

The Impact of Alternative Payment Models on Oncology Innovation and Patient Care

Amy M. Miller¹, Gilbert S. Omenn^{2,3}, and Marcia A. Kean⁴

Abstract

Oncology care is in a time of major transformation. Scientific discovery is driving breakthroughs in prevention, diagnostics, and treatment, resulting in tremendous gains for patients as the number of cancer survivors continues to grow on an annual basis. At the same time, there is mounting pressure across the healthcare system to contain costs while improving the quality of cancer care. In response to this pressure, private and government payers are increasingly turning to tools such as *alter-*

native payment models (APM) and clinical pathways to improve the efficiency of care, inform coverage decisions, and support shared decision-making. As APMs, clinical pathways and other tools are utilized more broadly, it will be critical that these models support the evidence-based use of innovative biomedical advances, including personalized medicine, and deliver patient-centered, high-value care. *Clin Cancer Res*; 1–7. ©2016 AACR.

In July 2015, the **Turning the Tide Against Cancer** initiative convened a roundtable composed of a multidisciplinary group of stakeholders to discuss key considerations for oncology-focused APMs. This article highlights five policy considerations resulting from this roundtable discussion that were considered critical to ensuring APMs, clinical pathways, and shared decision-making tools support the delivery of high-quality oncology care while supporting innovation:

- APMs should keep pace with rapidly emerging science by incentivizing the adoption of innovative medicines and technologies that have the potential to improve patient outcomes and make healthcare more efficient.
- APMs should include mechanisms to encourage patient participation as appropriate in clinical trials as well as ongoing postmarket clinical research.
- Clinical pathways should be transparent and evidence-based, and updated regularly to reflect current scientific evidence and clinical advances within the overall continuum of care.
- When providers and patients are making treatment decisions, patients should be given a clear, comprehensive picture of their treatment options, including cost information that is tailored to the specific patient's insurance coverage and treatment plan.

- APMs should require that clinical data be aggregated and integrated into providers' workflows via electronic health records in order to support learning healthcare systems. Providers should have access to data that will support their shared decision-making with patients. Similarly, patients should have access to research results collected through a learning healthcare system.

These policy considerations are intended to represent meaningful solutions agreed upon by a variety of stakeholders in the field of oncology, all focused on the ultimate goal of supporting oncology research and care that is innovative, evidence-based, and personalized.

Introduction

The U.S. healthcare system, and oncology care in particular, are undergoing a major transformation. New avenues of research are leading to potentially breakthrough cancer treatments, giving patients and the public renewed hope and optimism. At the same time, pressures to contain costs while simultaneously improving the quality and efficiency of our healthcare system are greater than ever. In response, private and government payers are turning to new methods of payment and delivery in cancer care known as *alternative payment models* (APM). These APMs can take different forms, including accountable care organizations (ACO), episode-based payment models, and oncology patient-centered medical homes (1–3). APMs can also be used in conjunction with tools to improve the effectiveness and efficiency of care, such as clinical pathways used by clinicians and patients to support shared decision-making and evidence-based medicine and by payers to inform more specific coverage policies.

In early 2015, the Centers for Medicare and Medicaid Services (CMS) set a goal to have 50% of Medicare payments linked to value-based reimbursement models, such as APMs, by the end of 2018 (4). APMs, if structured appropriately, can encourage shared decision-making between healthcare providers and their patients and increase the value of the care delivered. However, as providers,

¹Personalized Medicine Coalition, Washington, District of Columbia. ²Department of Computational Medicine & Bioinformatics, University of Michigan Medical School, Ann Arbor, Michigan. ³Health Policy Committee, American Association for Cancer Research, Philadelphia, Pennsylvania. ⁴Feinstein Kean Healthcare, Cambridge, Massachusetts.

Corresponding Author: Marcia A. Kean, Feinstein Kean Healthcare, 245 First Street, Cambridge, MA 02142. Phone: 617-577-8110; Fax: 617-557-8985; E-mail: marcia.kean@fkhealth.com

doi: 10.1158/1078-0432.CCR-16-0892

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payers, and policymakers design and test APMs, they must also consider the importance of innovative and personalized approaches to oncology research and seek to ensure that any new approaches enable the incorporation of validated diagnostic and therapeutic advances to deliver on the promise of patient-centered, high-value cancer care (5).

