Leveraging ICER Reports for Prescription Drug Affordability

Presentation to Maryland Prescription Drug Affordability Board

May 24, 2021

ICER

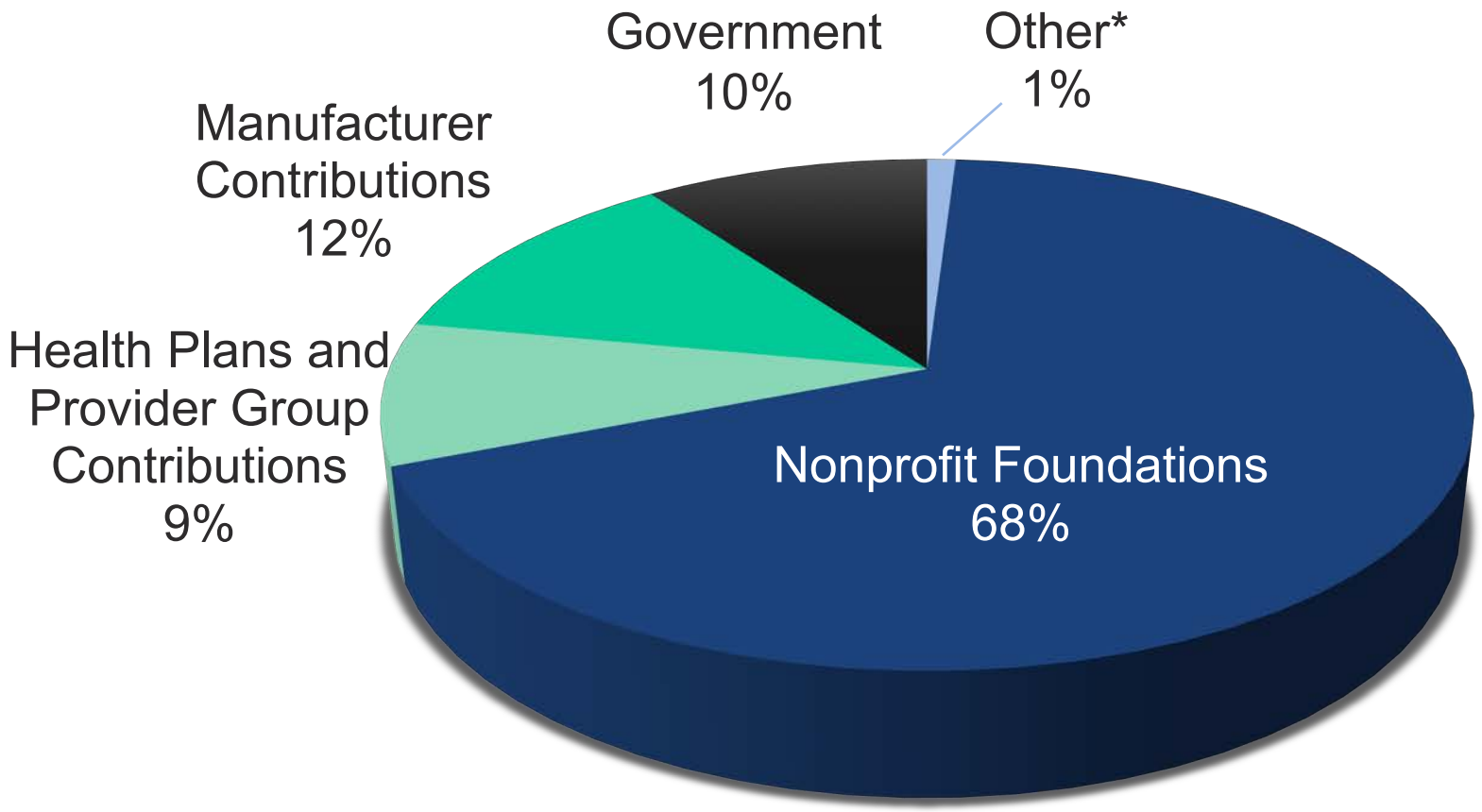
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Institute for Clinical and Economic Review (ICER)

