



HOPA

Hematology/Oncology Pharmacy Association

September 12, 2016

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

Re: National Call for Proposed Improvements to 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 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:

- 1. Methods to integrate patient and clinician perspectives on the value of interventions that might not be adequately reflected in the scientific literature, elements of value**

intended to fall in the current value framework within “additional benefits or disadvantages” and “contextual considerations.”

- HOPA is involved with The Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) which is promoting the development and use of standards for biosimilar drugs that is "value" oriented. In order to ensure consistency we believe that the BBCIC should be included in the Framework.
- The Academy of Managed Care Pharmacy (AMCP) is leading an effort to promote the use of SNOMED CT codes for documenting therapy management services which adds value for patients. We recommend that this effort be acknowledged and included within the Framework.

2. Incremental cost-effectiveness ratios: appropriate thresholds, best practice in capturing health outcomes through the Quality-Adjusted Life Years (QALY) or other measures.

- There is a need for new metrics that measure outcomes and are transparent to all stakeholders. 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.
- An analysis of the statistical methodology used to compute the value determinations should be completed in order to address areas of concern.
- Much of the criticism surrounding the Framework involves the concept of "fail first" before a drug can be used. By developing better predictive diagnostics, and requiring companion diagnostics, personalized care can be provided that works as first line therapy.

3. Methods to set a threshold for potential short-term budget impact that can serve as a useful “alarm bell” for policymakers to signal consideration of whether affordability may need to be addressed through various measures in order to improve the impact of new interventions on overall health system value.

- The cost-effectiveness threshold commonly used in pharmacoeconomics may not apply to cancer care. More research is required to determine the “acceptable” threshold for determining cost-effectiveness in the oncology population.
- Once the model is complete, an independent disease specialty advisory group (including physicians, pharmacists, nurses and other healthcare providers) should be convened to review the model before completing all of the calculations.

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



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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 Scarpase Peters, PharmD, MPH, BCOP
President