

ICER Value Assessment Framework: 1.0 to 2.0



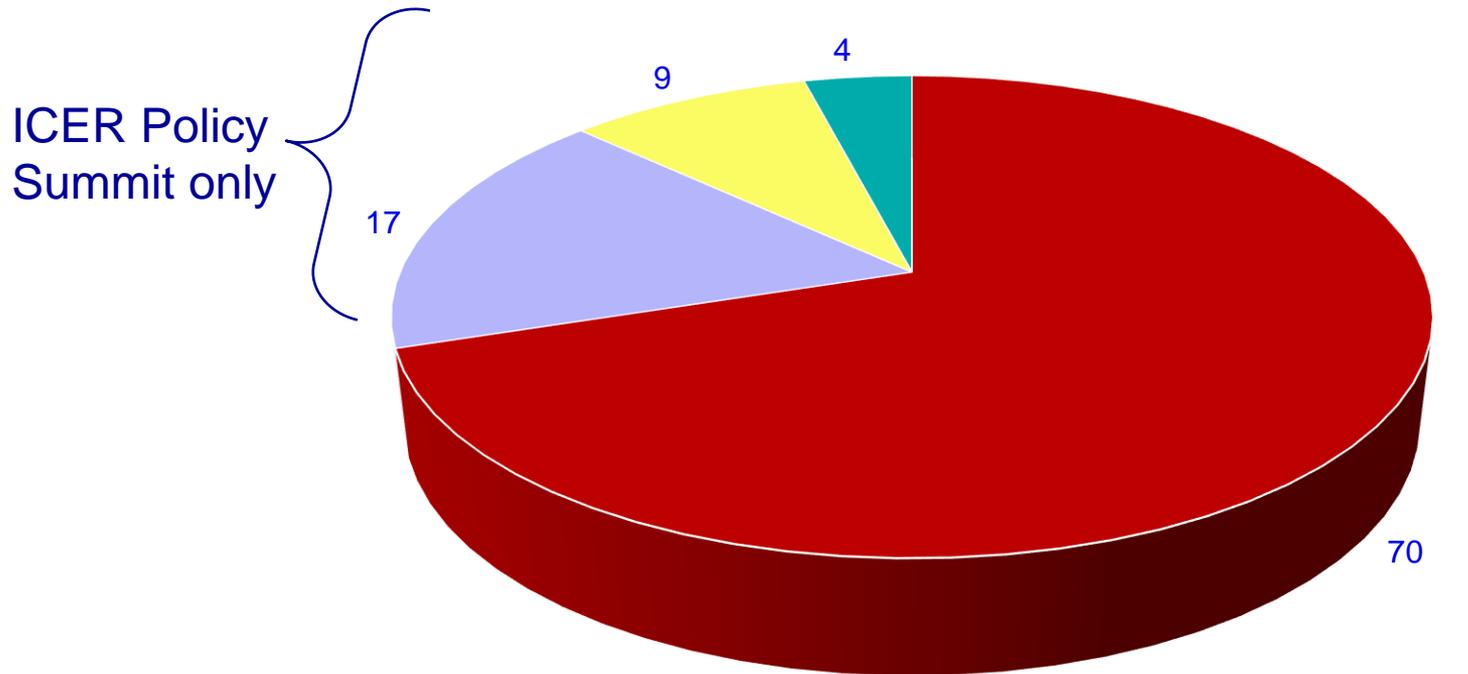
Outline

- Background on ICER
- Version 1.0 development
- Conceptual basis for ICER value assessment framework
- Domains of value
 - Long-term perspective (value for money)
 - Short-term perspective (affordability)
- Key areas for potential revision
- Process towards version 2.0

ICER

- Independent non-profit research institute in Boston nearing its 10th birthday
- Multidisciplinary staff of ~20
 - Collaboration with faculty at UCSF, BWH, UW
 - External commissioning of economic models
- Mission and major programs
 - Improve the interpretation and use of evidence throughout the health care system to improve patient care and control costs
 - Help make discussion of value more transparent
 - Value assessment reports on tests, treatments, delivery system innovations
 - Recent increased focus on drugs
 - Public deliberation through CTAF, New England CEPAC, Midwest CEPAC
 - Proven Best Choices with FamiliesUSA

Sources of Funding (%)



- Non-profit foundations
- Life Science companies
- Insurers and Provider Groups
- Government contracts

Is Value Assessment New?

