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

HPR62

Jane Ha, PharmD, MS[1]; Nicole Piaskowski, PharmD, MBA[1]; Andrew Devendorf, MA[1]; Kimberly Westrich, MA[1]
[1]Xcenda LLC, Carrollton, TX

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.

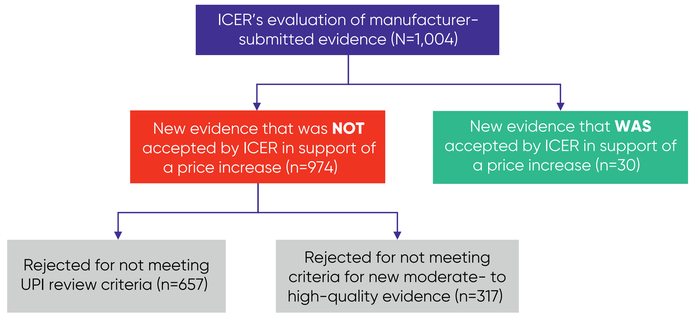
Table 1. Overview of ICER price increase determinations, by UPI report

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.

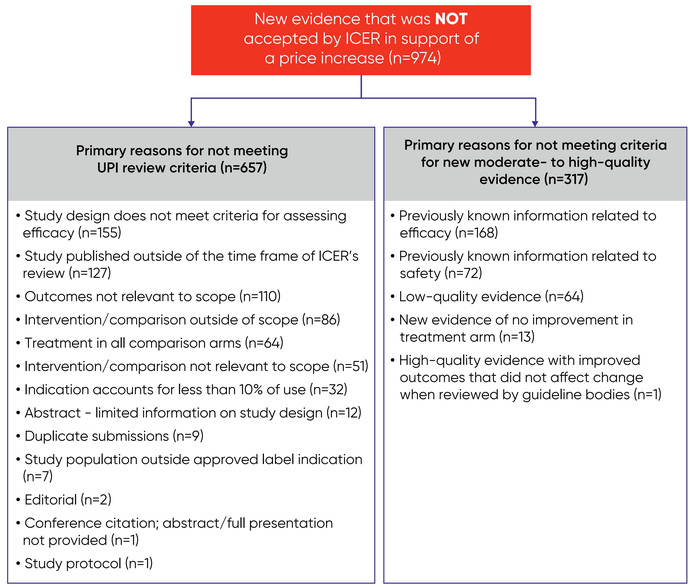
- Of 1,004 pieces of evidence, 974 (97%) were not accepted by ICER (**Figure 2**).
  - Nearly two-thirds (n=657) did not meet ICER's UPI review criteria (**Figure 3**).
    - The most common reasons cited by ICER included the following: study design did not meet criteria for assessing efficacy (n=155), 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



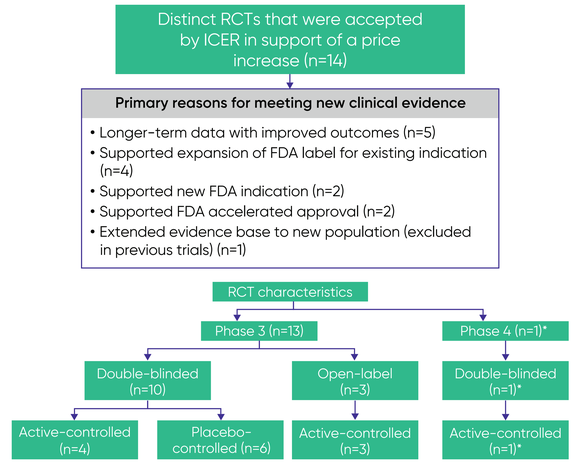
Key: ICER – Institute for Clinical and Economic Review; UPI – unsupported price increase.

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

AmerisourceBergen
Xcenda

Presented at ISPOR 2023
May 7-10, 2023 | Boston, MA
Funded by Xcenda

Please direct questions to Jane Ha at Jane.Ha@xcenda.com