The Turning the Tide Against Cancer (T3) initiative identified APMs as a priority issue for further analysis, with a focus on ensuring that society continues to benefit from the expanding potential of personalized oncology care, while integrating patient centeredness and value into everyday cancer research and care (6, 7).

In July 2015, the T3 co-conveners¹ hosted a roundtable discussion of a multidisciplinary group of stakeholders, including providers, patient advocates, academic researchers, payers, and industry representatives,² in Washington, DC. The objective of this roundtable was to identify and discuss key considerations for oncology-focused APMs and clinical pathways, with the ultimate goal of understanding how APMs can best support the delivery of patient-centered, high-quality oncology care, while promoting innovation.

Cancer care has featured prominently in the national conversation about value-based healthcare, which is not surprising given the health and economic burdens of cancer in the United States, as well as the unique needs of cancer patients. In 2014, the Center for Medicare and Medicaid Innovation launched the Oncology Care Model (OCM), a demonstration program for oncology patient-centered medical homes (8). As new payment models and clinical pathways are tested, it is necessary that they keep pace with emerging scientific and clinical advances in oncology.

This paper captures the key themes from the roundtable discussion and describes related policy considerations. The T3 co-conveners are planning follow-up discussions throughout 2016.

"We have a responsibility to guide this discussion, to move it in a direction that will ensure we improve the quality of care for patients, access to care for patients, and support innovation in the development of new treatments for patients."

—Richard L. Schilsky, MD, FACP, FASCO, American Society of Clinical Oncology

"Many different organizations and hospital systems are matching patients to drugs based on diagnostics and through clinical trials. We need to keep up with that rapid pace of knowledge gain in clinical research, and I believe that part of the concern about APMs is that flexibility will be stifled."

—Amy M. Miller, PhD, Personalized Medicine Coalition

"The way cancer patients are being treated today is changing quickly and often, which is largely due to our ability today to more rapidly translate research discoveries into the cancer care delivery process. Therefore, APMs need to be dynamic and flexible to account for the progress we are making in fighting cancer."

—Jon Retzlaff, MPA, MBA, American Association for Cancer Research

¹The Turning the Tide Against Cancer (T3) co-conveners are the American Association for Cancer Research, the Personalized Medicine Coalition, and Feinstein Kean Healthcare.

²See Appendix A for a full list of roundtable participants.

"The opportunity alternative payment models bring to the table is the chance to enhance the quality of cancer care for patients."

—Ted Okon, MBA, Community Oncology Alliance

"We have to accept the fact that reducing spending on healthcare is a mandate now, and it's a question of how you get there best. Alternative payment models offer an opportunity for the healthcare industry to take some of that control back."

—Erin Smith, Post-Acute Care Center for Research

Key Themes and Policy Considerations

Through a facilitated discussion, several roundtable participants shared their experiences in implementing APMs at their institutions and the lessons learned from these different approaches. Participants also discussed how to leverage APMs to encourage continued innovation in oncology care and research, how each APM strategy may affect personalized medicine and oncology care, and which APM mechanisms are most able to recognize and incorporate rapid changes in science and clinical care of cancer patients.

Over the course of the roundtable discussion, several main themes arose regarding how APMs could incentivize, and even bolster, innovative, patient-centered oncology care now and in the future. Several considerations for APMs to maximize this potential are noted below.

Policy Consideration for Emerging Payment and Delivery Reform

Considerations for Alternative Payment Models

1. APMs should keep pace with rapidly emerging science by incentivizing the adoption of innovative medicines and technologies that have the potential to improve patient outcomes and make healthcare more efficient.
2. APMs should include mechanisms to encourage patient participation as appropriate in clinical trials as well as ongoing post-market clinical research.

Considerations for Clinical Pathways

3. Clinical pathways should be transparent and evidence-based, and updated regularly to reflect current scientific evidence and clinical advances within the overall continuum of care.

Considerations for Shared Decision-making and Continuous Learning

4. When providers and patients are making treatment decisions, patients should be given a clear, comprehensive picture of their treatment options, including cost information that is tailored to the specific patient's insurance coverage and treatment plan.
5. APMs should require that clinical data be aggregated and integrated into providers' workflows via electronic health records in order to support learning healthcare systems. Providers should have access to data that will support their

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shared decision-making with patients. Similarly, patients should have access to research results collected through a learning healthcare system.