- Whose value? Whose assessment?
 - Individual patients and clinicians
 - Innovators
 - Insurers
- Explicit frameworks in the U.S.: different strokes...
 - The American College of Cardiology
 - American Society of Clinical Oncology
 - National Comprehensive Cancer Network
 - DrugAbacus
 - ICER

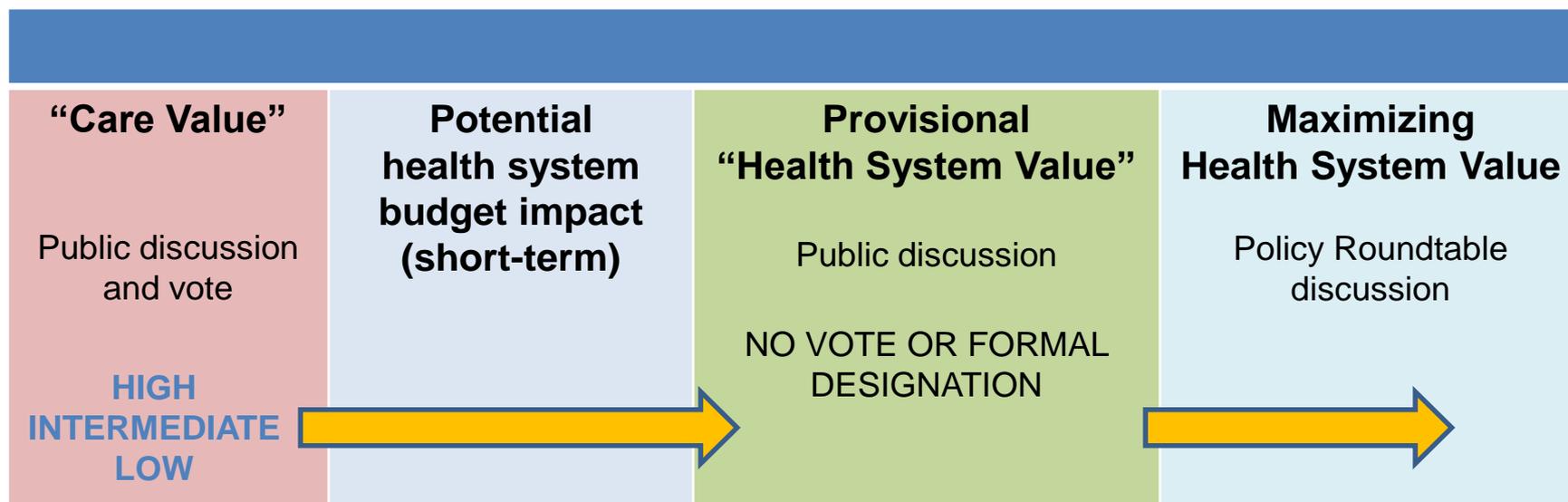
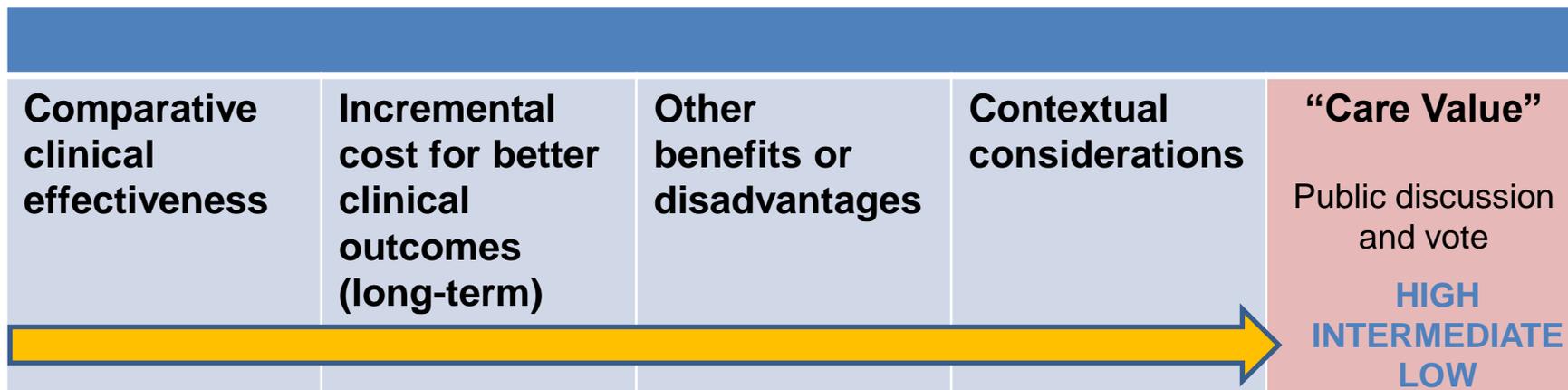
The ICER Value Framework