- **Independent, non-partisan** health technology assessment group whose reviews are funded by non-profit foundations
- Develop **publicly-available value assessment reports** on medical tests, treatments, and delivery system innovations for nearly 15 years
- Convene regional independent **appraisal committees** for public hearings on each report
- For some analyses, use cost-effectiveness analysis to determine **health benefit price benchmarks**
- Produce annual list of Unsupported Price Increases using **comparative clinical effectiveness** expertise
- Coming soon: annual **"Fair Access"** report examining whether insurers are providing fair access to fairly-priced drugs

ICER

2021 Funding



*Individual / matching contributions and speech stipends

Foundations of our Mission

- Transparent, public, multi-stakeholder approach to all our work
  - Life sciences manufacturers, patient and consumer advocacy organizations, health plans, state and federal policymakers, clinicians, health systems
- Distinctive combination of academic rigor and practical application
- Guidance to improve the health system so it better serves patients

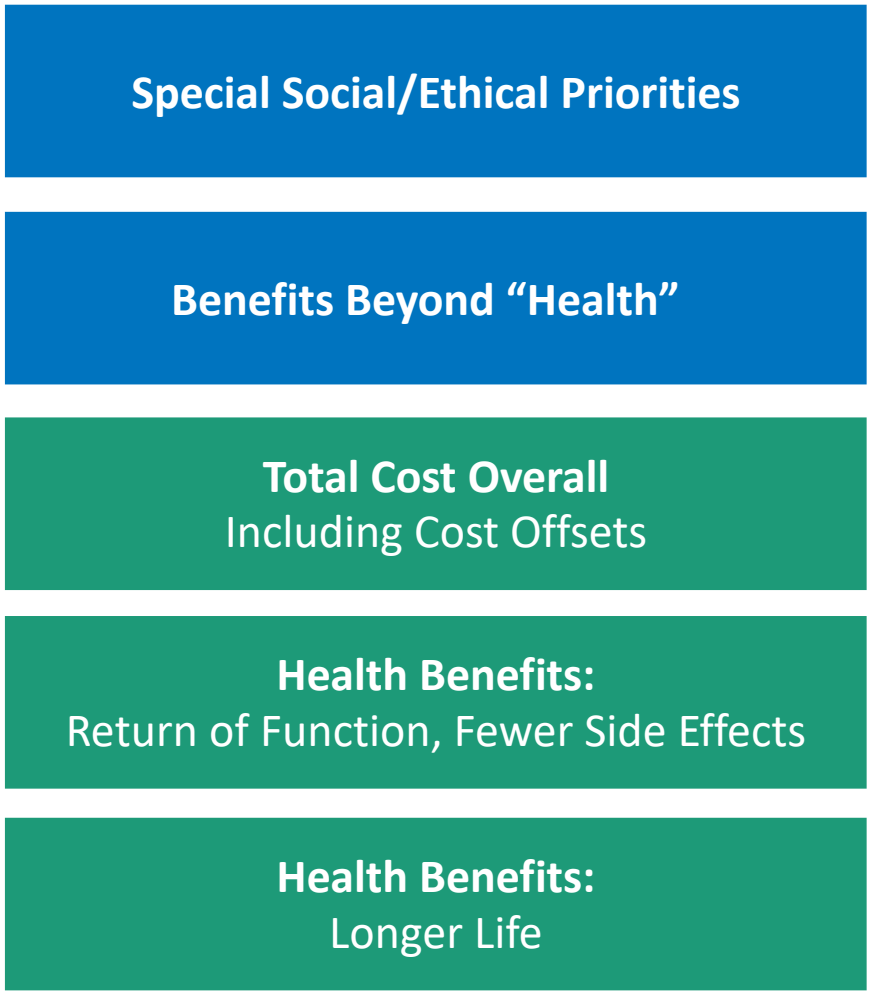
Fair Pricing.

Fair Access.

