

## **Adaptations to the ICER methods for evaluation of therapies for COVID-19**

*Updated July 18, 2020*

Due to the unprecedented immediacy and scale of COVID-19, all facets of the health system have adapted existing procedures to meet the needs of patients and policymakers. Life science companies are rapidly testing therapies by changing the way they design and conduct clinical trials, and how results of those trials are shared with the public; hospitals are making tremendous changes in staffing, infrastructure, and procedures related to triage and care. State and federal governments have mobilized resources and created novel mechanisms to produce, procure, and pay for potentially effective vaccines and treatments. ICER's goal is to continue to provide objective evaluation of the clinical effectiveness and comparative value of health care interventions, with a primary focus on informing discussions related to access and pricing. To meet the needs of policymakers in the current environment, ICER will adapt its standard evaluation procedures so that our analyses retain their independence, rigor, and transparency while providing timely information that reflects the exceptional scale of the clinical challenge facing the nation.

Therefore, the following adaptations to ICER's standing value assessment framework methods and procedures will be implemented for therapies for COVID-19:

1. ICER will adopt a flexible timeline for producing its initial report on an intervention. If data emerge publicly and suggest a very rapid timeline for FDA emergency or regular approval, ICER will seek to produce its report so that it is available for policymakers as quickly as possible upon FDA approval.
2. In light of the need for rapidity, ICER will perform necessary internal validity checks on its analyses but may not be able to engage in discussions with all relevant stakeholders to receive formal comment prior to public dissemination of a report. Manufacturers, however, will be notified when a rapid review is undertaken and given a chance to provide input.
3. When there is reasonable information available, ICER will seek to produce cost-recovery analyses in conjunction with cost-effectiveness analyses to inform broader consideration of fair pricing in the setting of a pandemic.
4. ICER will continue to produce price benchmarks related to commonly cited cost-effectiveness thresholds but ICER will emphasize the price related to the \$50,000 threshold in the context of the scale of patients likely to require treatment and in light of the shared goal of making new treatments available rapidly and equitably for all in need.
5. The complexity of the societal impact of the COVID-19 pandemic makes it impossible to accurately estimate the impact of non-curative treatment on factors such as unemployment, taxes, education, etc. Even for a universally effective vaccine or treatment, we believe it is unlikely that policymakers will find pricing recommendations that shift broader societal economic benefits to a single life science company relevant or appropriate. We will therefore focus our efforts on generating cost-effectiveness results from the health system perspective for COVID-19 therapies but will consider whether some form of modified societal approach is

feasible and relevant on a case by case basis.

6. Any report produced without a period of formal public comment will be subject to near-term revision based on emerging data and public comment received after the posting of the initial report. No specific timeline for update will be announced given the need to remain flexible as new information and comment are received.
7. All report updates will include a full description of all changes made to the previous model.