- The “problems” the value framework was intended to address
 - Need for improved transparency and consistency of value determinations by HTA groups and payers
 - Mismatch between concepts and terms used to describe value across patients, clinicians, innovators, and payers
 - Need for a more explicit and transparent way for HTA groups and payers to analyze and judge value
 - Framework for population-level policy decisions sensitive to patient and clinician perspectives
 - Addressing potential tension between long-term and short-term perspectives

ICER Value Assessment Inputs

- ***NB: All participants provided input into the development of the value assessment framework but none should be assumed to approve of its approach**
- **ICER Public Deliberation Panel Participants**
 - CTAF, New England CEPAC
- **Insurers and Pharmacy Benefit Management Companies**
 - Aetna
 - Wellpoint
 - Kaiser Permanente
 - OmedaRx
 - Premera
 - America's Health Insurance Plans (AHIP)
- **Consumer Organizations**
 - FamiliesUSA
- **Physician Specialty Societies**
 - ASCO
- **Manufacturers**
 - Merck
 - Covidien
 - Lilly
 - GSK
 - Philips
 - Amgen
 - National Pharmaceutical Council (NPC)
 - Biotechnology Industry Organization (BIO)

ICER Value Assessment Framework 1.5

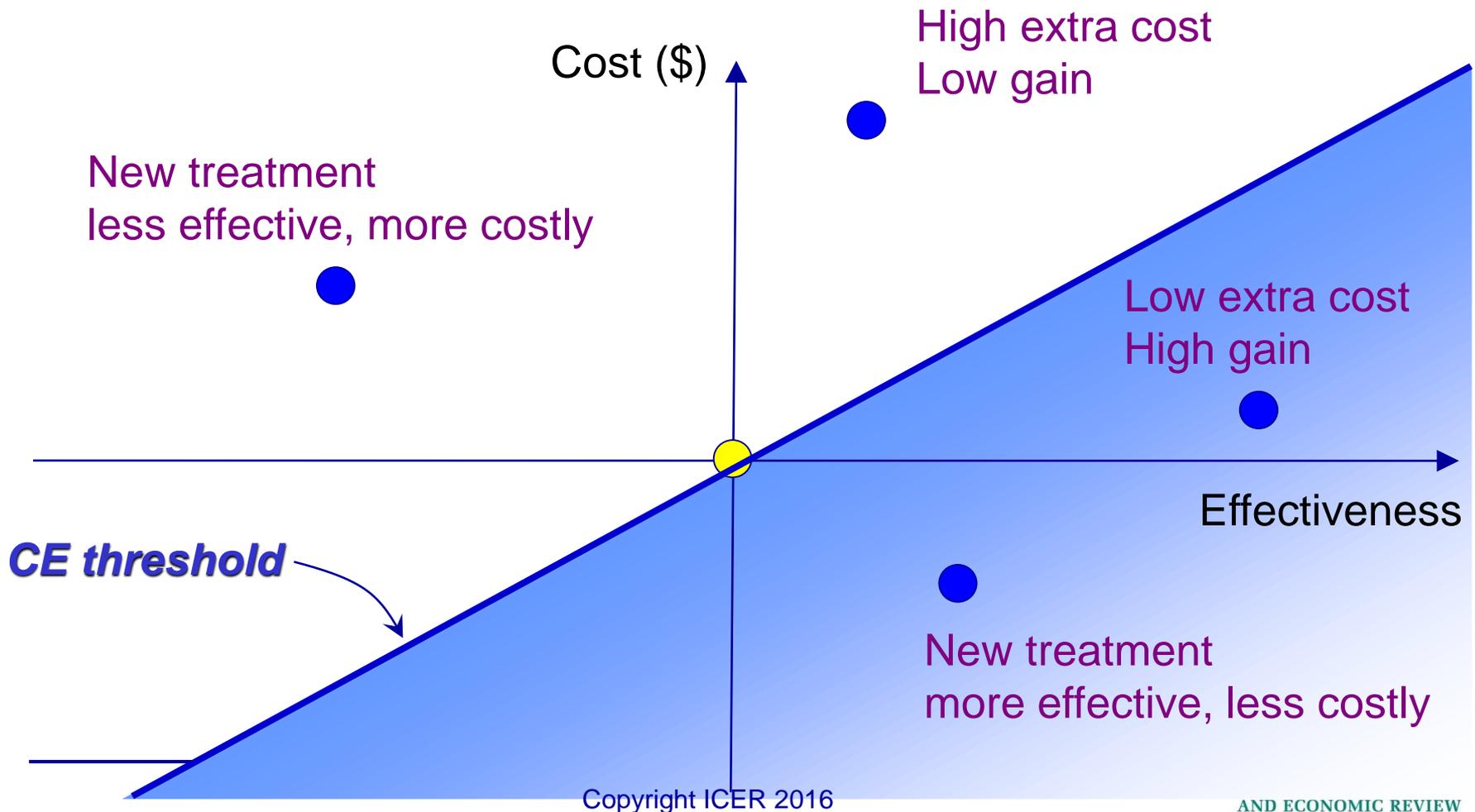


Comparative Clinical Effectiveness



- Comparative clinical effectiveness reflects a joint judgment of the magnitude of the comparative net health benefit and the level of certainty in the evidence on net health benefit.
- Patient groups inform what outcomes are important, differences across severity, time in disease course, etc.
