

Transforming the Market for New Drugs: The ICER Emerging Therapy Assessment and Pricing (ETAP) Program

ICER is an independent non-profit research organization dedicated to helping decision-makers understand and apply evidence to improve value throughout the health care system. Among its leading programs, ICER directs the [New England Comparative Effectiveness Public Advisory Council \(CEPAC\)](#) and the [California Technology Assessment Forum \(CTAF\)](#). These programs are known for their value assessment methods and policy recommendations that have had major impacts on insurance coverage decisions. Through its engagement with payers, purchasers, manufacturers, and other key stakeholders, ICER holds a unique leadership position at the interface of evidence policy development and the production of trustworthy evidence reviews that can move the market.

ICER's new Emerging Therapy Assessment and Pricing (ETAP) Program addresses a major area of conflict in the U.S. health care system: rapidly rising costs for innovative new drugs. Although it is widely agreed that strong incentives should exist to reward innovative treatments, costs for new drugs have been increasing significantly, and many observers feel that the U.S. market is structured to allow manufacturers the freedom to price new drugs at levels that do not reflect their value to patients and the health care system. One important impediment to progress has been the lack of an adequate infrastructure to produce independent, publicly available analyses of the comparative effectiveness of new drugs at the time of their introduction. Moreover, objective "value-based price benchmarks" to guide negotiation over pricing have not existed. Insurers, provider groups, patients, policy makers – and manufacturers themselves – all need a trustworthy source for this information to anchor discussions regarding appropriate use, pricing, and payment for new drugs. The overarching goal of this program is to meet this need and thereby transform the market for new drugs in the U.S.

Two components of the ETAP program will function together to achieve the program's goals:

- 1. Authoritative assessment and price benchmark reports.** ICER will produce reports for ETAP on specialty pharmaceuticals at or near the time of FDA approval. These reports will include rigorous analyses of evidence on clinical effectiveness, cost-effectiveness, and potential budget impact. These analyses will also be combined, through the ICER [value framework](#), to calculate in an objective, transparent fashion a "value-based price benchmark" for each therapy.
- 2. Public engagement with all stakeholders to enhance legitimacy, dissemination, and impact.** Many ETAP reports will be the subject of public deliberation through the CTAF and CEPAC programs. CTAF and CEPAC convene independent panels of trusted clinicians and lay representatives from the region to discuss the evidence on treatment options for a particular condition. At the public meetings prominent clinical experts, public advocates, manufacturers, provider groups, and insurers all participate, lending added legitimacy and impact to the findings of an ETAP evidence report.

The ETAP program will complement and accelerate ICER's mission to improve the application of evidence across the U.S. health care system.