

The Evolving Role of Independent Drug Value Assessments

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What's on the Horizon?



Institute for Clinical and Economic Review (ICER)

- **Independent** 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
- Use cost-effectiveness analysis to determine **value-based price benchmarks**
- Convene regional independent **appraisal committees** for public hearings on each report

Independent Appraisal Committees

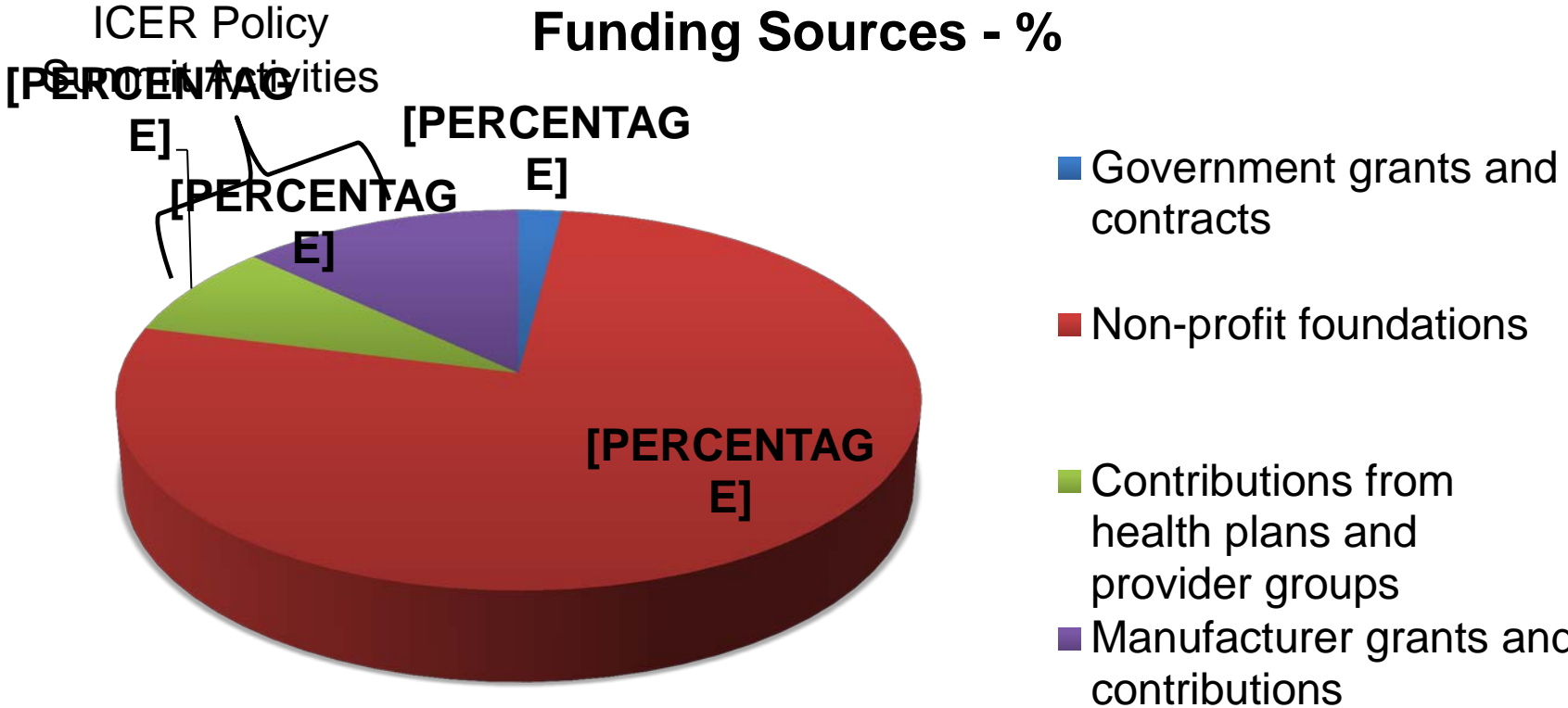


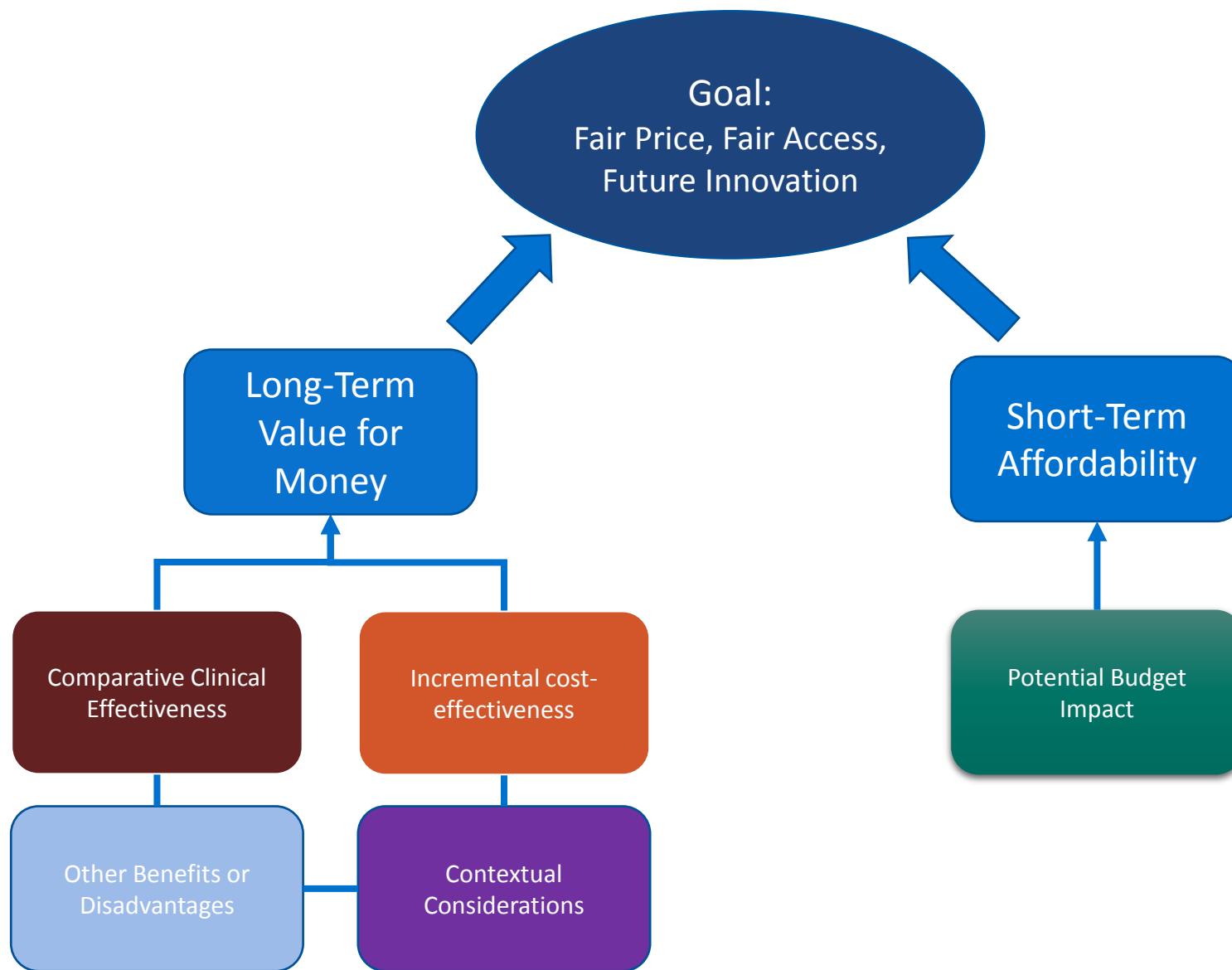
 **CTAF**
CALIFORNIA TECHNOLOGY
ASSESSMENT FORUM