- Patient groups inform re: opportunities for using or generating real-world evidence

Incremental cost-effectiveness ratios

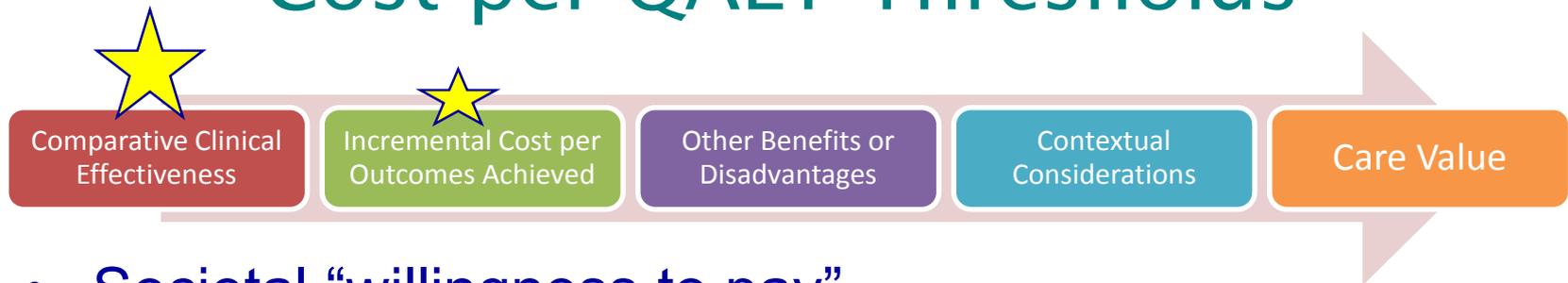


Incremental Cost per Outcomes Achieved



- Long-term perspective on clinical outcomes and cost
- Costs from health system (payer) perspective – all health care costs
- Standard measures of health gain
 - Additional life-years gained
 - Improvement in quality of life
 - Cost per quality-adjusted life year gained, aka “cost per QALY”

Cost per QALY Thresholds



- Societal “willingness to pay”
 - WHO 1-3x per capita GDP (\$50,000-\$150,000)
- Individual “willingness to pay”
 - ~2 times annual salary (\$100,000)
- “Opportunity cost” for the health system
 - ~1x GDP in UK, Latin America
 - Extrapolated ~\$50,000 per QALY in the US
- ICER: \$100,000-\$150,000 per QALY

Other Benefits or Disadvantages



- Patient groups and others asked about benefits or disadvantages offered by the intervention to the individual patient, caregivers, the delivery system, other patients, or the public that would not have been considered as part of the evidence on comparative clinical effectiveness.
 - Methods of administration that improve or diminish patient acceptability and adherence
 - A public health benefit, e.g. reducing new infections
 - More rapid return to work or other positive effects on productivity (if not considered a benefit as part of comparative clinical effectiveness)
- To be judged not by ICER but by one of its independent public appraisal committees

