

# Evaluating the value of new drugs

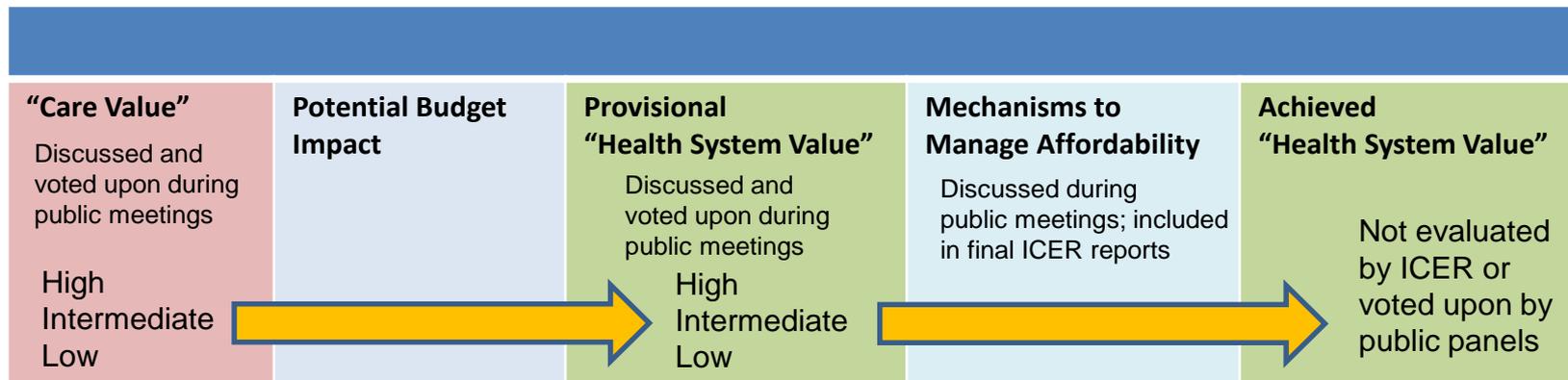
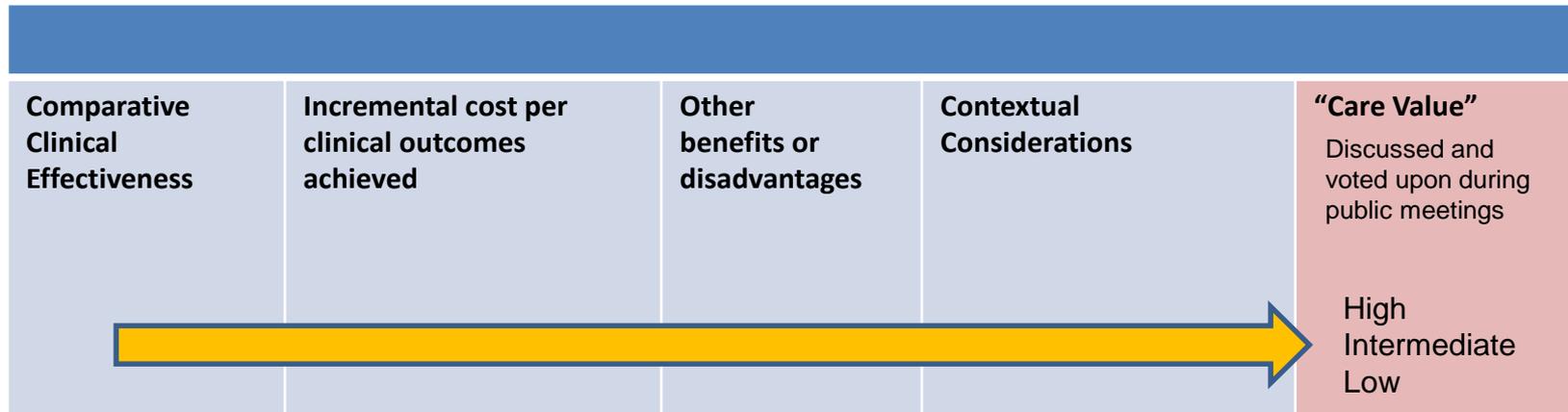


# The ICER value framework

- The framework includes
  - Content
    - A list of *elements* to consider
  - Measurement options
    - *Methods to measure* or judge each element
  - Assessment process
    - *Process by which to integrate measurements* and other information in an assessment of overall value

# What is the Overall Structure?

# A value flowchart



# Definitions of Care Value and Health System Value

- ***Care value*** is a judgment comparing the average per-patient costs, clinical outcomes, and broader health effects of two alternative interventions or approaches to care.
- ***Health system value*** is a judgment of the degree to which the short-term budget impact of a new care option can be afforded by the health care system without displacing care of equal or greater value or causing an increase in health insurance premiums so steep that access to affordable care for all patients would be adversely affected.