 **MIDWEST**
CEPAC
COMPARATIVE EFFECTIVENESS
PUBLIC ADVISORY COUNCIL

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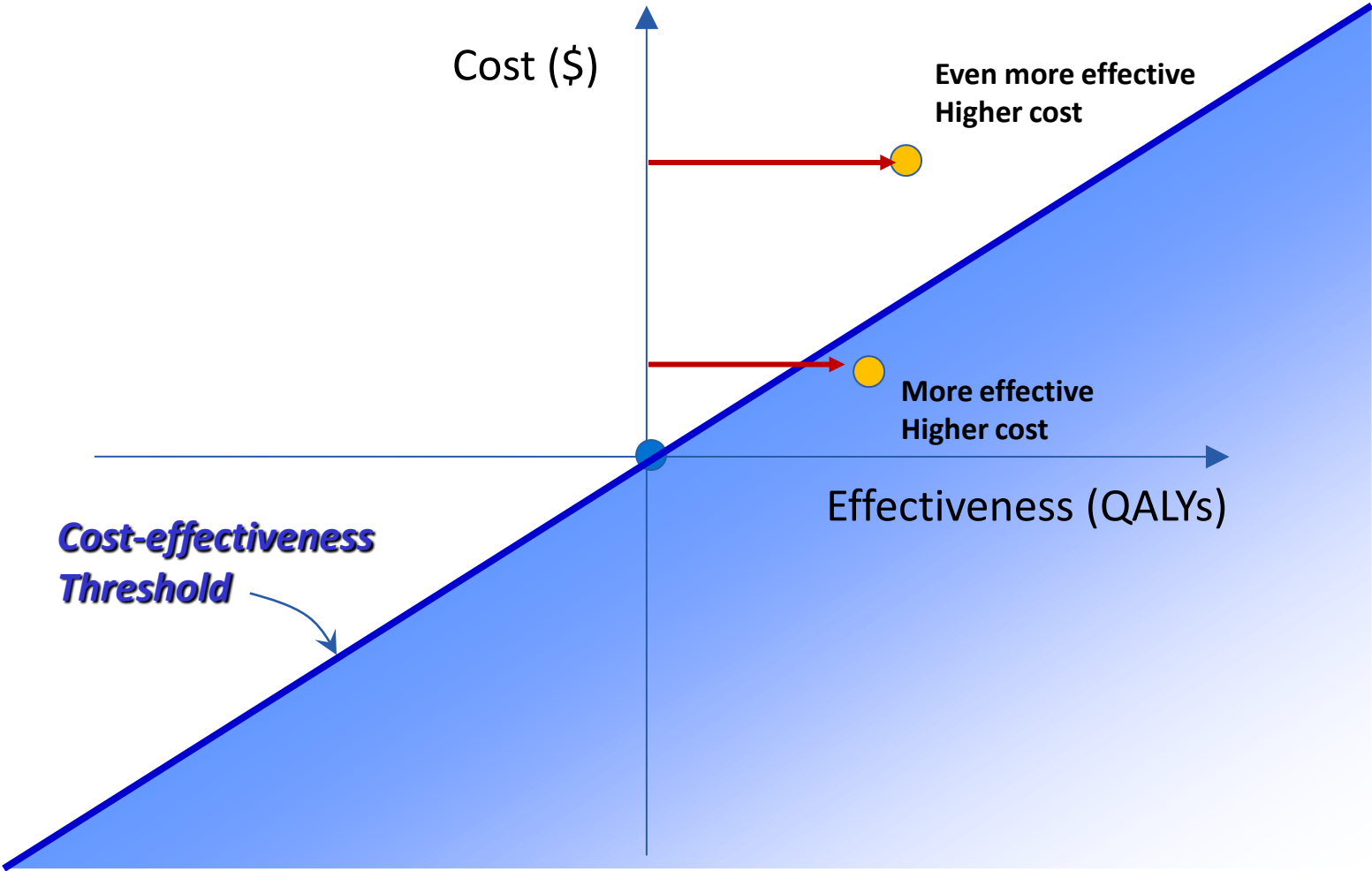
Sources of Funding, 2019





ICER's Value-based Price Benchmarks

Determining value-based price benchmarks



ICER's Value-based Price Benchmarks (2018)

Drug category	Recommended Discount*
Luxturna for childhood blindness	50-75%
Kymriah (CAR-T) for ALL	0%
Yescarta (CAR-T) for NHL	28%-11%
Hemlibra for hemophilia A	Cost-saving
Cystic Fibrosis	72%-77%
CGRPs for migraine prevention	25%-46%
Elagolix for endometriosis	15%-25%

Drug category	Recommended Discount*
Apalutamide, Xtandi, Abiraterone for prostate cancer	0% (apalutamide)
Psoriasis IL-23s and Cimzia	37%-57%
Inotersen, patisiran (amyloidosis)	90%-95%
Hereditary Angioedema	28%-68%
Opioid Use Disorder (new agents)	53%-69%
Eosinophilic asthma biologics	62%-80%