Contextual Considerations

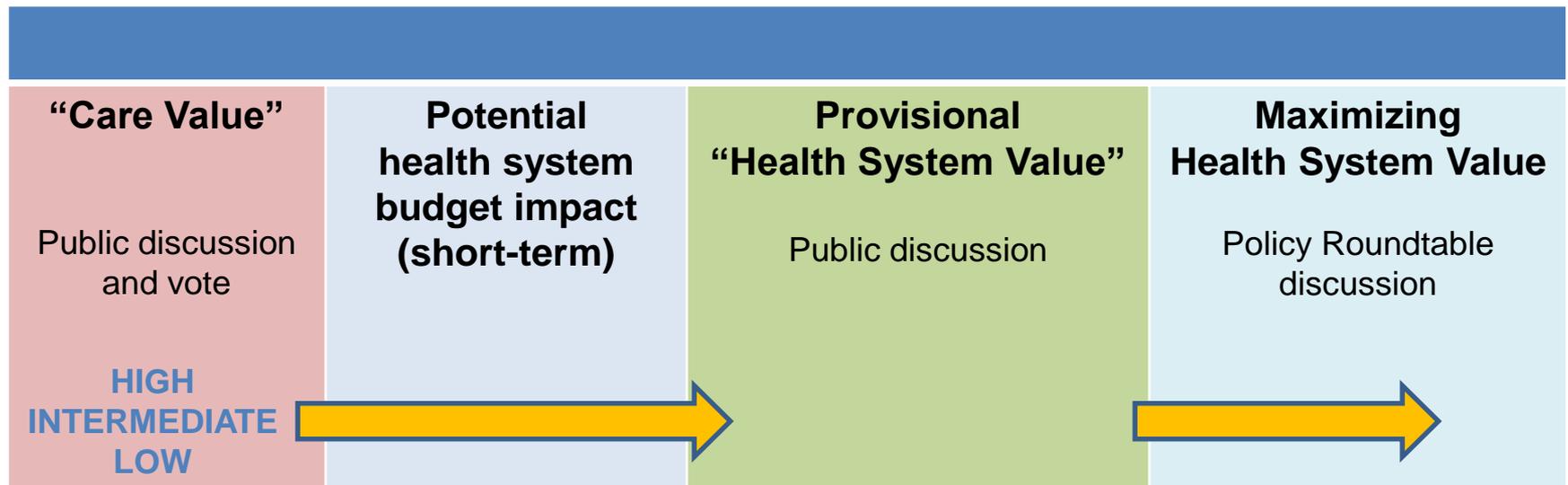
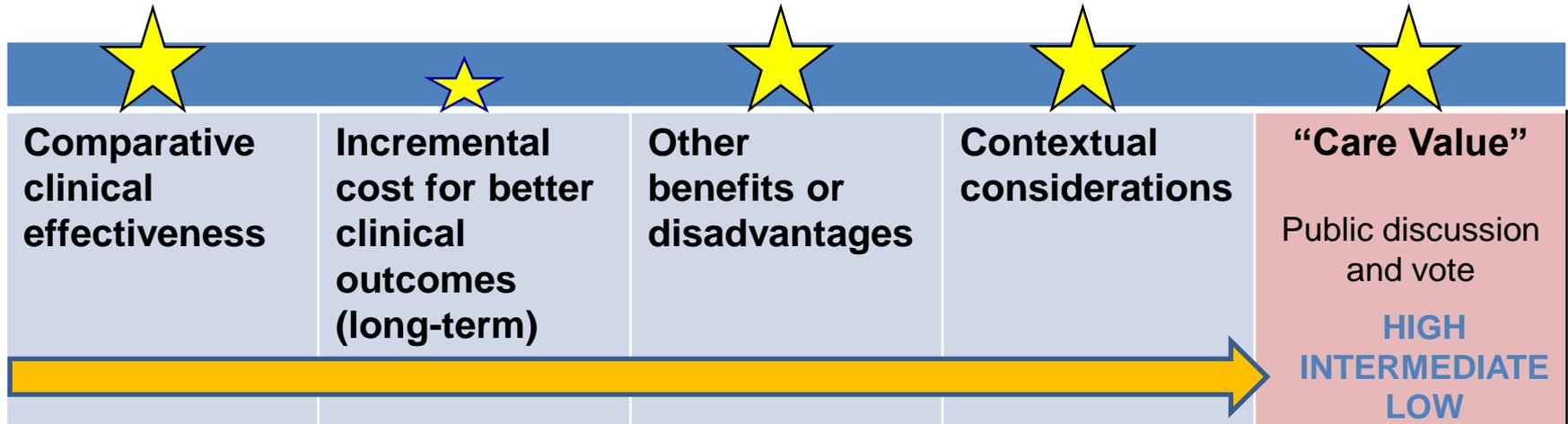


- Contextual considerations include ethical, legal, or other issues that influence the relative priority of illnesses and interventions.
- Specific issue to be asked of patient groups and others:
 - Is this a condition of notably high severity for which other acceptable treatments do not exist?
 - Are other, equally or potentially more effective treatments nearing introduction into practice?
 - Would other societal values accord substantially more or less priority to providing access to this treatment for this patient population?
- To be judged not by ICER but by one of its independent public appraisal committees.

Connecting cost-effectiveness results and care value votes: Drugs

Draft report cost/QALY estimate	Significant benefits or contextual factors	Probable CTAF/CEPAC Care Value votes
< \$100K/QALY	- sig benefits or context factors	High or Intermediate
< \$100K/QALY	+ sig benefits or context factors	High
\$100-150K/QALY	- sig benefits or context factors	Intermediate
\$100-150K/QALY	+ sig benefits or context factors	Intermediate or High
> \$150K/QALY	- sig benefits or context factors	Low
> \$150K/QALY	+ sig benefits or context factors	Low or Intermediate

ICER Value Assessment Framework



“Provisional Health System Value”?



