# Timing of Health Technology Assessment in the United States: An Evaluation of ICER Reviews Over Eight Years

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PT19

## Introduction

In many countries, there is a delay between regulatory approvals of new therapies and health technology assessments (HTA) that inform pricing and coverage decisions. In the United States (US), once a drug is FDA approved, it moves through market access relatively quickly. The Institute for Clinical and Economic Review (ICER) aims to issue HTA reports at or near the time of approval by the US Food and Drug Administration (FDA) to provide a timely, independent evaluation of the benefits, risks, and economic considerations surrounding a new therapy.

## Research Questions

1. What is the time in days between FDA approval and price announcement in novel drugs included in ICER assessments from 2017 to 2024?
2. What percentage of ICER assessments were published before, on, or after FDA approval?
3. What percentage of trials included in ICER assessments were published in peer-reviewed journals before FDA approval, price announcement, and ICER assessment?

## Methods

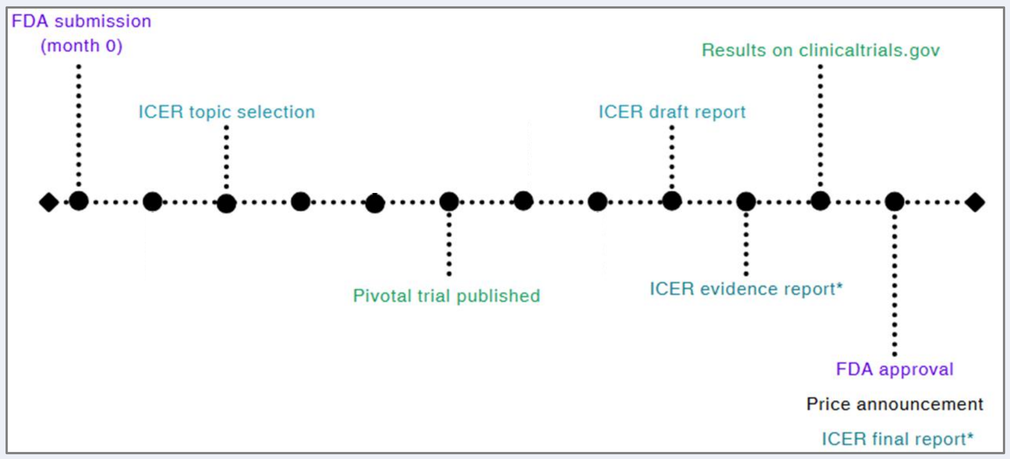
- We included ICER assessments from 2017 to 2024, the drugs they evaluated, and their pivotal trials.

This report covers **61** ICER assessments of **92** drugs evaluated in **171** pivotal trials

- For each drug, we collected data on FDA submission and approval date, type of FDA review, the ICER report dates, type of data available for ICER HTA, peer-reviewed publication date of pivotal trials, and price announcement date.

## Results

### Figure 1. Median Time Across All Drugs from FDA Submission to Eight Time Benchmarks




Notes: Each dot represents one month. Data included are the reports included in research question 1. There were some data missing from each timepoint for various reasons: four trials were not published; one review did not have a final report; two drugs did not have a final report due to COVID-19; six trials had no results on posted on CT.gov.
*ICER public meeting occurs between evidence and final report.

## Results

### Research Question 1: Time Between FDA Approval and Price Announcement

Median **0 days**
Range 0 to 242 days

### Research Question 2: ICER Draft Assessments Published Before or After FDA Approval and Price Announcement

**81% of drugs** were assessed in ICER report published *before* FDA approval
Median time in between: **130 days**

In assessments published *after* FDA approval, **73%** of drugs had **priority review**
Median time in between: **70 days**

### Figure 2. FDA Review Designations of ICER-Assessed Drugs

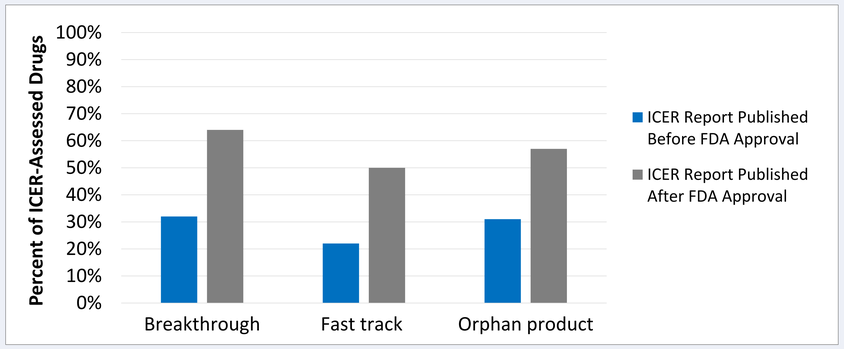



**Figure Legend**: We gathered data on whether the drugs we reviewed were granted breakthrough, fast track, or orphan product designations by the FDA. Here we present the proportion of drugs granted each designation based on whether their ICER assessments were published before or after the FDA approval date.

### Research Question 3: Data Availability at Time of FDA Approval, Price Announcement, and ICER Assessment

Of the 171 pivotal trials included in ICER assessments…

**67% had peer-reviewed publications before ICER draft assessment publication** | **33%** had no publications

**70%** were published before the **ICER evidence report**

**70%** were published before **FDA approval**

**66%** were published before **price announcement**

In absence of peer-reviewed publications, ICER used…

- Conference abstracts
- Clinicaltrials.gov
- Data submitted by manufacturers
- Press releases
- Data from the FDA

## Key Takeaways

- ICER reports are well timed to inform fair pricing and access decisions:
  - The majority of ICER draft reports are published before or at the time of FDA approval and price announcement
  - Those published after FDA approval were mostly granted priority review; thus had a shorter FDA review timeline.
- Most trials are published in peer-reviewed journals before FDA approval and ICER report publishing.
  - In the absence of published trials, other sources lacked necessary detail, which can impact certainty in the evidence.
- Improved data and information sharing can ensure that HTA is most informative to stakeholders.

**ABBREVIATIONS** | FDA: Food and Drug Administration, HTA: health technology assessment, ICER: Institute for Clinical and Economic Review, PDUFA: Prescription Drug User Fee Act

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