**Clinical pathways are tools used by clinicians and patients to support shared decision-making and evidence-based medicine and by payers to inform more specific coverage policies.*

Considerations for alternative payment models

- (1) *APMs should keep pace with rapidly emerging science by incentivizing the adoption of innovative medicines and technologies that have the potential to improve patient outcomes and make healthcare more efficient.*

While APMs are not completely static in nature, most rely on annually calculated spending benchmarks and infrequently updated episode-of-care definitions. As such, APMs may not account for the costs associated with new advances that improve care and may be expensive in the short term, but that may result in savings over the long term. In these cases, APMs may create unintended barriers to patient access (e.g., limiting coverage for a new medicine that may be more expensive but has fewer side or long-term effects than existing treatments) potentially discouraging future innovation. Additionally, some APMs are seen as being too proscriptive (9)—constraining the ability of physicians to tailor treatment to their patients' specific needs—while also not taking into consideration practice characteristics, such as location or patient demographics, or how care is actually delivered within a specific care setting.

Roundtable participants agreed it is crucial that new payment models recognize and incentivize continuous innovation, which can occur as breakthroughs or via continued incremental advances that yield better outcomes for patients over time. With 73% of cancer drugs in the research pipeline potentially becoming personalized medicines (10), payer coverage needs to encompass validated innovative treatments and their companion diagnostics that will enable identifying which patients will respond best to targeted therapies, thereby avoiding the cost of treating patients who will *not* benefit or may be harmed, including the cost of accompanying side effects and delays in identifying other treatments that may benefit those patients.

At a minimum, APMs, such as bundled payments and accountable care organizations that measure success in part on static financial benchmarks, should incorporate payment mechanisms to encourage the use of innovative drugs and devices supported by sound evidence, including those that have been designated by the FDA as orphan drugs, breakthrough therapies, fast track products, and priority review products. Similar strategies to the Medicare Outpatient Prospective Payment System's pass-through payment should be considered³, potentially safeguarding patient access to

treatments that may be particularly effective for their cancers and allowing providers to continue to individualize treatment.

APMs should not only preserve but also incentivize a physician's ability to appropriately tailor treatment to individual patients' needs and preferences. Payment models should support how care is delivered and reflect the complexity of services needed to effectively treat patients with cancer. Doing so allows providers to spend time fully explaining treatment options and addressing complications associated with treatment side effects or comorbid conditions (11).

Roundtable participants stressed that there is no one-size-fits-all APM model. Different models will incentivize efficient and effective care delivery to different degrees depending on geographic region, practice characteristics, setting, and other factors. Medical practices need to be willing to negotiate with payers to implement the payment model that may most benefit their patients and patient subgroups. On the payer side, CMS and commercial payers should consider implementing multiple types of APMs to assess how different models perform in different segments of the population and care delivery system. As demonstration projects are ongoing for some APMs, participants cautioned against scaling up new models or starting an existing model in a new market without first making sure that the demonstration project was successful; also, demonstration projects should be implemented with a focus on incorporating patient feedback throughout the process.

"Any of these payment models or value frameworks or care pathways have to be dynamic. If they're static or offer a snapshot in time, you are going to be practicing yesterday's or last decade's medicine."

—Newton F. Crenshaw, Eli Lilly and Company

"If you've seen one alternative payment methodology or contract, you've seen one. We need standardization of process and science, so that we can be liberated to take care of patients. There's a lot of ways of approaching it. The idea is that the biggest opportunity with APMs is to really realign patient, payer, and provider incentives, and I think that it can be done."

—John D. Sprandio, MD, FACP, Oncology Management Services

"Cancer is a disease of each patient's genome and is uniquely personal. Therefore, comprehensive genomic profiling validated in peer-reviewed literature should be incorporated as a central feature of an alternative payment or care model, so that it can be used as a navigational tool and serve as the backbone of clinical pathways or guidelines. Ultimately, this would result in a better, more patient-centered process and enable personalized medicine."