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

2019 update on use of ICER assessments

- **For policy makers:** 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 appropriate access
- **For payers and provider groups:** helps guide coverage decisions and pricing negotiations

Use of ICER Assessments: Drug Makers and Payers

- **Dupixent for severe atopic dermatitis, 2017**
- **Praluent for high cholesterol, 2018**
 - New data shared with ICER before public release
 - ICER updated its value-based price benchmarks
 - Drug makers commit publicly to ICER price range in conjunction with “streamlined” access from payers
 - Express Scripts and drug makers announce a deal
- **Sharing of data pre-FDA approval**

Use of ICER Assessments: Payers and Providers

- **Medicaid programs: New York**
 - 2017 law establishing drug spend target
 - If spending ahead of trend allowed to identify drugs for evaluation of value
 - If companies and Medicaid cannot come to agreement on lower price Medicaid can trigger public process to determine specific target price for supplemental rebate
 - 2018 experience and Orkambi

Threshold Price Analysis for Orkambi

Annual cost at WAC	Annual Price to Achieve...					
	\$50,000 /QALY	\$100,000 /QALY	\$150,000 /QALY	\$200,000 /QALY	\$300,000 /QALY	\$500,000 /QALY
\$272,886	\$58,790	\$70,991	\$83,193	\$95,394	\$119,797	\$168,604

- New York Medicaid DURB deliberation and vote

Use of ICER Assessments

- **Medicaid programs**
- **VA**
 - Monthly calls to debrief reports and potential applications
 - Pipeline discussion
 - Development of VA budget impact threshold
- **Private payers and PBMs**

Use of ICER Assessments: Payers

- Ongoing use by most payers to inform internal process
- CVS new benefit design for self-insured employers
 - Newly launched drugs, breakthrough drugs excluded
 - After negotiation, drugs that fail to reach a cost-effectiveness level of \$100K/QALY (top of \$50-100K/QALY range) can be designated a non-covered benefit
- Experience to date: ?
- Push-back against CVS benefit design

March 2019: Systematic Application of Value Assessment in Benefit Designs and Payment Policy



- Option 1 (private payers): **Special tier, step therapy, or exclusion** for drugs whose best negotiated price remains above the value-based price benchmark; can be woven into rebate-free formulary structure
- Option 2 (private or public payers): Include drugs on formulary but only **pay up to** the value-based price benchmark
- Option 3 (public payers): Allow CMS and/or Part D plans to **negotiate with price arbitration fallback**; value assessment reports used to create spectrum for proposals or as part of proposals to arbitrator
- All options could be used for “all” drugs or only a subset

Other initiatives at ICER in 2019

- Unsupported Price Increase (UPI) Report
- “Valuing a Cure” Methods Development Project
- ICER Evidence Compendium™

ICER Evidence Compendium™ under development

Medicine	Condition	Date of Review	Annual List Price (WAC)	Price Needed to Achieve \$150K per QALY	Price Needed to Achieve \$100K per QALY	Price Needed to Achieve \$50K per QALY	Discounts Needed to Achieve \$150K/100K/50K per QALY Thresholds
Praluent®	High Cholesterol	Nov-15	\$14,350	\$7,700	\$5,400	\$3,200	46% / 62% / 78%
Repatha®	High Cholesterol	Nov-15	\$14,350	\$7,700	\$5,400	\$3,200	46% / 62% / 78%
Nucala®	Asthma	Mar-16	\$32,500	\$12,100	\$7,800	\$3,500	63% / 76% / 89%
Tresiba®	Diabetes Mellitus	Mar-16	\$7,800	\$7,200	\$7,000	\$6,900	8% / 10% / 12%

Conclusion

- What is the role of independent drug assessment reports in 2019?
 - Poised for further systematic application to formularies and benefit designs, with additional innovative approaches seeing initial pilots
 - Applications by public insurers and the VA expected to continue/grow
 - As gene therapy at >\$1-2M arrives, public and political interest in value-based pricing will continue to gain momentum
 - With increased use and interest will come increased push-back
 - As 2020 nears many policymakers will see value-based pricing as a core component of efforts to address drug pricing and value