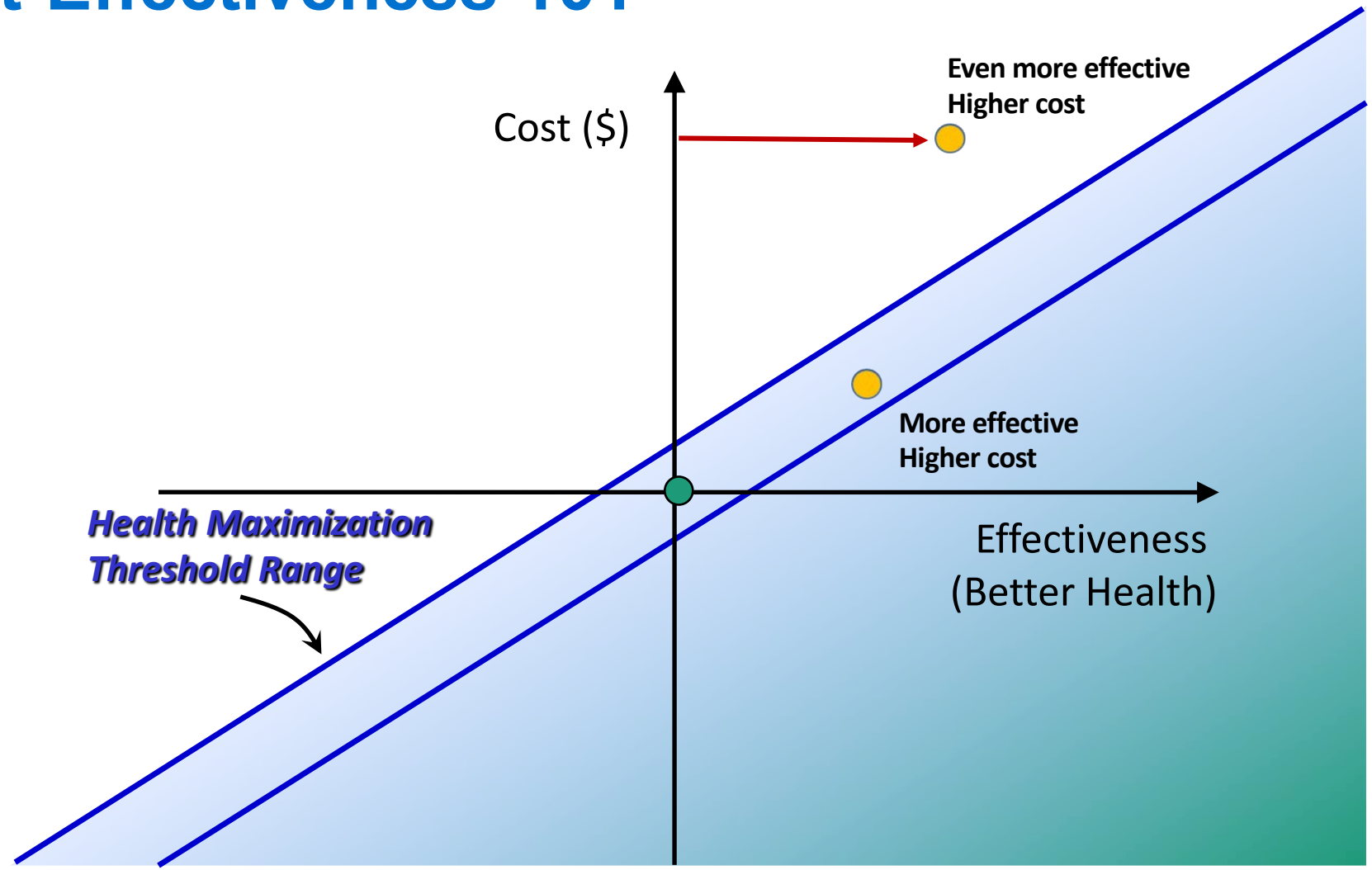
Future Innovation.