# 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. ICER reports use ICER's EBM matrix to describe staff estimate.
  - Magnitude of the *comparative* net health benefit
    - Measurement options
      - Disaggregated
        - » Specific clinical outcomes, e.g. disease-specific mortality, sustained viral response
      - Aggregated
        - » QALYs
  - Level of certainty in the evidence on net health benefit

# Incremental Cost per Outcomes Achieved and Care Value



- Incremental Cost per Outcomes Achieved
  - Cost per aggregated health measure (QALY)
    - Diverse health economic and policy analyst perspectives on mechanisms to set and use cost/QALY thresholds
    - Common practice: WHO recommended thresholds linked to national GDP (1xGDP ~ \$50,000 in the United States)
    - ICER will use the following in its reports and in its guidance to CTAF and CEPAC:
      - High care value
        - < \$50,000/QALY if no “substantial” other benefits and/or contextual considerations
        - < \$50,000-\$100,000 per QALY if “substantial” other benefits and/or contextual considerations
      - Intermediate care value
        - \$50,000 - \$100,000/QALY if no “substantial” other benefits and/or contextual considerations
        - \$101,000-\$150,000/QALY if “substantial” other benefits and/or contextual considerations
      - Low care value
        - \$101,000-\$150,000/QALY if no “substantial” other benefits and/or contextual considerations
        - > \$150,000/QALY

# Other Benefits or Disadvantages



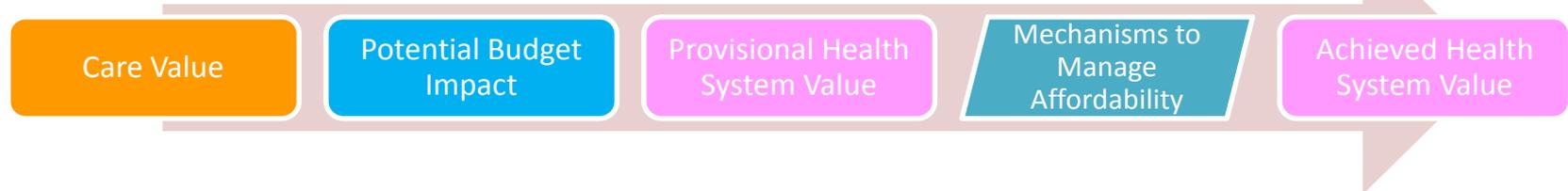
- Any significant benefits or disadvantages offered by the intervention to caregivers, the delivery system, or other patients in the health care system that would not have been captured in the available “clinical” evidence.
- Examples include (but are not limited to)
  - Mechanisms of treatment delivery that require many fewer (or more) visits to the clinician’s office
  - Treatment outcomes that reduce disparities across various patient groups
  - New mechanisms of action for treatments of clinical conditions (e.g., mental illness) that have demonstrated low rates of response to currently available treatments

# Contextual Considerations



- Contextual considerations can include ethical, legal, or other issues (but not cost) that influence the relative priority of illnesses and interventions.
- Examples include
  - Do other acceptable treatments exist?
  - Is there a particularly high burden/severity of illness?
  - Does the condition include high-priority populations (e.g. children)?
  - Will the intervention be introduced through coverage with evidence development or other ways to reduce key uncertainties about patient outcomes and costs?

# Potential Budget Impact and Provisional Health System Value



- Provisional Health System Value
  - An early judgment of “provisional” health system value based on the potential budget impact of a change in care is used as a trigger for determining whether mechanisms need to be considered to help manage the affordability of a new intervention.
- Potential Budget Impact:
  - Estimated net change in TOTAL health care payer costs over an initial 2-year time-frame
  - Net change in costs includes
    - Costs and cost-offsets for all health care services (treatments, visits, hospitalization, etc)
    - Net costs of switching from existing care to new care option (ie subtracting discarded Rx costs from new Rx costs)
  - Base case will consider the net budget impact of *all currently treated patients* switching to new care option
    - This perspective serves as a measure of *potential* budget impact of unmanaged introduction of the new care option
  - Alternative scenario will measure net budget impact of *all known eligible patients* switching to or beginning new care option
    - This scenario will be used when the new care option offers significant advantages likely to bring into treatment many patients not previously treated (e.g. all-oral treatments for hepatitis C)

