August 9, 2018

Steven Pearson, MD, MSc, FRCP
President
Institute for Clinical and Economic Review
One State Street, Suite 1050
Boston, MA 02109 USA

Re: Antiandrogen Therapies for Nonmetastatic Castration-Resistant Prostate Cancer: Effectiveness and Value Draft Evidence Report

Dear Dr. Pearson,

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, we appreciate the opportunity to respond to the request for comments regarding the Institute for Clinical and Economic Review’s (ICER) Antiandrogen Therapies for Nonmetastatic Castration-Resistant Prostate Cancer: Effectiveness and Value Draft Evidence Report. As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of 44 licensed affiliates, more than 120 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than $40 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally.

Additionally, CSC is home to the Research and Training Institute—the only entity of its kind focused solely on the experiences of cancer patients and their loved ones. The Research and Training Institute has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry, various publications and peer-reviewed studies on distress screening, and the psychosocial impact of cancer and cancer survivorship. This combination of direct services and research uniquely positions CSC to provide valuable patient- and evidence-informed feedback on value frameworks such as ICER’s Value Framework. CSC is pleased to offer the following comments on this Antiandrogen Therapies for Nonmetastatic Castration-Resistant Prostate Cancer: Effectiveness and Value Draft Evidence Report.

Unrealistic Timeframe to Respond
The timeframe to read, consider, and respond to ICER documents continues to pose a challenge to many organizations and individuals who wish to respond. Four weeks to read, analyze, and respond to a document of this complexity is extraordinarily challenging for many individuals and
organizations. We ask that a minimum of 60 days is allowed for comments on any document included in the value assessment process.

**Concept of Value**

As we have noted in previous comments, it is critical to clearly delineate the differences between the concept of “value” as it pertains to medical treatments and devices, and assessment based primarily on the financial implications of those treatments and devices. ICER identifies the “primary anchor” of the value framework, which is “long-term value for money.” This is bolstered by the complementary perspective of “short-term affordability.” Although cost-effectiveness is a reasonable endpoint in the value discussion, the use of budget impact is inappropriate.

We continue to believe that any value framework cannot be a one-size-fits-all approach and the concept of value must be broader than budget impact and cost containment. Patients make different determinations regarding what they value most throughout their illness and care journeys.

While the short- and long-term financial impacts of drugs and devices are clearly important to consider, there are other aspects of value that are critical to include in any comprehensive “value assessment.” Meaningful patient and stakeholder representation is vital to all institutions determining value, including ICER. It would be helpful for ICER to not only post public comments but also transparently describe how they identify groups and individuals to provide feedback and which groups and individuals provided feedback on the documents and reports.

CSC recommends the following:

1. Limit inclusion of budget impact in the final value assessment, but rather report it as one endpoint.
2. Recognize value beyond 5-year timeline including late and long-term benefits and effects.
3. Allow sufficient time for new therapies to be studied in both clinical and real-world populations before rendering a value assessment.
4. Include and apply weights to user preferences. Ensure that user preferences are appropriately reflected in final assessment.
5. Ensure that outcomes reflect patient experiences and preferences and include value endpoints that are important to patients as reported by patients.
6. Utilize patient registries and survey databases to explore and incorporate patient experience data.
7. Incorporate review and approval from multidisciplinary, disease-specific experts as well as patients who have experienced the disease state under review.

**Evidence**

As we have noted in previous comment letters, evidence informing ICER’s value assessments cannot be limited solely to clinical and financial impact. The same holds true for evidence from randomized controlled trials (RCTs). RCTs are widely deemed the gold standard of research, allowing for limited bias and increased usefulness in judging clinical effectiveness. However, it is also not always possible to perform an RCT nor can an RCT encompass all of the available and relevant evidence from various sources. We commend ICER for promulgating a policy on inclusion of grey literature, but this alternative source of information must rise to a minimum of peer-reviewed and published literature which will exclude many sources of legitimate data.

Conway and Clancy (2009) state that “clinicians and patients need to know not only that a treatment works on average but also which interventions work best for specific types of patients.” The National Health Council (2016) outlines “patient-centered data sources” as integral to a patient-centered value model. They note that the value model should incorporate a variety of credible data sources that allow for
timely information and account for the diversity of patient populations. This information should come from real-world settings and be reported by patients directly. Patient registries and survey databases could provide opportunities to better understand patient experiences from a wide-range of individuals. While we appreciate ICER’s use of health-related quality of life, we ask that additional patient-defined outcomes be included in the assessment.