Assessing “Value”

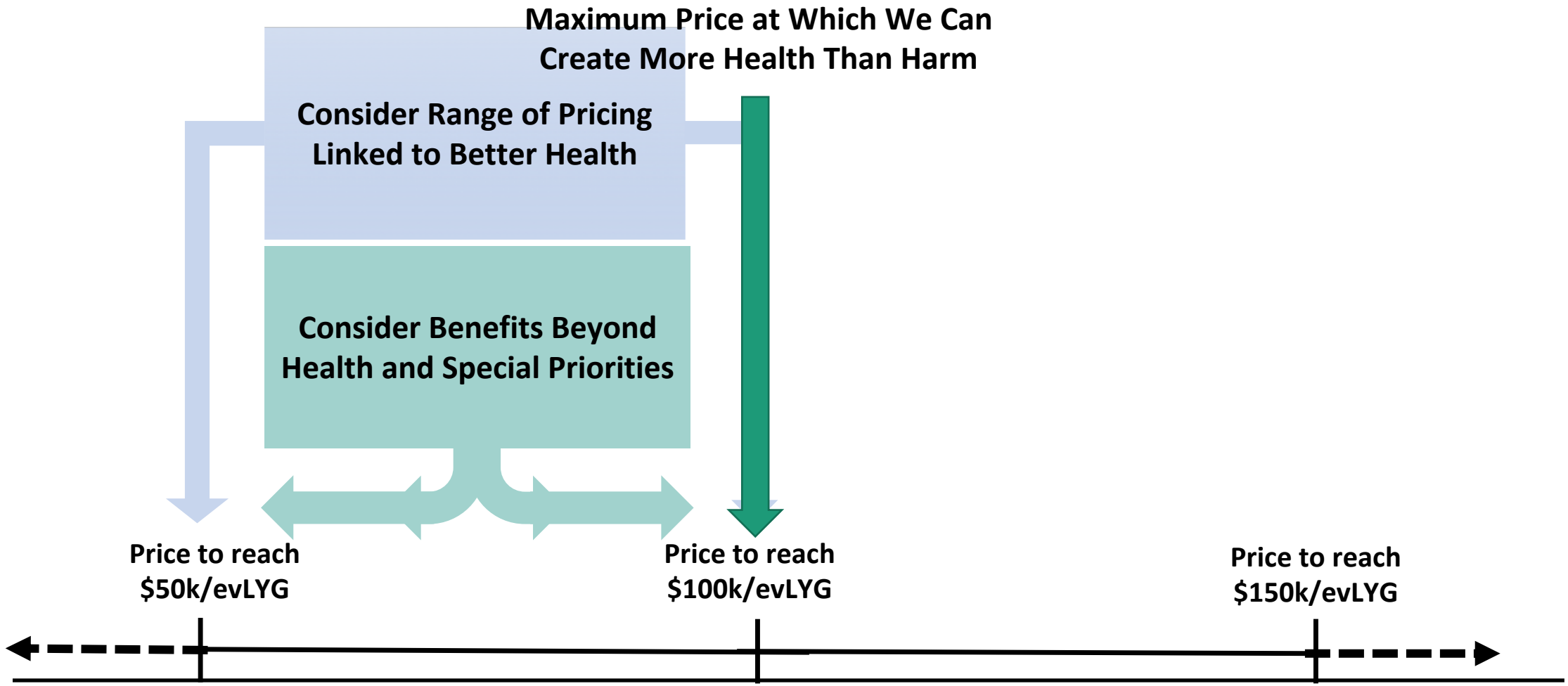
Value Assessment Framework: Long-Term Value for Money



Cost-Effectiveness 101



Integrating Elements of Long-Term Value for Money



ICER's Value-based Price Benchmarks (Examples)