# Potential Budget Impact Thresholds



- Theoretical basis of the budget impact threshold for new drugs
  - Maryland and Massachusetts, have legislated caps on state health care cost growth tied to a lower growth level: GDP + 0%.
  - The threshold used by ICER will be whether the net health care cost impact of a single new drug would be at a level contributing to growth in overall health care spending greater than the anticipated growth in national GDP + 1%.
  - The higher GDP+1% threshold is suggested by the trigger for action to reduce federal Medicare spending established by the ACA for the the Independent Public Advisory Board (IPAB).
  - In 2015-2016 the World Bank estimates US GDP growth at 3.1%, so GDP + 1% = 4.1%
- Calculating potential budget impact thresholds for individual new drugs
  - Last 2-year running average of new drugs approved annually in the US ~ 33
  - Current contribution of drug spending to total health care costs ~ 12.5%
  - If we **assume that the net health care cost impact for existing drugs does not change**, and allow the NET impact of all new drug costs to grow no faster than the average for all other health care costs (4.1%), then the average contribution to net health care cost per *new* drug is limited based on the following calculations:
    - 4.1% growth in drug costs on a base of 12.5% of all health care spending = 0.5125% net TOTAL health care cost growth allocated to all new drugs
    - $0.5125\% \div 33 \text{ new drugs} = 0.015\%$  average NET health care cost increase per drug
    - $0.015\% \times \text{total payer costs for healthcare in the US} = \$351 \text{ million}$
  - In order to identify those new drugs whose potential budget impact is significantly higher than the average, and therefore raises affordability concerns, CER will set its potential budget impact threshold at 2x the level of the “average” drug.
  - Thus, the potential budget impact threshold is  $0.015\% \times 2 = 0.03\%$  NET health care cost increase.
  - **The ICER threshold for NET budget impact for 2015 = 0.03% of TOTAL insurance costs. This translates into \$752 million per year, a figure that includes cost offsets of switching from other drugs as well as any potential reductions in hospitalizations or changes in other health care costs.**

# What if the Potential Budget Impact exceeds the threshold?



- Managing affordability is an action step, ideally supported by enhanced early dialogue among manufacturers, payers, and other stakeholders.
  - Determine the extent to which real-world constraints in uptake will limit the actual budget impact of the new service
  - Decide if the expected budget impact for this service is manageable in the context of the current health care landscape
  - Seek savings in other areas to optimize the entire portfolio of services
  - Change the payment mechanism (longer terms) and/or price (lower)
  - Prioritize Rx populations to reduce immediate cost impact
  - Share the costs with government or other funders
- The policy actions taken will determine the “achieved” health system value

# From value assessment to value-based prices: The ICER price benchmark

- The ICER price benchmark does two things:
  - First, in a consistent way across all types of drugs, it rewards innovation by assigning a higher price to a new drug in proportion to how much better it is at improving the length and quality of life for individual patients. In other words, it captures the “care value” of the drug.
  - Second, for expensive drugs that could be used to treat a large number of patients, the benchmark calculates a maximum price beyond which the costs for the drug could contribute to health care costs going up faster than the rest of the economy. A price higher than the ICER price benchmark suggests the need for a lower price or for manufacturers, insurers, and other stakeholders to consider special measures to manage the affordability of the drug.

# Calculating the ICER value-based price benchmark

- The ICER price benchmark includes a range from price \$A to price \$B
  - Price \$A or below represents “high value”
  - Price \$B or above represents “low value”
- This range of \$A-\$B is first calculated based on the incremental cost-effectiveness ratio (cost/QALY)
- The cost/QALY range differs depending on whether the public panel determines there are “significant” other benefits and/or contextual considerations leading to higher care value
  - If -- significant benefits the range is \$50-100K/QALY
  - If + significant benefits the range is \$100-150K/QALY
- Price ranges are always limited by any price at which the potential budget impact would exceed 0.03% total net health care cost increase

Draft report VBPB	Sig benefits and/or context	CTAF/CEPAC Care value vote	Potential Budget Impact	Provisional health system value vote	Final VBPB
< 50K/QALY Draft VBPB: 50-150K/QALY limited by 0.03% PBI	- sig bens	High	> 0.03%	Intermed/low	50-100K/QALY with 0.03% limit
			< 0.03%	High	
	+ sig bens	High	> 0.03%	Intermed/low	100-150K/QALY with 0.03% limit
			< 0.03%	High	
50- 100K/QALY Draft VBPB: 50-150K/QALY limited by 0.03% PBI	- sig bens	Intermediate	> 0.03%	Low	50-100K/QALY with 0.03% limit
			< 0.03%	Intermediate	
	+ sig bens	High	> 0.03%	Intermed/low	100-150K/QALY with 0.03% limit
			< 0.03%	Low	
100- 150K/QALY Draft VBPB: 50-150K/QALY limited by 0.03% PBI	- sig bens	Low	> 0.03%	Low	50-100K/QALY with 0.03% limit
			< 0.03%	Low	
	+ sig bens	Intermediate	> 0.03%	Low	100-150K/QALY with 0.03% limit
			< 0.03%	Intermediate	
> 150K/QALY Draft VBPB: 50-150K/QALY limited by 0.03% PBI	- sig bens	Low	> 0.03%	Low	50-100K/QALY with 0.03% limit
			< 0.03%	Low	
	+ sig bens	Low	> 0.03%	Low	100-150K/QALY with 0.03% limit
			< 0.03%	Low	

