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Institute for Clinical and Economic Review
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On behalf of the Board of Directors of the Community Oncology Alliance (COA), I would like to thank you for inviting the Community Oncology Alliance (COA) to provide suggestions for the 2020 Patient Guide of the ICER Value Assessment Framework. COA welcomes the opportunity for meaningful collaboration as ICER seeks to shape and improve its value guidelines.

For more than 16 years, COA has built a national grassroots network of community oncology practices who have come together to advocate for public policies that benefit the patients with cancer we serve. COA initiatives support all aspects of the cancer care delivery team, including oncologists/hematologists, pharmacists, mid-level providers, oncology nurses, patients, survivors, and caregivers. This involvement has extended to life science companies, as well as federal, state, and regional payers, employers, employer health groups, and others that impact this delivery system.

COA has an extensive track record of envisioning a cancer care system that is oriented to provide patients with quality, affordable cancer care close to where they live and work. We guided the formation of the first accredited Oncology Medical Home (OMH) program in 2014, which started with a historic gathering of payers, cancer advocacy groups, providers, administrators, and other champions to formalize the first set of quality and value measures for cancer care. This effort has catalyzed the promotion and support of various payment reform models for cancer care across the country. COA has currently identified 20 such active models, all of which are different and unique. Because of that, COA has also been strategic in identifying best practices within these models that might be shared with others.

Since its inception in 2005, ICER has grown in prominence and influence in the health care community. ICER's evidence reports evaluating the "value" of drugs and treatments are increasingly being cited by payers and stakeholders in their decisions surrounding payment and access. Practically speaking, this means patient access – or lack of access – to critically needed, groundbreaking cancer treatments is being increasingly influenced by ICER recommendations. As such, we feel that COA's perspective as a leader in cancer care, oncology payment and delivery reform, and stakeholder cross-collaboration is an important addition to the ICER process. Unfortunately, given the short nature of the comment period and late notice of it, COA's comments on these issues are forced to be brief. We hope that ICER will continue to have an open and honest dialogue on these issues with more opportunity for input in shaping the value framework.

The remainder of this document will be used to relay findings, lessons learned, and suggestions that COA believes may be useful to ICER in the further development of a universally accepted value framework.

Current Landscape of Value in Oncology

As mentioned, COA has identified at least 20 oncology payment reform models in cancer care that are currently active in the United States' health care marketplace. Recently, payment models are predominantly developing at regional levels with the self-insured employer community. The goals, strategies, and missions of these models are more focused on the employee who is a cancer survivor. The emphasis has been on cost with respect to services (value), site of care differentials, access issues, communication, collaboration and coordination, as well as general support.

These existing, active models that are driven by employers reflect a view of value that differs from other stakeholders. The emphasis on the employee who is a survivor requires a new approach, understanding, and set of skills. When done properly, these employer-driven reform models are growing in both number and scope and the base of participating employers is also growing. ICER could be a valuable resource to this evolving group of decision makers for high quality and value in health care.

The dominant oncology payment reform effort today is the Centers of Medicare & Medicaid Innovation (CMMI) Oncology Care Model (OCM). The OCM is the first CMMI specialty care model and serves approximately 35 percent of all Medicare beneficiaries with cancer. COA has provided significant support to approximately 80 percent of the participants in the OCM since its inception, and much of it is based on the Oncology Medical Home work that COA has led.

The impact of the OCM has been transformative; however, it has struggled in many areas. Based on qualitative and quantitative feedback COA has gathered, the primary issues affecting its success are the complexity and communications and timing delays in this model. The payment methodology within this model has many opaque multipliers and participants are challenging the end financial projections. While some reports indicate substantial improvements, these reports are not aligning with the expected performance-based payments. One of the main explanations for this disparity relates to how value in the OCM is measured between existing and new/novel therapies.

There are many lessons to promote value in cancer care that can be learned through the OCM and other oncology payment reform models that COA has observed. These will be addressed in the "Guidance" section to follow.

Guidance:

Community oncologists are concerned about the escalating prices and costs of cancer drugs, as well as the overall increasing total cost of cancer care. As leaders in the delivery of cancer care, we are mindful of our responsibility to be good stewards of costs we can control, including the utilization of drugs and services.

Much has been said regarding the drivers to the costs of cancer drugs and treatments. Although some of these impediments are being addressed, no true standard exists on how the price of a drug, or service, is being weighed against its benefit. For example, drug costs are typically viewed as a standalone metric with minimal regard to other costs that are being avoided, such as side effects, missed work hours, caregiver needs, and

more. COA commends ICER for undertaking the challenge of viewing drug value in its entirety and “*translating evidence into policy decisions that lead to a more effective, efficient, and just health care system.*” This sets the stage for a functional, universal, and practical model that manufacturers and provider teams can use to prove the value of a drug or service – and before ICER evaluates these products.

COA has researched and discussed value statements and missions of some of the leading cancer therapy companies. Each and every one of these companies has a value assessment tool in use. However, there is minimal consistency between the processes employed by these companies and how they process metrics in the evaluation of value. The optimal goal would be a standard methodology, using existing evidence, that would promote a standard, patient friendly, easy-to-understand template to define this value. COA is prepared and interested in assisting ICER in such an endeavor. The following sections are organized by category, with details under each section.

