

DECODING ICER:
**SUCCESSFUL PHARMA
ENGAGEMENT WITH ICER
FOR US HTA REVIEW**

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EXECUTIVE SUMMARY

The Institute for Clinical and Economic Review (ICER) is an independent and nonpartisan research organization that objectively evaluates the clinical and economic value of prescription drugs, medical tests, and other healthcare and healthcare delivery innovations.

ICER is focused on delivering assessments to support payers, physicians, patients, and the government in making decisions in the healthcare system. The organization continuously evolves to the needs of their external stakeholders and focuses on frequent and transparent communication.

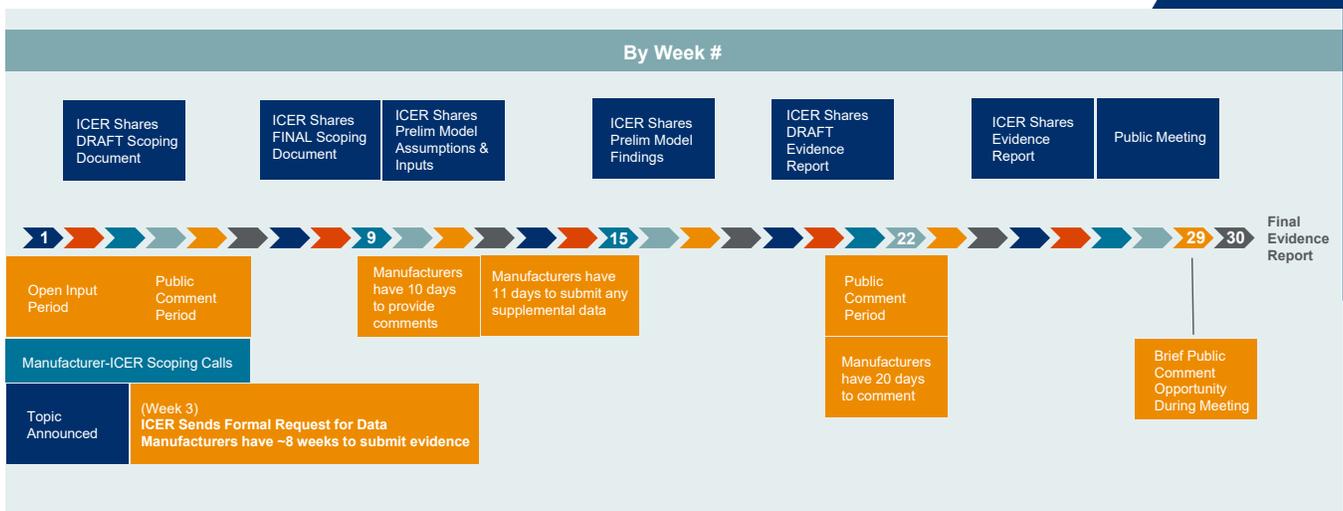
Recent accomplishments have included reviews prior to launch of high-profile therapies, which allows players to leverage their findings in price and coverage negotiations at launch.

Manufacturers will be impacted by an ICER review as a regular part of their business, both for launch and in-line products, anticipate ICER reviews when designing clinical trials, and be prepared with a multi-stakeholder communication and action/engagement plan.

How pharmaceutical and Biotech companies engaged ICER drives the outcome. Reactive responses to ICER review have led to poor outcomes and numerous downstream impacts to payer access and pricing. Cohesive enterprise engagement has demonstrated significantly better recommendations and less pressure for the US payer community. Unfortunately, 'reactive-response' is more common than 'enterprise engagement.'

KEY SUCCESS FACTORS ICER ENGAGEMENT

Managing an ICER review is a time critical process with multiple checkpoints and opportunities to engage in the process. The process will define a transparent flow (see figure 1). However, the large number of steps combined with speed or review requires that the manufacturer has plans and all data available long before the review begins.





EVERSANA has completed a retrospective review of recent ICER responses and has identified several key factors that improve the outcome of a review:

- Regular engagement with ICER outside a product review
- Plan as early as Phase II clinical trials to look to how ICER models data in their review process
- Understanding of how to measure value of technologies that could be targeted in future HTA assessments (ex., Companion diagnostics, precision medicines)
- Prepare for re-reviews of existing categories that face innovation or sustained high price (ex., oncologics)
- Developing a comprehensive corporate strategic engagement plan inclusive of HEOR, medical, advocacy, policy, market access, KOL engagement to ensure key influencers and stakeholders are aware of product value prop in light of likely review outcomes

ICER will continue to expand its influence on the US market forcing pharmaceutical and biotech firms to meet and build a sustainable strategy to engage the process. Health Strategies Insights by EVERSANA has developed a comprehensive set of resources to help you:

Even though EU and US biosimilar markets are very different, there are clearly two very similar buyer models that emerge. Successfully entering the market, or defending the current position requires that pharmaceutical companies look beyond the geography and focus on the behaviors and requirements of the buyers.

- Develop in-depth understanding of ICER's approach to value assessments
- Assess customers' current and future perspectives, while anticipating their probable responses to ICER outputs
- Utilize strategic insights to proactively develop response plans for upcoming ICER reviews of pipeline or inline products
- Customize workshops to help ensure your organization has a comprehensive, coordinated, strategic approach to ICER review response with key stakeholders who may be influenced by the ICER output