Dynamic Pricing:
Getting to the Right Signals for Innovation from an HTA Perspective

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ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

CEVR
Center for the Evaluation of Value and Risk in Health

Disclosures

- Employee of ICER, which produces publicly-accessible reports on comparative effectiveness and value of new interventions
- Part-time member of CEVR faculty, which receives funding from life sciences companies, academic institutions, and government agencies to support and maintain a number of research databases

"Genericization"

- Counters simplistic assumption 1:
  - On-patent pricing lives on forever

- Introduces simplistic assumption 2:
  - Allowing 100% of savings from generic price drops to accrue to manufacturer

HTA's Goals

- To identify
  - (a) interventions that improve population health, while
  - (b) exercising responsible stewardship of financial resources

- The traditional approach to identifying "high-value" interventions (the innovations we want):
  - Those that meet an agreed opportunity cost threshold

The Problem

- Traditional approach accounts only for point-in-time, static efficiency
- York framework is one method that integrates long-term value (including genericization) and a cutpoint for sharing of value between industry and society

Key Assumptions in the York Framework

Price During On-Patent Period	Remains unchanged
Generic/biosimilar Uptake	Immediate and complete at end of patent
Generic/biosimilar Pricing	Equivalent to marginal cost of production
CEA Findings	Dictate launch price in system
Comparator Price During On-Patent Period	Remains constant

Key Realities in the U.S.

Price During On-Patent Period	Can increase and decrease (and increase again!) during the on-patent period
Generic/biosimilar Uptake	<100% at entry (may still compete with originator drug), increasing with new entrants
Generic/biosimilar Pricing	Typically above marginal cost of production initially; may only meaningfully decrease with competition; can also increase or decrease over time
CEA Findings	May inform but not dictate pricing decisions
Comparator Price During On-Patent Period	Can increase and decrease as above, depending on whether patented or generic
Timing of Patent Expiry	Anyone's guess!

Patent Extension: The IRA's "Poster Child"

- On US market for 27 years w/no biosimilar competition
- One of 10 drugs targeted for initial round of IRA negotiations
- Negotiated price reflected time on market rather than value or leverage
- With lengthy time on patent:
  - Is it now obsolete?

Other Approaches

- Simply assuming a generic price drop ignores drug obsolescence
- Some have argued for a “stacked cohort” approach to address this
- Concern about sharing the value of price drops between industry and society remains

Next Steps

- ICER working with York and a team of US academic advisors to examine feasibility of adapting the dynamic efficiency framework to the US
- Adjustments along the lines previously described being tested
- Data from ~20 prior ICER reviews to be assessed

Thank you!

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Questions?