style="list-style-type: none"> • Clinical trial name • Trial sponsor • Clinical Trials.gov ID • Phase I IND if not registered • Signed consent documented (Y/N) • IRB approval documented (Y/N) <p>Standard of Care Details:</p> <ul style="list-style-type: none"> • Standard drug/procedure/treatment • Standard staging frequency • Reference source for standard • Documentation that patient is aware of standard of care treatment options (Y/N) <p>Additional Care Needs:</p> | <p>Trial Details:</p> <ul style="list-style-type: none"> • Investigational drugs, procedures, or devices: • Is the cost of the investigational treatment covered/provided by the trial sponsor? (Y/N) • Type of staging studies required or planned by the trial: <ul style="list-style-type: none"> - Type of study - Frequency of staging studies - Are staging studies covered by the trial sponsor? (Y/N) • Study-required supportive care drugs (pretreatment drugs, antiemetics, prophylactic antibiotics or antivirals, etc) <ul style="list-style-type: none"> - Specify nonroutine elements - Provided by sponsor? (Y/N) • Study-required tumor markers/analysis: <ul style="list-style-type: none"> - Specify - Frequency - Provided by sponsor? (Y/N) • Study-required procedures to monitor for adverse events/adverse effects or collect data (radiology, ECG, ECHO, PFT, etc) <ul style="list-style-type: none"> - Specify - Frequency - Provided by sponsor? (Y/N) • Study-required blood draws <ul style="list-style-type: none"> - Specify - Frequency - Covered by study? (Y/N) <p style="text-align: center;">Documentation That Patient Understands Out-of-Pocket Expenses (Y/N)</p> |
|---|--|

The majority of these data elements are trial-specific and could be formulated onto a template. The documentation questions require only a yes or no answer and not transmission of those documents to the payer or plan manager. The inclusion of these details will increase trial transparency for patients and payers. These data would also allow payers to not only provide appropriate support but collect valuable data for comparative effectiveness research and outcomes.

DOB indicates date of birth; ECHO, echocardiogram; ECOG, Eastern Cooperative Oncology Group; ID, identification; IND, Investigational New Drug; IRB, institutional review board; PFT, pulmonary function testing; PS, performance status.

Looking in the Mirror: Responsibilities of All Stakeholders Under the ACA

A comprehensive discourse of healthcare ideology versus economics is beyond the scope of this article. However, for the foreseeable future in the United States, clinical research costs will be paid for by some combination of study sponsor, payer, employer, and patient. None of these entities have unlimited resources, and all must determine how to fairly allocate what resources they do have. Not every trial gets funding. No institution or physician can provide treatment free of charge to every patient. Not every patient can afford, or even qualifies, to receive whatever experimental therapy he desires. Payers cannot subsidize the research elements of every oncology clinical trial that goes unfunded. However, we believe promoting the production

and conduct of high-quality clinical research should be high on every payer's agenda.

One positive aspect of the ACA that will help with an area of current contention with certain plans, as voiced by the medical directors of AHM, is coverage for the drugs on phase III trials, for which most of the drugs would have been used regardless. Currently, because they are being used on a trial, some employer-funded plans have refused their coverage. The way we interpret the ACA, drug coverage in these situations will be mandated, which we wholeheartedly support.

A topic that received lengthy discussions both within our internal group and within the PPI subgroup relates to the coverage of drugs or procedures that are commercially available or approved for 1 indication but being used in an unfunded clinical trial (whether formally approved or not) to test efficacy for

a different indication. Because such interventions are already available on the market, the need to obtain an Investigational New Drug (IND) number and/or disclose the trial to the payer may not be clear to all investigators. Although this scenario may not be common at accredited cancer institutes, these types of studies are carried out in a variety of other settings, with the charges for investigational components passed to the payer. Unless these components are on a precertification list, it becomes the payer who unknowingly funds the study. If the claims are denied, the burden shifts to the patient. Some of the data elements we propose collecting were in response to this particular situation and will help all stakeholders know, ahead of time, whether the drugs or devices being used outside of a funded trial are considered investigational and fall outside of coverage policies. As much as we support clinical research, we must also be fiscally responsible.

Even the routine costs associated with trials can be denied if the trial does not meet the ACA requirements for “qualified study.” For the majority of oncology clinical trials, qualification is straightforward. However, in the type of situation we mentioned, a trial would not qualify unless either an IND number is obtained or the trial meets the definition of IND-exempt. The PPI subgroup reviewed the 2010 Department of Health and Human Services draft document offering guidance to investigators and industry as to when research can be conducted without an IND number.² Pending finalization, education about which of these types of trials qualify for coverage will be a key component of determining financial consequences to all stakeholders. Some of the data elements we postulate collecting will help payers determine whether the trial qualifies for routine care coverage.