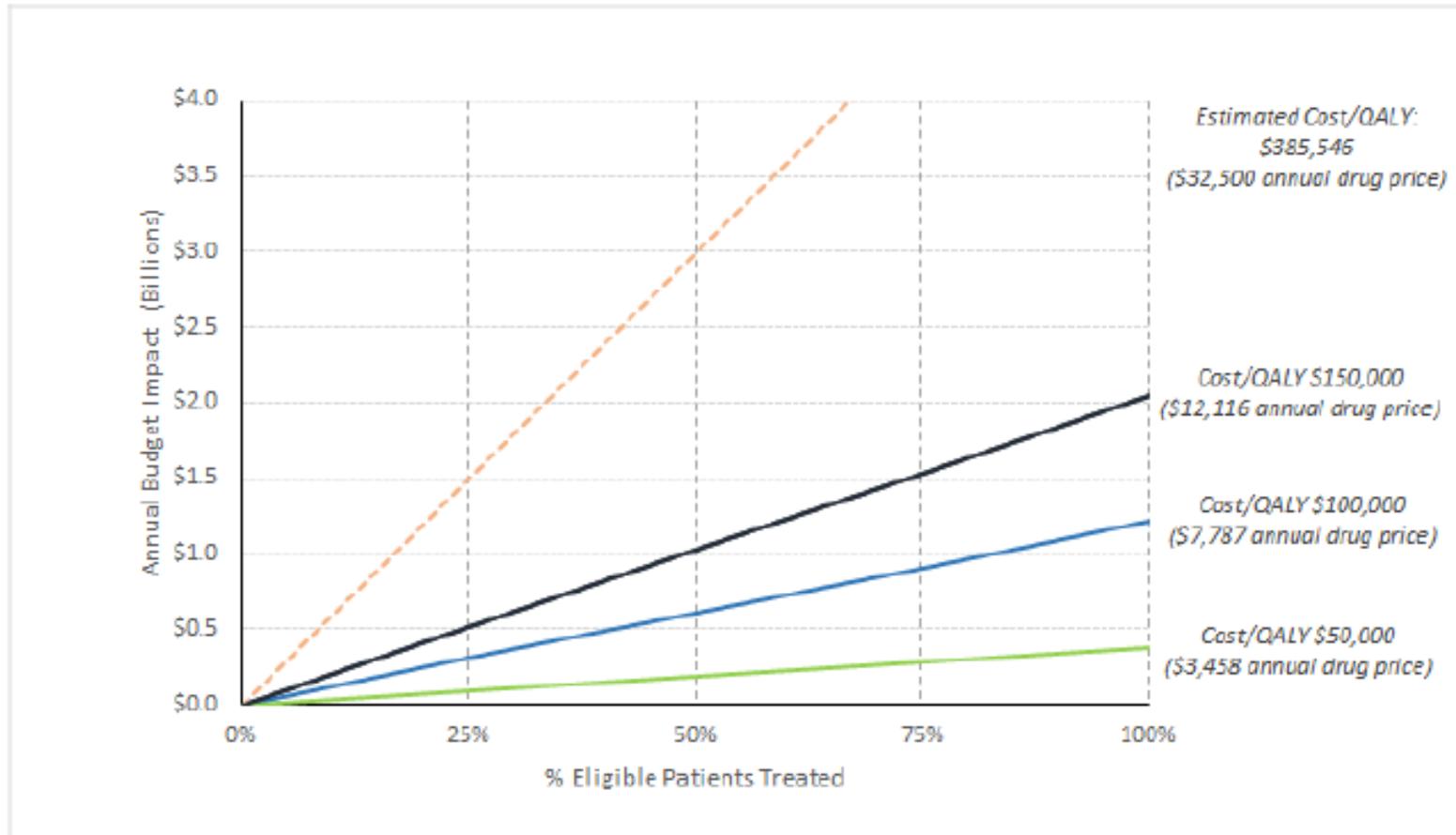
- Provisional Health System Value
 - Trying to address possible tension between long-term and short-term perspectives on value to the health system
 - Provisional health system value is intended to represent a judgment of whether a new intervention with acceptable long-term care value may yet have short-term costs so substantial as to displace more valuable services for patients (opportunity cost) and/or lead to unsustainable short-term increases in overall health spending.
 - “Short term costs”= potential short-term budget impact

How does ICER estimate potential budget impact?