Defining Fundamentals of Value:

- A) Patient friendly:** Patients with cancer are, in many ways, the victims within our health care delivery system. This is particularly true for cancer. The term financial toxicity was born out of unexpected financial hardships. Some of these hardships could be prevented if the patient was better informed and more involved in the care process. Focusing on the patient for value discussions will require different strategies and a new vocabulary. There are countless examples of patient communication techniques that were used in the OCM. Many of these techniques failed due to their inability to communicate effectively with patients with cancer. Trust becomes a key ingredient in effective patient guidance and support through care improvement efforts. It fosters a common language that is shared between care teams, manufacturers, and other supportive entities.
- *We encourage ICER to ensure that patients are the focus of all definitions of value and that their firsthand input is both encouraged and accepted.*
- B) Compare total costs of care:** Once a comprehensive, functional model is created for value it should be used for comparative analysis. Science is changing rapidly. This has been most evident in cancer care with the introduction of immune-oncology and cellular therapeutic agents. On the surface it would appear that these classes of drugs are incredibly expensive. However, when these new therapies, and the attendant annualized total cost of care, are compared to traditional care, the total annual cost is not as high. This is due to the reduced dependence on costly supportive care, lower risk of adverse events and hospitalizations, and improved progression free and increasingly overall survival. This will only be understood if new therapies are compared to historical treatments with all inputs considered. Creating a total, comparative picture promotes greater understanding of the total cost of care.
- *We encourage ICER to ensure that the definition of value weights the total historic cost of care against new treatments or therapies.*
- C) Transparency:** The lack of transparency has worked against some of the reform models – including the OCM. Explanations on why, or why not, a drug or therapy provides value should be clear, evidenced-based, and reproducible. Graphics and other information regarding the value of a certain drug should be easily understood. Teams that represent and impact value need clear communication that can be used in conversations with care team managers. These managers will then be able to understand the value positions well enough that they can share and explain the same document with

their care teams AND patients, as applicable. Patients should be able to interpret the information without requiring detailed explanations of abbreviations, methodology, and metrics.

- *We encourage ICER to ensure complete transparency and communication in the definition of value.*

D) Effective communications: The most successful reform models have routine and clear lines of communications with participating cancer care teams and beneficiaries. Although this sounds elementary, and even to be expected, the lack of effective communications has hindered participation, enthusiasm, and support of reform models. Those models that have been successful have open lines of communication for questions, feedback, suggestions, etc. This thoughtful approach facilitates improvements that are implemented efficiently. The same applies to their reporting and other updates.

- *We encourage ICER to ensure effective and helpful communications as value positions are developed and shared.*

Unique Nature of “Value” in Cancer Care:

A) Broader than a single episode: The majority of all active oncology reform models are typically evaluating costs and quality in six-month episodes. This is a marked improvement from viewing this information at the event or cycle level. However, there is some momentum building to view care for a full year. This perspective is more comprehensive and facilitates annual budgeting which should prove helpful for actuaries involved in predicting costs.

- *We encourage ICER to reflect the cost of a therapy for a minimal duration of 6-12 months.*

B) Beyond the individual treatment only: Therapies are changing rapidly. Traditional therapies included a sequenced list of supportive drugs before, during, or after the anti-cancer agent. These additional drugs add to the cost of the cancer treatment. These expenses increased further when uncontrolled toxicities prompted emergency room visits and hospitalizations. The OCM has made some progress in encouraging the calculation and communication of total cost of care in treatment plans but doing so has not necessarily been easy or correct.

- *We encourage ICER to ensure that related costs are included in the total cost of care calculations that inform value decisions.*

C) Accounting for all that are touched by cancer: Other stakeholder groups are now more active in reshaping health care delivery systems. Their interests and goals are often more patient-centric than most prior innovations. These groups include employers, employer health groups, patient advocacy groups, and insurance benefit advisers. Oftentimes, they are emphasizing site of care differences, access issues, value-based insurance design (VBID), improved coordination of care, and timely delivery of care or therapy. These entities have demonstrated their understanding of the complications and misalignment of incentives that are plaguing the attainment of quality and value-based cancer care. Ongoing dialogue and working relationships with these groups have been incredibly helpful in guiding COA’s efforts to make real improvements in cancer care.

- *We encourage ICER to include stakeholders from all of these groups in the continued development of sound guidance in defining value.*

D) Defined end goals: There has been much debate on the *best* measure of value in cancer care. Is it Overall Survival (OS) or Progression Free Survival (PFS)? Is it something else that includes both? The OS advocates are champions for extended life, regardless of the costs. Costs could potentially increase up until time of death when measuring OS. PFS advocates argue that PFS translates to a stable disease and potentially a cure. The PFS camp argues that treatment has not intensified and therefore the costs would also be stabilized. COA has come to understand that drug companies will emphasize one over the other based on the goals and documentation within the clinical trials for the product. This position is obvious within the product's package insert. This messaging is consistent for that product and after the launch of that product. This inconsistency can prove challenging as we work together to evolve towards a standard measurement.