Another purpose for some of our data elements is to help clarify which studies associated with the trial are not considered routine. The ACA does not require coverage for such studies; thus we designed specific data elements to help payers sort this out. Many trials require data collecting studies at specified times, not necessarily clinically indicated, to have standardized intermediate assessments. Cancer is the poster child disease category for advancements in histologic, molecular, and radiologic markers, and there are many nonvalidated tests available to assess response to therapy. ASCO has put much effort into systematically sorting through which tests have evidence to support their use in the evaluation of certain diseases, with resultant guidance published. Such efforts to standardize types and frequencies of testing will clearly help all stakeholders design and conduct clinical trials without excessive expenditures. Again, payers do not have unlimited resources and have a fiduciary duty to decipher what charges related to the trial are considered to be routine care.

Although much of the focus has been on payer responsibility, we would like to encourage all stakeholders to evaluate

and uphold their own responsibilities in this area. Institutional review boards might consider tightening their scrutiny of patient care—necessary versus data collection—necessary tests and procedures when approving trials. Perhaps they could require investigators to sign off that they are aware of and will disclose to the patient what, if any, financial impact there may be for trial participation. Investigators should be certain they consider these issues when they are writing and/or deciding to participate in clinical trials. Clinicians should either inform the patient that certain components of the trial are considered nonroutine and the patient may be held financially responsible for those costs, or not perform nonstandard treatment or testing unless it is paid for by the trial. Trial sponsors or manufacturers of experimental products should critically examine proposed trials for any unnecessary elements, provide the products being studied (as well as any necessary nonroutine support, testing, and data collection costs to patients on trials), and accept responsibility for adverse events attributed directly to their investigational products.

All stakeholders, whether they agree or not, must accept that payers have the right under the ACA not to cover routine care charges related to unqualified trials. They have the right not to cover the cost of the actual investigational therapy itself, regardless of ACA qualification. This does not mean patients cannot enroll onto and be treated on such trials, only that the financial responsibility resides elsewhere. Patients need to be informed ahead of time about their likely financial burden in these circumstances. Although it is difficult for most physicians to balance our internal desire to “give it all we have,” with an individual patient’s financial circumstances, the reality of the burden of cancer care costs leaves us with no real choice.

Seeking Mutual Respect and Common Ground

Breaking down the barriers between the multiple stakeholders involved in cancer care is critical to the future of this entire specialty, not just for the promotion of clinical research. There were some tense exchanges between payer and provider representatives on the PPI. All parties held strong views, and it was difficult not to feel defensive when those views were challenged. We hope that, by articulating some of the new directions payers are taking, we can lessen the perceived disparities between payer-employed and practicing physicians with regard to patient dedication. Ultimately, both as a profession and as professionals, we must all come to the realization that health-care economics is an integral and inseparable part of health-care delivery. It is not a matter of economics versus effective cancer care. We must stand together, on the same team, to produce effective cancer care that is economically sustainable.

Physicians in managed care have undergone an evolution in training and focus over the past 20 years. In the previ-

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■ **Table.** Summary of the 14 Recommendations From “Moral Science: Protecting Participants in Human Subjects Research”¹

| Recommendation Number | Recommendation Title | Recommendation Summary |
|-----------------------|--|--|
| 1 | Improve accountability through public access | Make a core set of data elements publicly available for research programs. |
| 2 | Improve accountability through expanded research | Support systematic approaches to assess effectiveness of human subject protections and expand research related to ethical and social considerations. |
| 3 | Treating and compensating for research-related injuries | Adhere to an ethical obligation not to hold research subjects responsible for the cost of treating research-related injuries. |
| 4 | Treating and compensating for research-related injury follow-up | Make a clear policy public regarding compensation or treatment for research-related injuries. |
| 5 | Make the ethical underpinnings of regulations more explicit | Clearly articulate core ethical standards. |
| 6 | Amend the common rule to address investigator responsibilities | Articulate responsibilities and obligations of investigators to build a stronger culture of responsibility. |
| 7 | Expand ethics discourse and education | Establish rigorous education in bioethics for investigators at all levels of experience. |
| 8 | Respect equivalent protections | Develop a process to evaluate requests from foreign governments and other non-US institutions to determine whether the research provides equivalent protections for human subjects. |
| 9 | Promote community engagement | Develop a standardized framework for community engagement and conduct research to prospectively evaluate the effectiveness and further strengthen it. |
| 10 | Ensure capacity to protect human subjects | Funders of research: ensure that researchers and sites have the capacity to support patient protections. |
| 11 | Evaluate responsiveness to local needs as a condition for ethical site selection | Develop and evaluate justifications for site selection, as well as produce guidance for investigators. |
| 12 | Ensure ethical study design for control trials | Reconcile the scientific demands for rigorous study design with the interests of research subjects and ethics of using a placebo or an agent that might not represent the best-proven approach. |
| 13 | Promoting federal reform efforts | Restructure research oversight. Eliminate continuing review for certain low-risk studies. Reduce unnecessary, redundant institutional review board review in multisite studies. Make standardized consent form templates available with clear, understandable language. Harmonize regulations. Work toward a standardized data collection system for adverse event reporting. |
| 14 | Responding to recommendations | Respond to this report with changes to the status quo or explain reasons for not changing. |