- Estimated *net* change in *total* health care costs over an initial *5-year time-frame*
- New interventions are assigned to one of 4 potential uptake patterns based on consideration of condition/market criteria
 - Very high 75% uptake at 5 years
 - High 50% uptake at 5 years
 - Intermediate 25% uptake at 5 years
 - Low 10% uptake at 5 years

ICER Integrated Value Graph

Figure 6. Combined Cost-effectiveness and Potential Budget Impact Graph for Mepolizumab



Potential Budget Impact Threshold

- At what magnitude of potential budget impact do policymakers need to be concerned?
- Theoretical basis of a potential budget impact threshold
 - Based on state (Mass/Maryland) and ACA legislation
 - The amount of net cost increase per individual new intervention that would contribute to growth in overall health care spending greater than the anticipated growth in national GDP + 1%
 - A potential budget impact for an individual drug estimated to contribute significantly to cost growth above this threshold serves as an “alarm bell” for consideration of whether utilization management, lower prices, reallocation of resources, etc. are needed

Summary of 2015–2016 Potential Budget Impact Threshold Calculations

Item	Parameter	Estimate (Drugs)	Estimate (Devices)	Source
1	Growth in US GDP, 2015-2016 (est.) +1%	3.75%	3.75%	World Bank, 2015
2	Total health care spending (\$)	\$3.08 trillion	\$3.08 trillion	CMS NHE, 2014
3	Contribution of drug/device spending to total health care spending (%)	13.3%	6.0%	CMS NHE, Altarum Institute, 2014
4	Contribution of drug spending to total health care spending (\$) (Row 2 x Row 3)	\$410 billion	\$185 billion	Calculation
5	Annual threshold for net health care cost growth for ALL new drugs (Row 1 x Row 4)	\$15.4 billion	\$6.9 billion	Calculation
6	Average annual number of new molecular entity or device approvals, 2013-2014	34	23	FDA, 2014
7	Annual threshold for average cost growth per individual new molecular entity (Row 5 ÷ Row 6)	\$452 million	\$301 million	Calculation
8	Annual threshold for estimated potential budget impact for each individual new molecular entity (doubling of Row 7)	\$904 million	\$603 million	Calculation

Potential budget impact: Experience to date

- Exceeded alarm bell threshold
 - PCSK9 inhibitors for high cholesterol
 - Entresto for heart failure (over by 9%)
 - CardioMEMS system for heart failure
 - Ocaliva for NASH
- Did not exceed alarm bell threshold
 - Nucala for severe eosinophilic asthma
 - New drugs for multiple myeloma
 - Tresiba for diabetes
 - Ocaliva for primary biliary cholangitis
 - Diabetes prevention programs
 - Palliative care in the outpatient setting