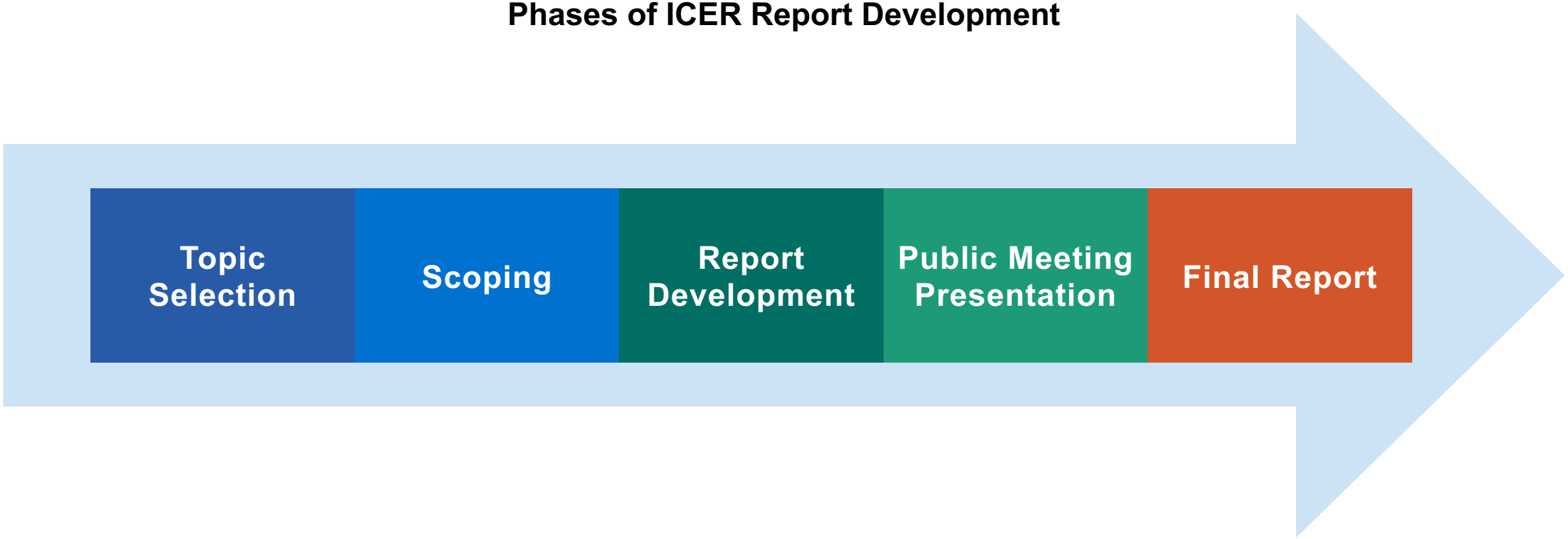
Assessment	Drugs	Discount Needed*
Spinal Muscular Atrophy	Spinraza	83-90%
	Zolgensma	0%
Type 2 Diabetes	Rybelsus	32-36%
Opioid Use Disorder	Probuphine and Vivitrol	53-69%
Rheumatoid Arthritis	Rinvoq	25-26%
Asthma	Xolair, Nucala, Cinqair, Fasenra, Dupixent	62-80%
Treatment-Resistant Depression	Spravato	25-52%

Assessment	Drugs	Discount Needed*
Cardiovascular Disease	Vascepa	0%
	Xarelto	0%
Migraine	Nurtec, Ubrelvy	0%
CAR-T for Leukemia and Lymphoma	Yescarta and Kymriah	0%
Hemophilia A	Hemlibra	0%
Cystic Fibrosis	Kalydeco, Trikafta, Symdeko, Orkambi	74-79%

** For new drugs, discount from list price or anticipated net price needed to meet common thresholds of cost-effectiveness. For drugs already in use, discount is from **post-rebate price***

The ICER Process

Phases of ICER Report Development



Public Meetings

- Public deliberation of report contents and policy implications by independent appraisal committees
- Patients and patient organizations play a central role at public meetings
- Participation by clinical experts, manufacturers, patients and caregivers
- The voting panels are comprised of clinicians, patients, and health policy experts

Use of ICER assessments

- **For policymakers:** independent evaluation of value and suggested value-based prices figure in multiple proposals
- **For drug makers and payers:** helps negotiation over prices in conjunction with fair access
- **For payers and employer groups:** helps guide coverage decisions and pricing negotiations

Use Cases: Federal and State Government

- Department of Veterans Affairs:
  - *"The collaboration shows that a health care system in the US can utilize independent cost-effectiveness analyses as an additional information resource to help make more focused clinical and financial decisions. Through this effort the VA has gained an objective, transparent standard to guide its drug price negotiations, and the results have not undermined in any way the clinical focus of the VA drug coverage process. We look forward to a continued collaboration on behalf of our Veterans and US taxpayers in the quest to provide crucial medications at the most reasonable prices possible."*
- States
  - Prescription Drug Affordability Boards: Maryland, New Hampshire, Maine, New Mexico, others enacted or exploring

*Glassman, et al, "VA and ICER at Three Years," *Health Affairs*, June 15, 2020 https://www.healthaffairs.org/do/10.1377/hblog20200611.662048/full/