**Insights Gained from Discussions with Patients and Patient Groups**

While we appreciate the inclusion of insights gained from discussions with patients and patient groups, the information provided is limited. We also believe that insights gained from patient experience data should be included in the body of the report and given the same amount of weight as the clinical and economic data.

Patient experience data including quality of life information regarding a host of factors is vital to an assessment regarding prostate cancer treatment. We commend ICER for inclusion of this information particularly regarding psychosocial impacts, fatigue, and financial toxicities. However, as we report below, there are other factors that are important to consider and we urge ICER to review measures and findings which fully capture the patient experience.

In 2017, we learned from our prostate cancer specialty registry that many patients report a substantially worse quality of life than the national average for fatigue (20% of respondents), anxiety (18%), physical functioning (14%), depression (12%), and social functioning (11%). Patients report that treatment is not the only source of stress and that “watching and waiting” can produce elevated levels of worry and anxiety. We found the following factors to be the top concerns across prostate cancer patients in our registry: 1) intimacy, sexual function, and/or fertility; 2) eating and nutrition; 3) exercising and being physically active; 4) worrying about the future and what lies ahead; 5) worrying about family, children, and/or friends; 6) sleep problems; 7) feeling sad or depressed; 8) feeling irritable; 9) moving around (walking, climbing stairs, lifting, etc.); and 10) feeling too tired to do the things they need or want to do.

From our Prostate Cancer Specialty Registry Report (2017), we gained significant insights into the patient experience. These include the following that we believe are important to this report:

- 20% of patients report worse fatigue than the national average
- 38% of patients are at risk for clinical depression
- 51% are concerned about sexual intimacy and function yet 24% said they did not feel comfortable speaking with anyone on their health care team about sexual side effects. Another 65% reported that they did not engage in sexual intercourse
- 50% felt they were not sufficiently knowledgeable about erectile dysfunction prior to treatment
- 51% are concerned about eating and nutrition
- 45% are concerned about exercising and remaining physically active
- While 84% were involved in treatment decision making, only 48% felt fully prepared to make a decision

When selecting a prostate cancer treatment option, we found the following factors as “most important” to patients: 1) higher chance for survival; 2) higher chance for cure; 3) doctor’s recommendation; 4) fewer side effects; 5) high chance to preserve sexual function; 6) higher chance to preserve urinary continence; and 7) family’s recommendation.

We recognize that many men survive prostate cancer, yet the impact on their overall lives and wellbeing can be significant as noted by the 57% of respondents who felt that their lives changed for worse.
compared to their lives prior to diagnosis. Decisional regret was a theme for the patients who participated in this study.

**Potential Other Benefits and Contextual Considerations**

While we appreciate ICER’s inclusion of potential other benefits and contextual considerations, it appears after ICER has made its conclusion. While it’s unclear the weight that the considerations had in the conclusion, from an optics perspective, it appears that these considerations are an afterthought rather than a critical component of the overall evidence report. We ask that these considerations be included prior to the conclusion, both in terms of ICER’s process as well as the visual representation in the report.

**Voting Questions**

We appreciate ICER’s inclusion of “potential other benefits” but ask that they are given the same weight as clinical evidence. We recommend re-titling this section “Patient Experience Evidence and Benefits” and indicating an equal level of importance to clinical evidence. We also ask for clarification and a definition of “reduced complexity” in question 6a. Further, we strongly urge ICER to include sexual dysfunction, urinary continence, and social and emotional health in this section. We also encourage ICER to include a component in this section inquiring whether the intervention meets any current unmet needs for specific populations of prostate cancer patients.

Finally, we seek clarification regarding the scoring process of the draft voting questions. Are certain questions given more weight than others? How is the final determination of value determined and by whom?

We appreciate the opportunity to provide feedback on ICER’s Antiandrogen Therapies for Nonmetastatic Castration-Resistant Prostate Cancer: Effectiveness and Value Draft Evidence Report. Please feel free to contact me at 202.650.5369 or efranklin@cancersupportcommunity.org if you have questions or if we can serve as a resource.

Sincerely,

Elizabeth Franklin, LGSW, ACSW
Executive Director, Cancer Policy Institute
Cancer Support Community Headquarters

References