ICER Value-Based Price Benchmark

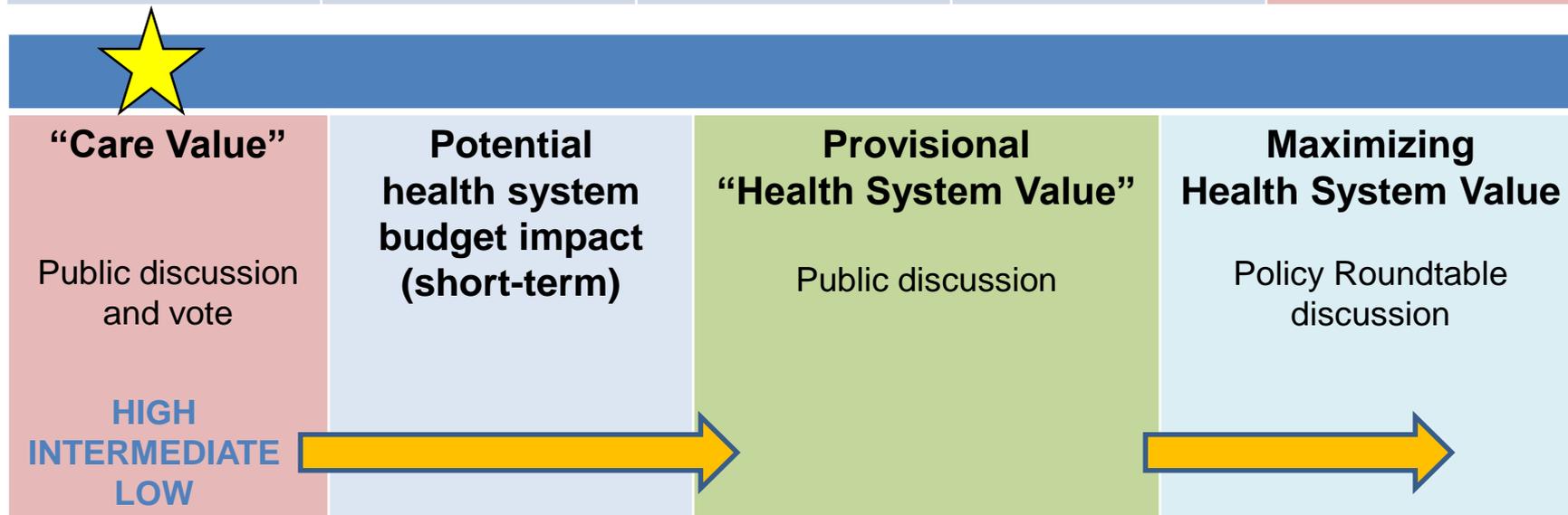
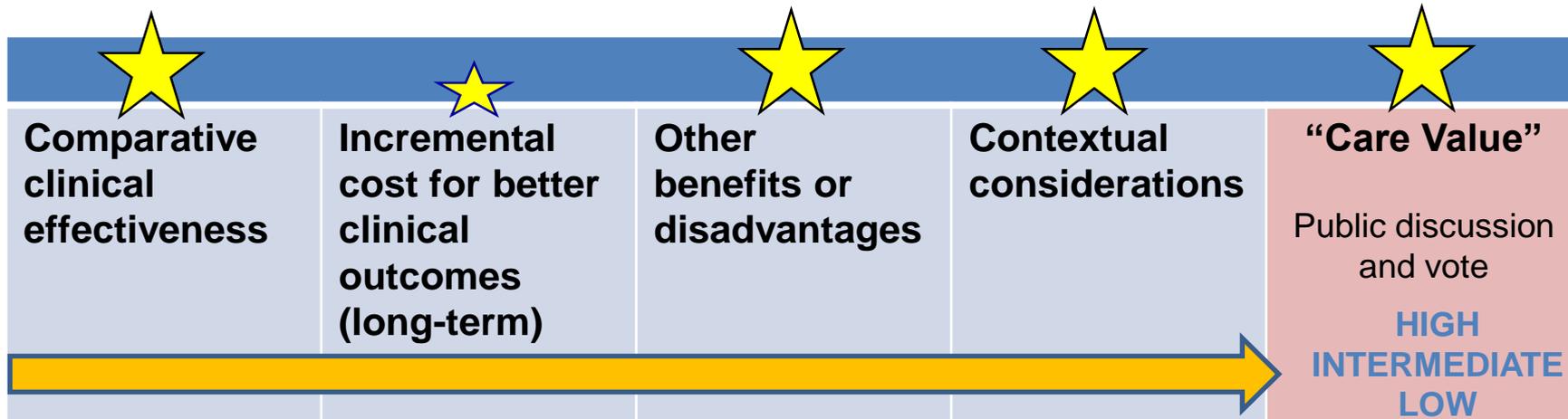
- Two components:
 - Step 1: Long-term cost-effectiveness
 - Price at which the cost per quality-adjusted life year gained = \$100,000-\$150,000
 - Range leaves room for the role of other factors
 - Step 2: Potential short-term budget impact
 - \$904 million NET *per year* per new drug = affordability “alarm bell”

From Value Assessment to “Value-Based Price Benchmarks”

	Price to Achieve \$100K/QALY	Price to Achieve \$150K/QALY	Price at Short-Term Affordability Threshold
PCSK9 Drugs <i>List price \$14,350</i> (n=2,636,179)	\$5,404 46%-62% discount	\$7,735	\$2,177 

	Price to Achieve \$100K/QALY	Price to Achieve \$150K/QALY	Price at Short-Term Affordability Threshold
Entresto <i>List price \$4,560</i> (n=1,949,400)	\$9,480 2-3x higher!	\$14,472	\$4,168 9% discount

ICER Value Assessment Framework



Key Areas for Potential Revision

- Terminology:
 - “care value” and “provisional health system value”
- Capturing and weighing “other benefits or disadvantages” and “contextual considerations”
- Technical aspects of the cost/QALY
 - Lifecycle prices for drugs
 - Use of normalized quality of life ratings for serious conditions and disabilities
 - ? Changing the cost/QALY threshold
- Potential short-term budget impact
 - Uptake estimations for new drugs
 - Assumptions about “background inflation” of existing drugs
 - Where and how to set the “alarm bell” threshold

Looking forward: ICER Value Assessment Framework 2.0

- Open solicitation for suggestions to improve the framework (closes September 12), posted on ICER website
- Discussion of prioritized options with multiple stakeholders
- Posting of draft Framework 2.0 with webinar approximately January 5, 2017