New York Medicaid Drug Cap

- Limit cost growth to 10-year average of CPI plus 4%, minus $85m rebate target
- DOH negotiates supplemental rebates for top 3% of drugs by net spending or cost/claim
- If negotiation fails, drugs referred to DURB for review, identification of rebate target
  - DURB may consider clinical effectiveness, cost-effectiveness, pricing, affordability, disease/condition severity, R&D costs to identify target rebate
  - 30-40 drugs identified as piercing cap each year
  - 3 drugs referred to DURB (Orkambi, Spinraza, biosimilar)
  - Overall, saved >$300m in supplemental rebates to date

Sources: https://www.health.ny.gov/health_care/medicaid/regulations/global_cap/ https://www.nysenate.gov/legislation/laws/PBH/280

Massachusetts Medicaid and Heath Policy Commission

- 2020 MA State Budget: MassHealth can negotiate supplemental rebates
  - If negotiations fail, HHS Secretary may propose value for drug and seek public input if drug costs ≥$25k or has ≥$10m in total annual state spend
- If negotiations still fail, drugs referred to HPC to determine if pricing is excessive, propose value/rebate for drug
  - HPC reviews similar information to NY State Medicaid
  - As of February 2021, 35 rebate agreements (13 manufacturers) prior to HPC referral
  - $95 million savings in year 1

Sources: https://malegislature.gov/Budget/FY2020/FinalBudget
https://www.mass.gov/service-details/drug-pricing-review
https://www.mass.gov/doc/slides-board-meeting-september-15-2020/download
https://www.specialtypharmacycontinuum.com/Policy/Article/12-20/Medicaid-Moves-To-Gain-Control-Over-Drug-Prices/61173

Use Cases: Improved Payer/Pharma Negotiations

- Dupixent for severe atopic dermatitis
- Praluent for high cholesterol
  - Three years after failed launch (“arms race”)
  - Drug makers commit publicly to ICER price range in conjunction with “streamlined” access from payers
  - Express Scripts and drug makers announce a deal
- Vascepa for cardiovascular disease
- Zolgensma for spinal muscular atrophy
- Remdesivir for COVID-19

Use of ICER Assessments: Drug Makers and Payers

- **Remdesivir for COVID-19**
  - Heightened urgency and concern about prices for COVID treatments and vaccines
  - First ICER analysis of clinical evidence ahead of Emergency Use Authorization estimated fair price between $2,800 and $5,000 for a course of treatment*
  - Analysts predicted prices up to $10,000
  - Gilead chose $3,100 for a 5-day course

*Updated analysis with new data show fair price range to be $70 (mild disease) to $2,470 (moderate to severe disease)

https://investor.amarincorp.com/news-releases/news-release-details/independent-drug-pricing-assessment-finds-vascepar-icosapent

Origins of the Unsupported Price Increases (UPI) Work

- States were frustrated with annual price increases without any metric to judge if a price increase was justified
- Can a price increase ever be justified?
  - We believe that prices should reflect clinical benefit patients receive
  - If a drug shows added benefit for patients, then a price increase *may* be justified
- With our UPI work, state policymakers can know that certain price increases are not justified

2020 UPI Report Highlights: 7 Drugs with Unsupported Price Increases = $1.2b in excess drug spend

Treatment	2018-19 WAC Increase	2018-19 Net Price Increase	Increase in US Drug Spending Due to Net Price Change (in Millions)
Enbrel® (etanercept, Amgen)	5.4%	8.9%	$403
Invega Sustenna®/ Invega Trinza® (paliperidone palmitate, Janssen)	6.8%	10.7%	$203
Xifaxan® (rifaximin, Salix)	8.4%	13.3%	$173
Orencia® (abatacept, Bristol-Myers Squibb)	6.0%	7.4%	$145
Tecfidera® (dimethyl fumarate, Biogen)	6.0%	3.7%	$118
Humira® (adalimumab, AbbVie)	6.2%	2.0%	$66
Vimpat® (lacosamide, UCB)	7.0%	5.6%	$58

Full report: https://icer.org/wp-content/uploads/2020/11/ICER_UPI_2020_Report_011221.pdf

Questions?