Making the cut: A review of evidence trends in the Institute for Clinical and Economic Review's Unsupported Price Increase reports

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Background

- Each year, the Institute for Clinical and Economic Review (ICER) releases its Unsupported Price Increase (UPI) reports which aim to identify major drugs with substantial price increases without adequate evidence to justify the increases.[1]
- Some payers and policymakers have started to take ICER's UPI reports into consideration for decision-making.
- For example, the National Academy for State Health Policy (NASHP) created model legislation for states to impose penalties on products with unsupported price increases identified in ICER's UPI reports.[2]
- However, ICER's methodology has received significant critique and concern from relevant stakeholders regarding restrictive criteria and lack of transparency.
- There is limited research on trends for evidence submitted by manufacturers and ICER's appraisal of that evidence.

Objectives

- To evaluate how ICER appraises evidence submitted by manufacturers.
- To identify trends in manufacturer submissions and ICER's evidence determinations.

Methods

- We reviewed evidence submitted by manufacturers for the 4 national UPI reports published from 2019 to 2022.
  - The scope of our analysis did not include ICER's California State UPI report or evidence identified from ICER's independent systematic literature review.
- A codebook was developed to compile and categorize types of evidence and ICER's reasons for rejecting or accepting evidence.
  - Our codebook was categorized to match the sequence of ICER's review process. Studies were first evaluated for whether they met ICER's UPI review criteria and then for whether they qualified as new moderate- to high-quality evidence.
- We identified submission and determination trends, as well as study characteristics (phase, blinding, and comparator arm) for accepted evidence.

Results

- From 2019 to 2022, ICER reviewed 44 drugs in the national UPI reports.
  - Manufacturers submitted evidence to ICER for 34 of those drugs.
- Manufacturers submitted a total of 1,145 pieces of evidence across the 4 reports. The number of pieces of evidence submitted per UPI report declined over time (**Figure 1**).
- Across the 4 reports, manufacturers submitted an average of 34 pieces of evidence per drug (**Table 1**), which decreased over time (n=67 in the 2019 report, n=28 in 2020 and 2021, n=17 in 2022).

Figure 1. Total pieces of evidence submitted, by UPI report (N=1,145)

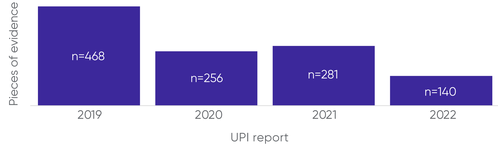


Table 1. Average pieces of evidence submitted per drug, by UPI report

UPI report	Average pieces of evidence submitted per drug
Overall	**34**
2019	67
2020	28
2021	28
2022	17

- Overall, ICER rejected 97% of evidence submitted by manufacturers (**Figure 2**).
  - Almost two-thirds (n=708) did not meet ICER's UPI review criteria (**Figure 3**). The remaining one-third did not meet ICER's criteria for new moderate- to high-quality evidence (n=399).

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

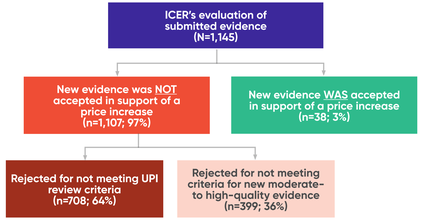
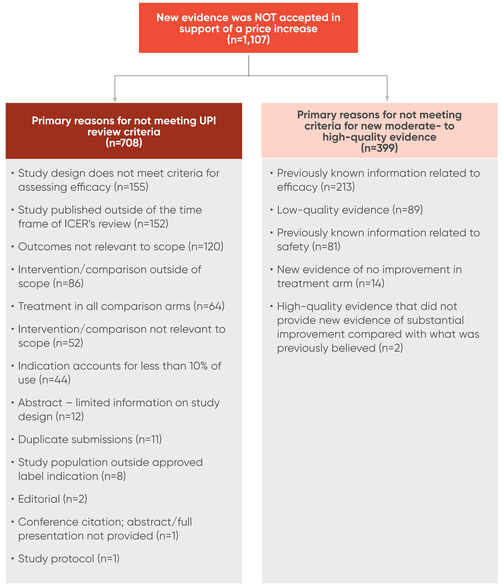


Figure 3. Overview of ICER's primary reasons for rejection



- Although the majority of evidence was rejected by ICER, there was a slight decrease in rejected evidence over time (99% in 2019, 97% in 2020, 93% in 2021, 94% in 2022) (**Figure 4**).
- ICER's reasons for rejection also shifted over time. More evidence met UPI review criteria, which is the first step in the sequence of ICER's review process.
  - In the later reports, ICER's rejection reasons shifted towards not meeting new moderate- to high-quality evidence (19% in 2019, 36% in 2020, 49% in 2021, 58% in 2022).