—Jerry Conway, Foundation Medicine

- (2) *APMs should include mechanisms to encourage patient participation as appropriate in clinical trials as well as ongoing post-market clinical research.*

Only 3% of patients with cancer report participating in clinical trials, where patients gain access to novel and

³The Medicare Outpatient Prospective Payment System (OPPS) provides a transitional pass-through payment for drugs and biologicals that are furnished as part of an outpatient hospital service. Normally, items and services provided in the hospital outpatient setting that are provided to a patient within a certain period of time are paid together in one inclusive, bundled payment. The exception is certain drugs and biologicals that receive "pass-through" status, and that are paid outside of the bundled payment. Pass-through status typically lasts for 2 to 3 years after a drug is approved.

potentially cutting-edge therapies, though the percentage is even lower for women and minorities (12). While there are many reasons why patient participation in clinical trials may be low, a number of the roundtable participants noted several reasons why APMs can make it difficult for practices to participate in clinical trials. One barrier mentioned is that clinical trials are not a source of revenue for oncology practices, and, in fact, may actually cost practices money. Providers may see a clinical trial as a further burden to their resources, thereby leaving patients unaware of the full range of treatment options available to them, significantly hindering research and discovery, and ultimately delaying innovation.

APMs can further discourage participation if their financial incentives are associated with treating patients according to a strict care protocol or clinical pathway, discouraging participation in clinical trials. In order to support improvement of cancer care and treatment, APMs must make it financially feasible for practices to enroll patients and participate in clinical trials. Further, roundtable participants identified several strategies to support clinical research within APMs such as supporting real-world data collection.

"One of the basic issues with clinical trials is financial—it's a hobby, not a revenue stream. Practices are struggling with trials. Generally what happens is we will see someone with mutation X, but by the time we go through the expense and effort to get a trial open, we don't have anyone eligible for the trial. So we've embedded genomic testing ahead of time in our COME HOME model, in hopes that you can test for a mutation early on; then, when the right trial comes along, we will have developed a database to go through, find everyone with the mutation, enroll the patients, and get the product to market. We are setting up a clinical research organization to certify practices as being able to provide the quality of data needed for a clinical trial. If we can do something like that, we will be able to deliver drugs to patients so they can stay home with their families and not spend all their family's money."

—Barbara L. McAneny, MD, New Mexico Cancer Center

Considerations for clinical pathways

- (3) *Clinical pathways should be transparent and evidence-based, and updated regularly to reflect current scientific evidence and clinical advances within the overall continuum of care.*

In order to lower the cost of cancer care, payers increasingly rely on tools to manage utilization of oncology treatments, such as clinical pathways that are used by clinicians and patients to support shared decision-making and evidence-based medicine and by payers to inform more specific coverage policies. It is critically important to understand how pathways affect provider decision-making and patient access; how these tools can be constructed to leverage the best available information; and how patients can be engaged in shared decision-making with their physicians.

Many roundtable participants voiced concern over the lack of transparency around pathways, making it difficult to

know whether such strategies are supported by good evidence, based on expert guidelines, created by individuals without conflicts of interest, and representative of the patient perspective. In addition, stakeholders have begun working together to identify best practices for clinical pathway development (13–15). With these considerations in mind, participants discussed the need for clinical pathways to do the following:

- Include input from patients, providers, and other relevant stakeholders via an open and transparent process for pathway content development.
- Make pathways used in public programs publicly available with pathway disclosures, including a description of the evidence and data sources used to construct each pathway.
- Assess different kinds of relevant and scientifically-produced health outcomes evidence, including data not only from randomized control trials, but also clinical practice guidelines and rigorously designed observational studies; each type of evidence has particular strengths and weaknesses when applied to specific healthcare questions and decisions.
- Include information on treatment costs that is patient-specific and facilitates shared decision-making between providers and patients.
- Engage practicing providers and clinical experts in leadership roles developing and selecting appropriate clinical pathways.

Also of concern to the roundtable participants was that rigid pathways may limit patient access to potentially beneficial treatments and restrict providers' ability to deliver care. It is imperative that pathways allow for flexibility and aid in the shared decision-making process between providers and patients, and ultimately provide patients with the treatment most aligned with their treatment goals. Furthermore, patients' potential economic concerns should be part of the decision-making process, while aligning the final treatment decision with patients' priorities and goals (e.g., treatment goals, side effects, quality of life, and costs).

