March 24, 2017

Steven D. Pearson, MD, MSc
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Proposed Updates to the Value Assessment Framework

Dear Dr. Pearson:

On behalf of the Hematology/Oncology Pharmacy Association (HOPA), I would like to thank you for the opportunity to submit comments on ICER’s proposed updates to the Value Assessment Framework. HOPA is a nonprofit professional organization launched in 2004 to help hematology and oncology pharmacy practitioners and their associates provide the best possible cancer care. HOPA’s membership includes not just oncology pharmacists, but also pharmacy interns, residents, technicians, researchers, and administrators specializing in hematology/oncology practice. The roles of our membership span from direct patient care, to education, to research. HOPA represents more than 2,500 members working in hundreds of hospitals, clinics, physician offices, community pharmacies, home health practices, and other healthcare settings.

Hematology/oncology pharmacists play an important role in the delivery of care for individuals living with cancer—they are involved with the care of cancer patients at all phases of their treatment; from assessment and diagnosis, to treatment decisions, medication management, symptom management and supportive care, and finally with survivorship programs at the completion of their treatment. Additionally, oncology pharmacists work closely with patients and their families to ensure access to the medications that are part of a patient’s treatment plan. As part of this work, oncology pharmacists are often faced with the challenge of helping patients overcome the high cost of many cancer therapies and other medications that are needed for quality cancer care.

This Framework is an important and needed first step in considering the balance of clinical benefit and financial toxicity when making treatment decisions. HOPA supports the need for improved transparency and consistency of value determinations in order to improve patient care and control costs. We would like to offer the following recommendations to the ICER Framework:

Other Benefits or Disadvantages and Contextual Considerations
HOPA supports the methods identified for the proposed modified multi-criteria decision analysis (MCDA) approach but recommends the inclusion of the impact on increased access for the underserved and reduction of healthcare disparities as an additional element to consider. We would encourage ICER to reference The American Society of Clinical Oncology (ASCO) policy statement *Disparities in Cancer Care*¹ which addresses the importance taking healthcare disparities into account across the continuum of care, from prevention to end of life.

There is also a need for new metrics that measure outcomes and are transparent to all stakeholders. We support ICER’s decision not to include the quality-adjusted life year (QALY) methodology in the framework. QALY, while an acceptable pharmacoeconomic concept, may not have enough literature support in cancer care to provide an adequate assessment of cost-utility without making assumptions. Drug development should include more quality of life information so that QALYs can be adequately determined. The concept of patient acuity is being included in many new payment models and value formulas, but there is not a mutually agreed upon objective measure. HOPA recommends that ICER work with other stakeholders to define patient acuity and include a measure in the framework. Without knowing the acuity of the patient (i.e. severity of disease, co-morbidities, etc.) a proper assessment cannot be completed.

Additionally, HOPA recommends that the framework include the method by which medications that are associated with a Risk Evaluation and Mitigation Strategy (REMS) program are evaluated. If the medications are being considered in the multi-criteria decision analysis (MCDA) due to specific requirements (i.e. post-marketing data/monitoring, health system requirements, pharmacy dispensing requirements, etc.) then there should be recognition in the framework that these steps are intended to mitigate some of the risks from the drug and therefore, some of the costs associated with that risk.

**Conclusion**

Cancer drugs are reaching new heights in cost, and reforms that will establish the least expensive, most effective therapy should be implemented. However, these reforms should not lead to barriers in patient access and choice. We hope that the recommendations above will improve the Framework’s utility in clinical practice, and we would welcome the opportunity to collaborate with you and other stakeholders to revise, implement, evaluate, and/or promote the Framework. We truly support the initiative by ICER to begin this important conversation to improve cancer patient care. Thank you very much for your consideration of our comments. If HOPA can be of any assistance to you, please do not hesitate to contact me or HOPA’s Health Policy Associate, Jeremy Scott (202/230-5197, jeremy.scott@dbr.com).

Sincerely,

Sarah Scarpace Peters, PharmD, MPH, BCOP
President

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