# Making the Cut: An Assessment of ICER's Acceptance of Evidence in Unsupported Price Increase Reports

HPR62

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## Background

- The Institute for Clinical and Economic Review's (ICER) Unsupported Price Increase (UPI) reports aim to identify drugs with substantial price increases without adequate evidence to justify the increases.[1]
- Due to resource constraints, UPI reports are intended to assess whether there is new evidence that could justify a drug's price increase, rather than determine whether a price increase is fully justified.[1]
- Several organizations and state Medicaid programs have started to take ICER's UPI reports into consideration when developing policies and legislation for drug transparency.
- For example, the National Academy for State Health Policy (NASHP) created model legislation for states to impose penalties on products with "unjustified" price increases in ICER's UPI reports.[2]
- However, ICER's methodology and criteria for accepting evidence have received significant critique from relevant stakeholders.
- There is limited research on how different types of manufacturer-submitted evidence are appraised and adjudicated by ICER.

## Objectives

- To review ICER's determinations for manufacturer-submitted evidence.
- To identify trends in ICER's decisions to accept or reject evidence that could justify a drug's price increase.
- To identify characteristics of evidence accepted by ICER in support of a price increase.

## Methods

- The scope of this research included 3 national UPI reports published from 2019 to 2021. Our analysis only includes manufacturer-submitted evidence and does not include new evidence identified from ICER's independent systematic literature review (SLR).
- Our evaluation mirrored the sequence of ICER's review process:
  - In ICER's reports, studies were first evaluated for whether they met ICER's UPI review criteria and then for whether they met criteria for new moderate- to high-quality evidence (**Figure 1**).
  - We examined ICER's determinations for accepting or rejecting evidence and organized studies into several categories, based on determination criteria.
- A codebook was developed to categorize each type of evidence along with ICER's determination.
  - For accepted evidence, we identified study characteristics related to phase, blinding, and comparator arm used in the clinical trial. Findings were quantified to identify trends in the data.

**Figure 1. Sequence of criteria for ICER's evaluation of evidence**

Key: ICER – Institute for Clinical and Economic Review; UPI – unsupported price increase.

## Results

- ICER reviewed 31 drugs that were found to have substantial price increases across the 3 national reports from 2019 to 2021 (**Table 1**).
- Of those, manufacturers submitted evidence for ICER to consider as new clinical information for 26 drugs.

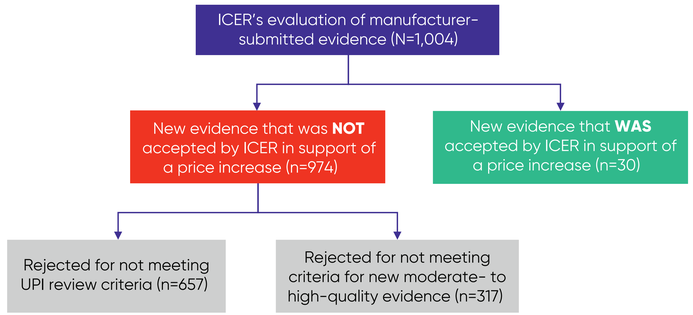
**Table 1. Overview of ICER price increase determinations, by UPI report**

| 2019 UPI Report (N=9)[3] | 2020 UPI Report (N=10)[4] | 2021 UPI Report (N=12)[1] |
|---|---|---|
| Genvoya* | Entresto* | Cimzia* |
| Revlimid* | Entyvio* | Entresto* |
| Cialis | Xtandi* | Venclexta* |
| Humira* | Enbrel* | Emflaza* |
| Lyrica | Humira* | Fanapt |
| Neulasta* | Invega Sustenna/Trinza | Humira* |
| Rituxan* | Orencia* | Krystexxa* |
| Tecfidera* | Tecfidera* | Lupron Depot* |
| Truvada* | Vimpat* | Promacta* |
| | Xifaxan* | Trokendi XR |
| | | Tysabri* |
| | | Xifaxan* |

Key: ICER – Institute for Clinical and Economic Review; UPI – unsupported price increase.
Drugs with price increases with new clinical evidence.
Drugs with price increases unsupported by new clinical evidence.
*Drugs with evidence submitted by manufacturers.