Clinical pathways should include viable options for off-pathway treatment when consistent with patients' goals and supported by evidence, and accompanied by appropriate data collection to track interventions and associated outcomes and costs.

Roundtable participants also agreed that pathways should incentivize real-world data collection, with the goal of building an evidence base that can be assessed to determine if pathway updates are needed and to encourage continuous innovation. Economic data alone should not be used to exclude an effective treatment from a pathway or to limit access to equally effective treatments.

"You can imagine a model where you treat patients according to evidence-based pathway, but when you need to go off pathway, you're doing that within a system that is able to report both toxicity and outcomes data, and to help understand the real world impact"
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of the pathway deviation. As treatments rapidly evolve, some pathways will always be struggling to keep up; clinicians need the flexibility to do what's right for the patient, while at the same time, enabling the broader community to learn from the intervention. And eventually we should end up in a place where part of the inputs into pathways are real data."

—Robert J. Green, MD, MSCE, Flatiron Health, Inc.

"I think we underestimate the value of transparency with respect to patients. I have had a payer medical director say to me, "Patients don't want to know about pathways, and, even if they did, they wouldn't understand them." I think that's wrong. I think that pathways are a very well-kept secret that's impacting the delivery of oncology care for better or for worse, and patients can't even define them. We need to engage the patient. The only way that's being done right now is by making them pay more."

—Patricia J. Goldsmith, CancerCare

"One thing we need for APMs to work is transparency. We need a process that is sufficiently transparent and open to capture the patient voice and truly focus on what the patients want out of their healthcare, recognizing that variability will occur. We also need transparency to know APMs are adapting to changes in clinical practice and technology."

—Randy Burkholder, Pharmaceutical Research and Manufacturers of America

Considerations for shared decision-making

- (4) *When providers and patients are making treatment decisions, patients should be given a clear, comprehensive picture of their treatment options, including cost information that is tailored to the specific patient's insurance coverage and treatment plan.*

In order for patients to be fully informed during the shared decision-making process, they need access to comprehensible information on efficacy, toxicity, and cost. While the costs of many oncology drugs have come under close scrutiny, roundtable participants agreed that value-based care models should account for the entire spectrum of oncology care costs, not just medicines. Patients should have an opportunity to speak with a financial counselor and have access to cost information that is specific to them, particularly as it relates to their out of pocket, co-insurance, and deductible costs. In addition to outlining direct financial costs, the decision-making discussion between the physician and patient should encompass the full picture of how cancer treatment will affect a patient's everyday life, including ability to work, activities of daily living, or ability to care for family and loved ones.

If cost is incorporated into a decision support tool, it is important that it be conveyed in a way that is relevant, accurate, individualized, and understandable to the patient. Developers of decision support tools should also explore ways to incorporate real-time benefit checks, so that patients will know how much they may be expected to cover in out-of-pocket costs. Developers of APMs and clinical pathways can leverage the expertise of organizations such as the

National Council for Prescription Drug Programs to determine how to best integrate these types of capabilities into their models.

"We just assume when we talk about access [to medicines] that all patients want access to the same thing, but they don't. People make decisions based on multiple reasons, including their values, goals, and community. I've had conversations with many people about cost and treatment choice. Some people tell me, 'If I knew this drug was going to cost hundreds of thousands of dollars and would most likely only give me two months' more of life, I would not do it; because to me, the cost to society and to my family is too much.' Other people have said, 'I don't care about the drug costs. I want to be alive for those two months – that is the best for my family.' Both patients and doctors have to be given information about cost versus benefit in order to achieve informed decision-making."

—Gwen Darien, Cancer Support Community

"Clearly, it's not just about the price tag on the therapy; there are other non-healthcare costs, indirect costs, and other patient concerns at work when we are trying to optimize care."