- *We encourage ICER to understand the unique nature of cancer, consider all measures of value in this disease, and align them for consistency.*

The Multi-Stakeholders Perspectives:

The groups of participants that are interested in health care are more diverse than ever. These different groups are seeking reputable information and guidance related to quality and value in health care. This is particularly true in cancer care. Each has their own unique vocabulary and questions in pursuit of the better care. The below explores each of these groups. *COA believes that ICER's mission should include communication processes that are focused on each of these groups, and that their firsthand input be sought for any value reports undertaken in the oncology arena.*

- A) Patients:** Patients typically seek insights and opinions from individuals they trust. This can be their current provider, another provider that is recommended by a close friend, a family member, a co-worker, or trusted friend. Rarely does a patient or family have meaningful qualitative information to assist them with this decision.
- B) Patient groups:** The majority of patient groups focus on the cure and support for a specific disease. References for their mission and focus may come from many different sources. COA has been unable to find a consistent source of unbiased dependable information across these organizations.
- C) Care teams:** Oncology care teams have minimal information to guide them through the evolving emphasis of quality and value in cancer care. Although there is a vast library of tools and resources to assist with quality, there is much less evidence regarding value. There is even less trusted information on how these teams compare against their peers in the delivery of value. There have been some national attempts in this area, but the complexity of these attempts has overshadowed potential benefits.
- D) Payers:** Payer stakeholders of all shapes and sizes are demonstrating attention in these areas and some have implemented their own quality and value models. Unfortunately, patients and providers are not always included in the designs of these models. The payers' emphasis on tactics such as pharmacy benefit managers (PBMs), "fail first" step therapy policies, and secretive negotiated discounts with drug manufacturers, is working counter to the pursuit of transparent definitions of quality and value by others.

- E) **Employers:** Medium and large employers, both regional and national, who are self-insured are driving the more impactful reform models for cancer care. Their newfound education and understanding of misaligned incentives in health care are prompting radical changes in health care benefits designs and employee support systems. They are also in need of trusted and updated information that will support these continued changes. COA has recognized the importance of employers in patient-centered reform and is partnering with them directly in several markets to drive these efforts forward, toward success.
- F) **Employer health groups and coalitions:** Over the last 10-15 years, employer health groups and coalitions have become critical leaders in educating employers on value-based health care, opportunities to get engaged, and new initiatives. Their recent focus has been on the uncontrolled rising costs of drugs and treatments, as well as the site of care in which they are delivered. COA has routine discussions with these organizations and greatly respects their efforts.

Consider the Entire Cancer Journey

As mentioned above, measuring quality and value has evolved beyond a single treatment or cycle of treatments. Patients and caregivers are pursuing improvements in all aspects of the cancer care journey. Although ICER is not active in all of these phases, each are important to a comprehensive approach to quality and value. Lapses in any of the areas described below may have an adverse effect on the objectives of any quality or value-centered plan.

- A) **Pre-journey information:** The OCM emphasized the importance of structured communications to the patient and family before they began their cancer care journey. Information that is shared with the patient discusses expectations during and after treatment. The expectations are for the care team, the patient, and their family. Items that were discussed had a direct effect on how quality and value could be maximized for that specific journey. This information includes instructions on how the patient could support those goals.
- B) **Delivery of the care:** Many studies have produced findings regarding the processes used in care delivery. Processes that are chosen sometimes work to negate optimal achievement of quality and value. Some of these include site of care, timely access to oral drugs, and how adverse events are addressed. One of the challenges in health care reform is to identify and address these challenges effectively.
- C) **Improved end-of-life care:** Much has been discussed and debated regarding the decisions and timing of appropriate end-of-life care. Drug manufacturers are also confronting these same challenges as they measure OS versus PFS, and how to balance the value of those. That said, COA has heard troubling anecdotal reports of value-based efforts pre-emptively diverting patients with fully treatable and curable cancers to hospice without the input of trained oncologists. This is obviously horrific, immoral, and unacceptable. Patients with cancer and other life-threatening diseases should be given a chance to receive second opinions from trained physicians and all treatment options available when the evidence indicates the chance for survival is real. COA's hope is that the country will continue a dialogue about how we can best balance end-of-life care, hospice, and the accompanying costs with our definitions of value.

Conclusion

COA's unwavering commitment and steadfast determination to continually improve our cancer care system is driven by a mission to ensure that patients with cancer continue to have access to the highest quality, most affordable, and most accessible cancer care in the communities where they live and work.

COA appreciates ICER's efforts to better define and assess value. The U.S. health care system, and all of the industries that are touched by it, are in desperate need of a reputable source of information and guidance in this new era. As we noted earlier in this letter, given the abbreviated nature of the comment period and our late notice of it, unfortunately, COA's comments on these issues have had to be relatively brief.

We welcome the opportunity to work closely with ICER to advance meaningful, patient-centered, and value-driven policies relating to cancer care. We are available to discuss any of our concerns and recommendations provided in this letter.

We look forward to discussing these issues in greater detail with you and the ICER team.

Sincerely,



Michael Diaz, MD
President



Ted Okon
Executive Director