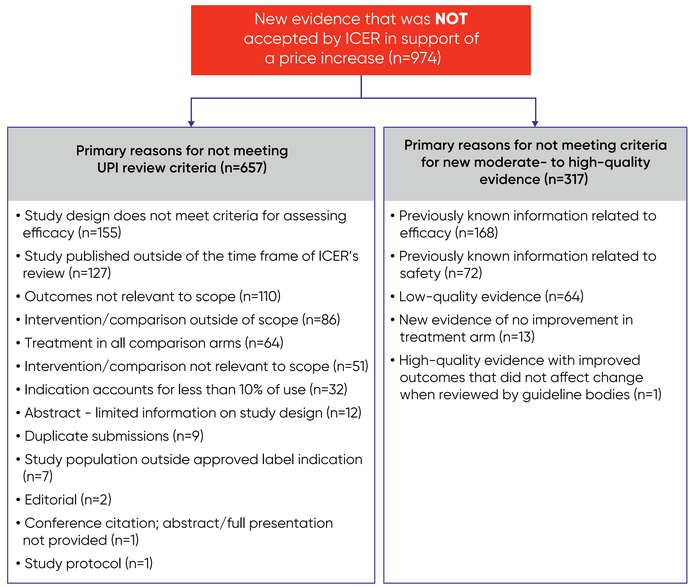
- Of 1,004 pieces of evidence, 974 (97%) were not accepted by ICER (**Figure 2**).
  - Nearly two-thirds (n=657) did not meet ICER's UPI review criteria (**Figure 3**).
    - The most common reasons cited by ICER included the following: study design did not meet criteria for assessing efficacy (n=155), study was published outside of the time frame of ICER's review (n=127), and outcomes not relevant to scope (n=110).
  - The remaining one-third (n=317) did not meet ICER's criteria for new moderate- to high-quality evidence.
    - The most common reasons cited by ICER included the following: previously known information related to efficacy (n=168), previously known information related to safety (n=72), and low-quality evidence (n=64).
- Only 30 pieces of evidence, representing 14 distinct randomized controlled trials (RCTs), were accepted as high-quality evidence demonstrating important new information (**Figure 4**).
  - All evidence deemed high-quality was from RCTs in phase 3 (n=13) or phase 4 (n=1).
  - More accepted RCTs were double-blinded (n=11) than open-label (n=3).
  - More accepted RCTs were active-controlled (n=8) than placebo-controlled (n=6).
  - Six RCTs supported Food and Drug Administration (FDA) label expansion for a new (n=2) or existing (n=4) indication, 5 demonstrated improved longer-term outcomes, 2 supported accelerated approval, and 1 extended the evidence base to new populations.
    - Note: One RCT was accepted twice in 2 consecutive UPI reports; this study was counted only once in our analysis.

**Figure 2. ICER's evaluation of manufacturer-submitted evidence**



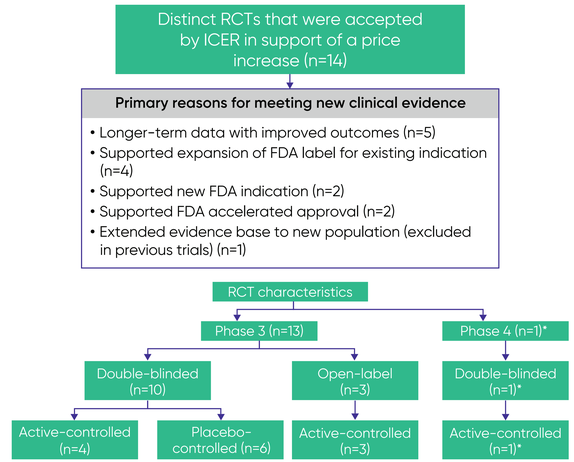

Key: ICER – Institute for Clinical and Economic Review; UPI – unsupported price increase.

**Figure 3. New evidence that was not accepted by ICER in support of a price increase**




Key: ICER – Institute for Clinical and Economic Review; UPI – unsupported price increase.

**Figure 4. Distinct RCTs that were accepted by ICER in support of a price increase**




Key: FDA – Food and Drug Administration; ICER – Institute for Clinical and Economic Review; RCT – randomized controlled trial.
*One RCT was accepted twice (in 2 consecutive reports) but was counted only once in our analysis.

## Limitations

- UPI reports included in this research were conducted by ICER from 2019 to 2021. Across the 3 reports, ICER made changes to its protocol and revised its methods, which causes difficulty in comparisons.
- ICER published its first annual report in 2019. Therefore, the long-term consequences of UPI reports are still unknown.

## Conclusions

- Our findings indicate the vast majority of evidence (97%) was not accepted by ICER in support of a price increase, calling into question the restrictiveness of its criteria.
- Accepted evidence was typically from a late-phase, double-blinded RCT that demonstrated information leading to an FDA label expansion, knowledge about improved outcomes or a new population, or strengthening the accelerated approval evidence base.

**References: 1.** Institute for Clinical and Economic Review. Unsupported price increase report. Updated March 15, 2022. Accessed April 10, 2023. https://icer.org/wp-content/uploads/2021/04/ICER_UPI_2021_Assessment_031522.pdf **2.** National Academy for State Health Policy. Model legislation: An act to protect consumers from unsupported price increases on prescription drugs. July 2020. Accessed March 19, 2023. https://www.nashp.org/an-act-to-protect-name-of-state-consumers-from-unsupported-price-increases-on-prescription-drugs/ **3.** Institute for Clinical and Economic Review. Unsupported price increase report. Updated November 6, 2019. Accessed April 10, 2023. https://icer.org/wp-content/uploads/2020/10/ICER_UPI_Final_Report_and_Assessment_110619.pdf **4.** Institute for Clinical and Economic Review. Unsupported price increase report. January 12, 2021. Accessed April 10, 2023. https://icer.org/wp-content/uploads/2020/11/ICER_UPI_2020_Report_011221.pdf

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