The full report is available at <http://bioethics.gov/cms/node/558>.

ous millennium, there was a sense among many in clinical practice that physicians employed by payers were somewhat less qualified. Much has changed since then, and physicians in the industry today have achieved clinical and academic excellence, as well as demonstrated expertise in the fields of bioethics, population health, and medical economics. Coverage decisions are made on the basis of scientific evidence and member-chosen plan specifics and not on cost.

The primary difference between payer-employed and practicing physicians today is that we have chosen to take the “if you cannot beat them, join them” approach to changing and improving the healthcare system. We have not lost our dedication to making a difference and improving patient outcomes. As physicians with expertise in medical economics and public health, we believe it is our duty to the patients we serve, as well as to the future cohesiveness of a markedly

fragmented medical system, to make sure that the voice of the physician is heard and understood when decisions about clinical policy are made. We are in a position to help define and strive for maximal value in healthcare. We strive to work together with practitioners in an atmosphere of mutual respect and understanding to accomplish this.

Additional Reasons for Data Collection

An additional internal goal when undertaking this endeavor was to determine what data would allow us to increase supportive services for providers. Oncology practitioners are busier than ever. This is a high-maintenance population with complicated needs and large amounts of information to be analyzed. The data we proposed collecting, in combination with patient-derived information, can drive patient support tools that are too complicated, time-consuming, or expensive for many practitioners to purchase. It is in the patients' best interests to take advantage of the many support services offered or being developed by the care management programs of payer organizations. Care management clinicians can function as office extenders when accurate data are available and there is good communication with providers. Programs that provide telephonic support and other resources help patients get the care they need early and may impact quality of life and reduce the need for emergency or hospital care.

Transparency for Patients

Although not specifically related to clinical trials in oncology, the recent exposure of extremely unethical clinical trial breaches prompted President Obama to commission a task force to report on the protection of patients participating in clinical trials in the United States. On December 15, 2011, the Presidential Commission for the Study of Bioethical Issues released a critical report concerning human subjects involved in clinical trials.³ The full report outlines 14 changes to current practices to enhance the protection of trial participants. These changes are intended to increase the accountability of those conducting trials and transparency for patients and payers (in this case, the federal government). These recommendations will impact the entire spectrum of stakeholders involved in oncology clinical trials.

The **Table** shows the 14 recommendations from the commission. A robust discussion of the implications this report has for oncology clinical research is not possible within the confines of this perspective; however, we believe an important part of creating the mandated change is to ensure that patients are clearly informed of what payers are not mandated to cover under the ACA. We are concerned about the significant out-of-pocket expenses patients with cancer may face because of discrepancies between the plans they have chosen

and the desire to be treated on a specific clinical trial. Patients must clearly understand all the risks, including the financial burdens, of participating in a clinical trial before treatment begins.

SUMMARY

We applaud ASCO for undertaking this endeavor. As strong supporters of clinical research, we hope that all stakeholders take this opportunity to make improvements in oncology care that go beyond the basic requirements of the ACA. This is a tremendous opportunity to step back and realize it is a complex system that cares for a patient enrolled onto a clinical trial, not just 1 physician. We believe there is no such thing as a single, sacred physician-patient relationship in modern oncology. Consider the patients who need combined-modality care to have the best outcome. Several physician teams, sometimes with different opinions, must work together, each without undermining the recommendations of the others for therapy to be successful and for the patient to have faith in his treating team. The majority of oncology care consists of networks of critical, dependent relationships. No single stakeholder has a right to disregard the needs and rights of the rest of the system components. Just as payers have responsibilities, they also have rights. Clinical investigators have both rights and responsibilities, as do trial sponsors. And although we all want patients' rights to never be forsaken, they must also uphold their own responsibilities for the plan choices they make. Only when all parties can come to terms with their own responsibilities as well as respect the rights of others will we be able to function as a unified team in producing a unique and robust clinical trial process.

We believe our proposal for the types of data elements that could be communicated to a payer or plan manager when a patient is considering enrolling onto a clinical trial has merit in terms of achieving the goals of better and more comprehensive communication, increased transparency, and patient protection. We look forward to future interaction and participation with the PPI as we all work together in the unique initiative to make certain we can continue to advance the treatment of cancer.

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