—Clifford Goodman, PhD, The Lewin Group

- (5) *APMs should require that clinical data be aggregated and integrated into providers' workflows via electronic health records to support learning healthcare systems. Providers should have access to data that will support their shared decision-making with patients. Similarly, patients should have access to research results collected through a learning healthcare system.*

To maximize the potential of APMs to support validated innovation and bolster the informed decision-making process, stakeholders must recognize them as a key component of learning healthcare systems. Several roundtable participants emphasized that healthcare data generated by the various modes of clinical care delivery and at different points of delivery can flow into a feedback loop, allowing for continuous learning. Rapid accumulation and assessment of healthcare data within APMs can enable a nimble healthcare system that can adjust and adapt to innovations in real-world treatment and in clinical trial design.

Any relevant research findings resulting from a patient's data should be shared with the patient to support an informed decision-making process.

"The opportunity I see is to finally get further along on the way towards a learning healthcare system by motivating or incentivizing or facilitating the new methods of evidence generation. There is a hunger for more – not just more data, but for more insight from the data. We need to stop talking about drowning in big data and start forcing big data to be used more productively."

—Marcia A. Kean, MBA, Feinstein Kean Healthcare

"Innovation is not just drug and diagnostic development. Innovation is care delivery."

—James Hamrick, MD, MPH, Kaiser Permanente of Georgia

"Alternative payment models, as currently structured, often take a snapshot in time and that's how we determine quality and cost, among other metrics. This limited view inhibits the ability to move to a truly patient-centered system, where we're taking into account functional status and other quality of life issues, which is a paradigm shift in how our current healthcare system treats patients and how patients receive care."

—Andrew J. Shin, JD, MPH, The Schwartz Center for Compassionate Healthcare

Conclusions

At a time when oncology care is increasingly innovative and costly, use of APMs and clinical pathways are becoming more widespread. To enable APMs to improve cancer care, rather than restricting physician flexibility and patient access to innovative treatments, stakeholders should think carefully about these considerations during the development, testing, regulation, and continuous maintenance of these value-based payment models. Ultimately, APMs can be a powerful means of driving innovation in treatment and care delivery, facilitating research and promoting access for patients with cancer to proven, individualized life-changing treatments. APMs may generate larger numbers of patients with multidimensional data leading to better-informed assessments of the real-world effectiveness of candidate therapies and modes of care delivery.

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This paper identifies key policy considerations that merit further analysis within the stakeholder community to ensure that new models of value-based care keep pace with—and indeed help to validate—emerging scientific and clinical advances in oncology. The Turning the Tide initiative is planning such follow-up discussions.

Appendix A*

Participants from the T3 Roundtable held in July 2015 are listed below. The views reflected in this paper are not necessarily the views of individual members of the roundtable or of the organizations they represent.

Clifford Goodman, PhD, The Lewin Group (moderator)
 Randy Burkholder, Pharmaceutical Research and Manufacturers of America
 Jerry Conway, Foundation Medicine
 Newton F. Crenshaw, Eli Lilly and Company
 Gwen Darien, Cancer Support Community
 Patricia J. Goldsmith, CancerCare
 Robert J. Green, MD, MSCE, Flatiron Health, Inc.
 James Hamrick, MD, MPH, Kaiser Permanente of Georgia
 Marcia A. Kean, MBA, Feinstein Kean Healthcare
 Barbara L. McAneny, MD, New Mexico Cancer Center
 Amy M. Miller, PhD, Personalized Medicine Coalition
 Ted Okon, MBA, Community Oncology Alliance
 Jon Retzlaff, MPA, MBA, American Association for Cancer Research
 Richard L. Schilsky, MD, FACP, FASCO, American Society of Clinical Oncology
 Andrew J. Shin, JD, MPH, The Schwartz Center for Compassionate Healthcare⁴
 Kirsten A. Sloan, American Cancer Society Cancer Action Network
 Erin Smith, Post-Acute Care Center for Research⁵
 John D. Spradio, MD, FACP, Oncology Management Services

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

Received April 7, 2016; accepted April 8, 2016; published OnlineFirst April 17, 2016.

*Note: Several representatives of payer organizations accepted the invitation to attend the roundtable but were unable to participate due to last-minute schedule disruptions.

⁴At the time of the roundtable, Andrew J. Shin was the Director of Health Care Policy and Life Science at ML Strategies.

⁵At the time of the roundtable, Erin Smith was a senior manager at Avalere Health.

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Clinical Cancer Research

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Clin Cancer Res Published OnlineFirst April 17, 2016.

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