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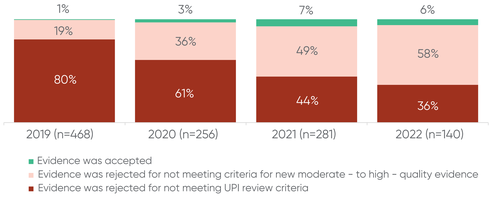
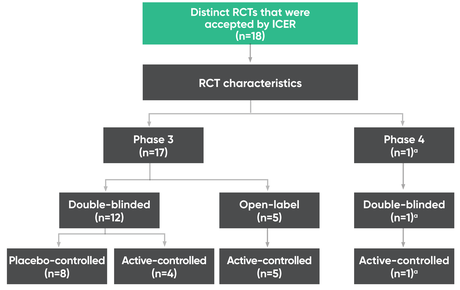
Figure 4. ICER's determinations of submitted evidence in support of a price increase, by UPI report



- From 2019 to 2022, only 3% (n=38) of evidence was accepted as high-quality evidence demonstrating important new information. This represented 18 distinct randomized controlled trials (RCTs).
  - All evidence deemed high-quality was from RCTs in phase 3 (n=17) or phase 4 (n=1) (**Figure 5**).
  - More accepted RCTs were double-blinded (n=13) than open-label (n=5).
  - More accepted RCTs were active-controlled (n=10) than placebo-controlled (n=8).

Figure 5. Study characteristics for accepted evidence



RCT – randomized controlled trial.
[a]One study was accepted twice (in 2 consecutive reports) but was counted only once for the total distinct RCTs that were accepted.

- In the later reports, ICER developed more descriptive categories when reporting reasons for accepting evidence (**Table 2**).
  - In 2019, ICER described the impact of accepted evidence using a single category: longer-term data with improved outcomes (n=4).
  - In subsequent years, ICER introduced new categories with each report, including:
    - Evidence that supported Food and Drug Administration (FDA) label expansion for a new (n=4) or existing (n=4) indication
    - Extended the evidence base to new populations excluded in previous trials (n=2)
    - Supported accelerated approval (n=2)
    - Strengthened the existing evidence base and guideline recommendations (n=1).

Table 2. ICER's descriptions of accepted evidence, by UPI report

UPI Report	Distinct RCTs that were accepted	ICER's Reasons for Accepting Evidence					
		Longer-term data with improved outcomes	Supported new FDA indication	Supported expansion of FDA label for existing indication	Extended evidence base to new population	Supported FDA accelerated approval	Strengthened existing evidence base and guideline recommendations
Overall	**18[a]**	**5**	**4**	**4**	**2[b]**	**2**	**1**
2019	4[a]	4	N/A	N/A	N/A	N/A	N/A
2020	5[b]	1	1	2	1[b]	N/A	N/A
2021	6[b]	0	1	2	1[b]	2	N/A
2022	4	0	2	0	1	0	1

FDA – Food and Drug Administration; N/A – not applicable; RCT – randomized controlled trial.
[a]One study was a pooled analysis of 2 RCTs and considered 2 distinct RCTs in our analysis.
[b]One study was accepted twice (in 2 consecutive reports) but was counted only once for the total distinct RCTs that were accepted.

Reasons did not exist during that respective UPI report.

Limitations

- Across the 4 reports published 2019–2022, ICER made changes to its protocol and revised its methods, which caused difficulties with comparison.

Conclusions

- Manufacturers submitted fewer pieces of evidence to ICER's UPI reports over time and appeared increasingly selective with the evidence they submitted.
- The vast majority of evidence (97%) was not accepted by ICER in support of a price increase; however, more evidence met UPI review criteria over time.
- Accepted evidence was typically from phase 3, double-blinded RCTs that demonstrated new information on improved outcomes or supported FDA label expansion.
- ICER developed more descriptive categories when reporting reasons for accepting evidence with each subsequent report.

References: 1. Institute for Clinical and Economic Review. Unsupported price increase assessment protocol. April 14, 2022. Accessed September 1, 2023. https://icer.org/wp-content/uploads/2022/04/ICER_UPI_2022_National_Protocol_041422.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 September 11, 2023. https://www.nashp.org/an-act-to-protect-name-of-state-consumers-from-unsupported-price-increases-on-prescription-drugs/

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