

August 29, 2017

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

Re: Potential Topics for Review in 2018

Dear Dr. Pearson:

The Academy of Managed Care Pharmacy (AMCP) thanks the Institute of Clinical and Economic Review (ICER) for the opportunity to provide comments on the “*Potential Topics for Review in 2018*” released on July 26, 2017. AMCP applauds ICER for considering new and emerging therapies, as well as incorporating public feedback, into the development of a robust review agenda for 2018. AMCP believes the topics proposed are timely and will be impactful in helping pharmacists, physicians, and nurses in managed care organizations and other health care decision makers critically evaluate these novel therapies. As highlighted in previous comments to ICER, AMCP continues to advocate for the development of value assessment frameworks that are transparent, adaptable, and updated as new evidence becomes available.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP supports the use of value frameworks as a resource for determining the value of pharmaceuticals and other health technologies when the frameworks are based on sound methods using good scientific evidence and economic models. However, for value frameworks to be meaningful they must be used in conjunction with other tools and resources, such as formulary review by pharmacists, physicians, nurses, and other health care professionals who make population health decisions. AMCP believes that value frameworks should adhere to the following principles:¹

- Developers should consider key stakeholder perspectives from across the healthcare continuum, including patients, providers, payers and other health care decision makers, and pharmaceutical manufacturers.
- Analytic methodology, and economic models used in the development of a value framework should be validated and made publicly available.

¹ AMCP Where We Stand on Value Frameworks. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22039>. Accessed August 29, 2017.

- Value frameworks should incorporate scientifically valid evidence from a variety of sources, including real-world evidence and patient-reported outcomes, as part of the evaluation of a medication or other health technology, a process fully described in the AMCP Format, v. 4.0.
- Value frameworks should provide interpretable outputs that allow health care decisions makers and health care providers to conduct assessments of medications and health technologies in order to make value-based policy and treatment decisions for patients.
- Value frameworks intended for patient audiences should provide sufficient information in formats that can be understood by patients.
- The identities, credentials, qualifications and/or conflicts of interest of those involved in the development or approval of value frameworks should be publicly available.
- Value frameworks should be updated with the most current product evaluation techniques and should continue to provide accessible information to stakeholders.

ICER’s value assessment framework is one of the many tools utilized by managed care pharmacists and other health care providers in their comprehensive and holistic approach to evaluating the totality of evidence in determining whether medications and other health services are appropriate for the patient populations they serve. While AMCP appreciates the recent updates to the ICER value assessment framework and believes they are a step in the right direction to align with the principles outlined above, additional areas should be re-examined, specifically transparency of the economic models and evidence inclusion, to further enhance the utility and relevance of the value assessment framework.

The Economic Models Used Should be Made Available to Managed Care Pharmacists and Other Health Care Providers

While AMCP appreciates that the general components considered in the ICER value assessment framework are transparent, the economic models used to evaluate treatments are currently not made publicly available. AMCP supports economic models that when appropriately used, should be transparent, disclosed, reproducible, accurate, and valid.² Furthermore, AMCP believes economic models should be made available to managed care pharmacists and other health care providers to download, audit, and test the model by modifying the assumptions of the model based on their perspectives and their covered populations. Specifically, the availability of the economic models would, at minimum, allow for the following:

- Realistic adoption rates that accurately reflect the anticipated uptake of a medication based upon utilization management programs and/or the relevance to the population served;
- Consideration of an appropriate quality-adjusted life year (QALY) threshold after consultation with available literature or an organization’s bioethics committee;
- Adjustment of the cost of a medication to more accurately represent the actual acquisition cost;
- Flexibility to extrapolate the data for a short-term (one year) versus long-term (five years) forecast to better understand the immediate budget impact versus overall value of the medication;
- Adaptability for rare diseases or precision medications; and
- Validation that the economic model is applicable to the relevant patient population.

² AMCP Partnership Forum: FDAMA Section 114—Improving the Exchange of Health Care Economic Data. *Journal of Managed Care & Specialty Pharmacy* 2016 22:7, 826-831.

In addition, AMCP urges ICER to consider a process by which stakeholders could be given an opportunity to test and validate the economic models when in draft format and provide feedback on how they can be improved prior to finalization. With this approach, the economic models are more likely to reflect current real-world conditions.

In supporting the need for transparent economic models, AMCP also recognizes the importance of ensuring that individuals who have access to the models have the appropriate training and qualifications to properly evaluate and modify the model. Therefore, AMCP recommends that ICER consider a free licensing process that would allow ICER to evaluate the qualifications of the requestor prior to releasing the economic model, similar to the approach used by the National Institute for Health and Care Excellence (NICE). Many managed care pharmacists have considerable expertise in pharmacoeconomics and therefore, ICER should work with AMCP and other stakeholders to develop the list of criteria to use in selecting eligible recipients of the economic models and the creation of a process to minimize barriers to access.

The Evidence Reports Should be Updated to Incorporate New Evidence as it Becomes Available

AMCP commends ICER for reviewing and incorporating a diverse catalog of studies in its evaluation and development of value assessment frameworks, and for being transparent with the current limitations to the methodology used. However, AMCP urges ICER to develop a process for incorporating real-world evidence (RWE), patient reported outcomes, and other forms of new evidence as they become available into the catalog of evidence that informs the economic models and then updating the evidence reports accordingly. This will become increasingly important as several of the therapies included in the review agenda for 2018 are likely to be approved by the FDA under the breakthrough therapy designation pathway with limited clinical information publicly available at the same of product approval. Therefore, continued evaluation of RWE will be critical for these therapies to truly understand their utility and value.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with ICER. Furthermore, AMCP encourages ICER to use AMCP and its members as a resource as AMCP members have a wealth of knowledge and experience in evaluating RWE and pharmacoeconomic information for credibility and relevance. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer