Evaluating the Value of New Drugs and Devices

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Value framework efforts

- International: NICE, PBAC, etc.
- Premera
- The American College of Cardiology
- ASCO value framework
- Memorial-Sloan Kettering Abacus®
- ICER

The ICER Value Framework

- The “problems” the value framework was intended to address
  - Poor reliability and consistency of value determinations by payers
  - Need for a more explicit and transparent way for HTA groups and payers to analyze and judge value
    - Tension between long-term and short-term perspectives
- The goal
  - A common language and mental model of the components of value across life science companies, payers, and other stakeholders
- A distinct goal for ICER
  - Underpin public HTA programs in California and New England that deliberate and vote on effectiveness and value

ICER Value Assessment Policy Development Group*

- ***NB: All participants provided input into the development of the value assessment framework but none should be assumed to approve of its approach**

- **Insurers and Pharmacy Benefit Management Companies**
  - Aetna
  - Wellpoint
  - Kaiser Permanente
  - OmedaRx
  - Premera
  - America's Health Insurance Plans (AHIP)

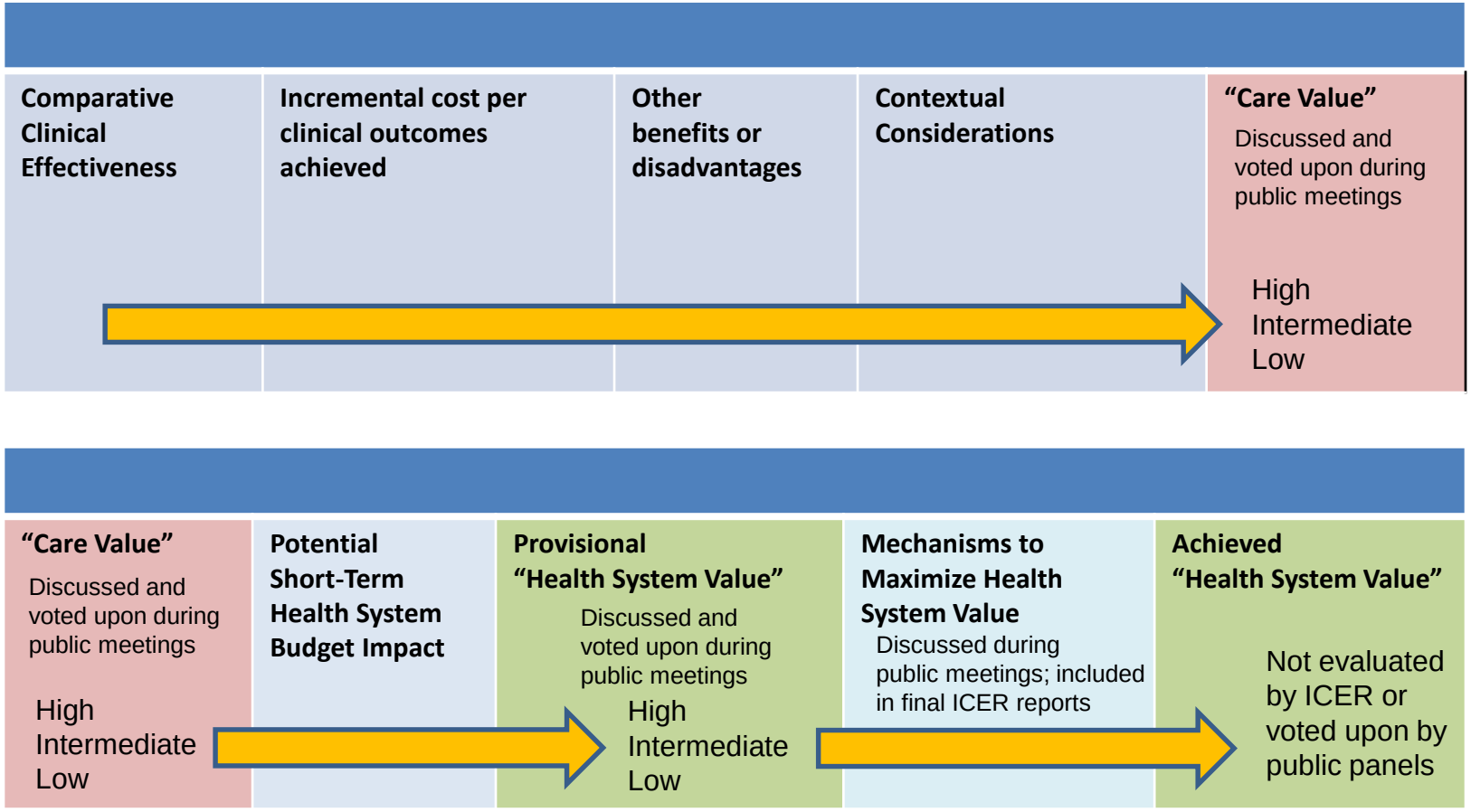
- **Patient Organizations**
  - FamiliesUSA

- **Physician Specialty Societies**
  - ASCO

- **Manufacturers**
  - Merck
  - Covidien
  - Lilly
  - GSK
  - Philips
  - Amgen
  - National Pharmaceutical Council (NPC)
  - Biotechnology Industry Organization (BIO)

What is the Overall Structure?

A Value Assessment Flowchart



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Comparative Clinical Effectiveness

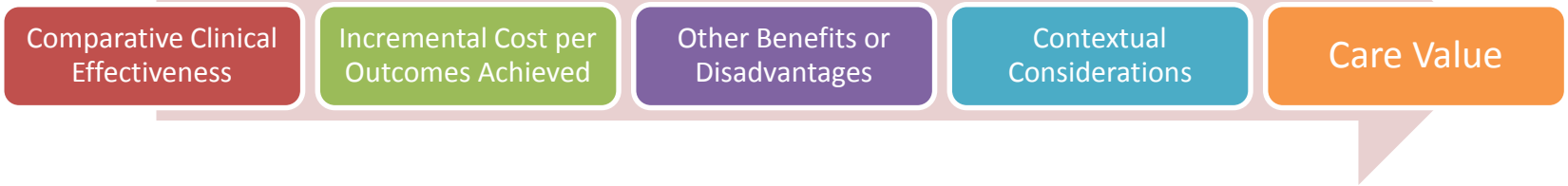
- Comparative clinical effectiveness reflects a joint judgment of the magnitude of the comparative net health benefit and the level of certainty in the evidence on net health benefit.

- ICER reports use the ICER EBM matrix (www.cercollaborative.org) to describe the scientific staff's judgment of comparative clinical effectiveness.

Incremental Cost per Outcomes Achieved

- Incremental Cost per Outcomes Achieved
  - Cost per aggregated health measure (QALY)
  - ICER uses commonly cited cost/QALY thresholds in its guidance to its public appraisal committees
    - Associated with high care value
      - <$100,000/QALY
    - Associated with intermediate care value
      - $100-150K/QALY
    - Associated with low care value
      - >$150,000/QALY

Other Benefits or Disadvantages



- 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
  - Treatment outcomes that reduce disparities across various patient groups
  - More rapid return to work or other positive effects on productivity (if not considered a benefit as part of comparative clinical effectiveness)
  - New mechanisms of action for treatments of clinical conditions (e.g., mental illness) for which the response to currently available treatments varies significantly among patients for unknown reasons (substantial heterogeneity of treatment effect)
- To be judged not by ICER but by one of its independent public appraisal committees

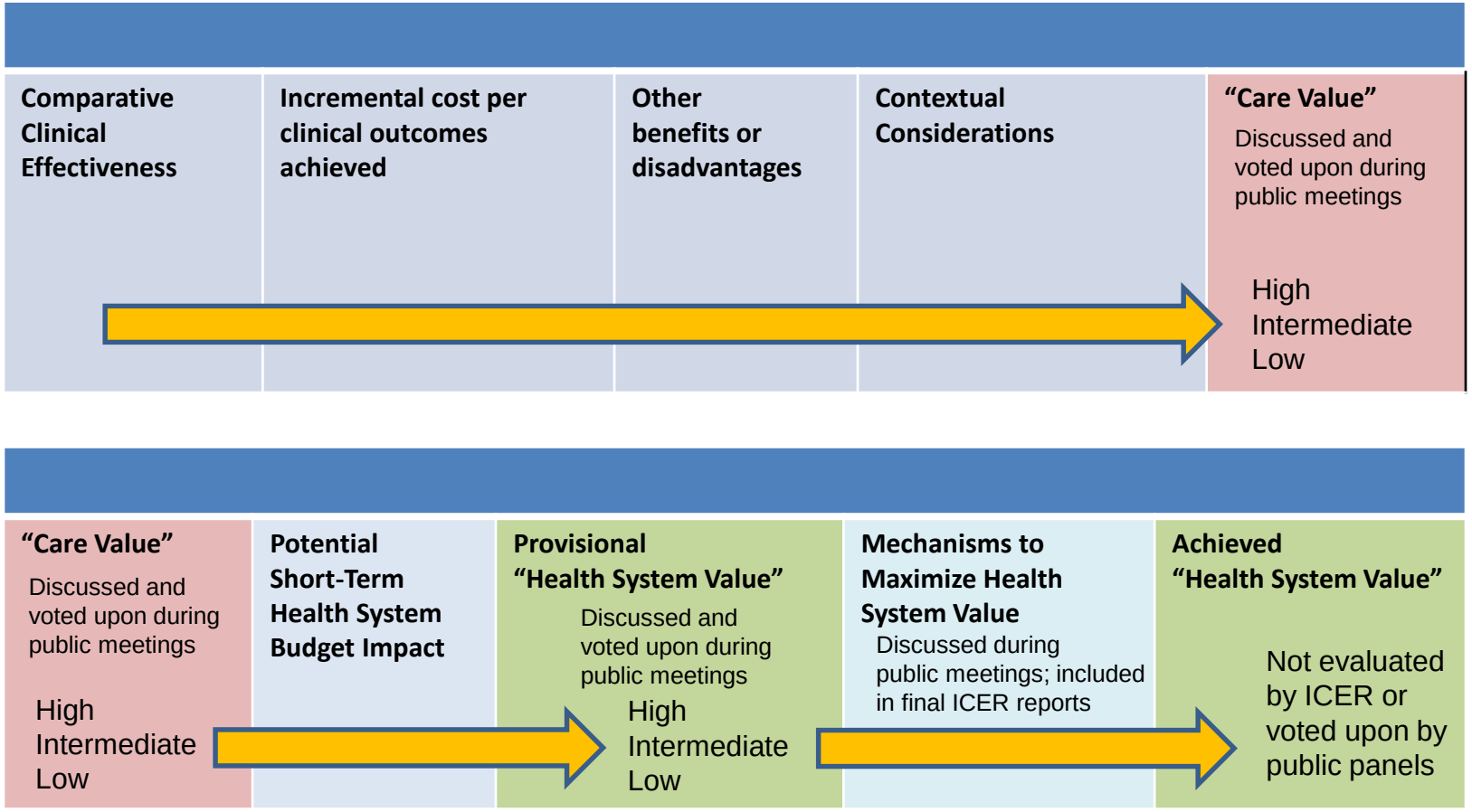
Contextual Considerations

- Contextual considerations include ethical, legal, or other issues that influence the relative priority of illnesses and interventions.

- Specific issue to be considered:
  - 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.

A Value Assessment Flowchart



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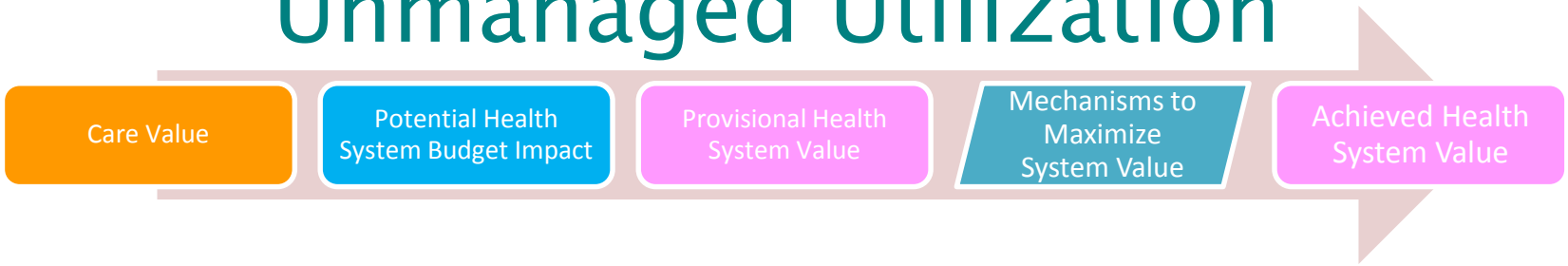
Provisional Health System Value

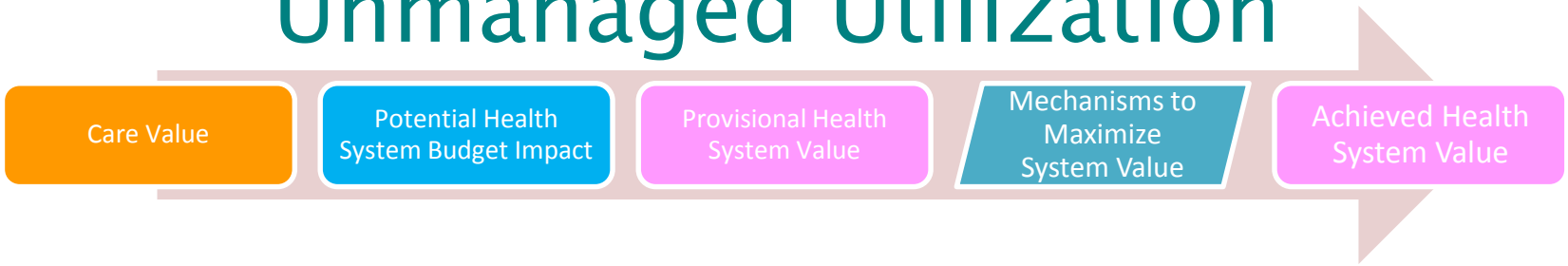
- Provisional Health System Value
  - Provisional health system value represents a judgment integrating consideration of the long-term care value of a new intervention with an analysis of its potential short-term budget impact.
  - If the potential budget impact of a new intervention would contribute to an increase in overall health care costs at a rate greater than growth in the overall national economy, health system value would be diminished.

Potential Budget Impact of Unmanaged Utilization



- Estimated *net* change in *total* health care costs over an initial *5-year time-frame*
- Calculations will be based on broad assumptions regarding the *unmanaged* uptake of new interventions, i.e. without estimating potential payer or provider group actions that might modulate uptake
- New interventions will be assigned to one of 4 uptake patterns – very high, high, intermediate, and low – based on consideration of 6 Rx/condition/market criteria
    - Magnitude of improvement in clinical safety and/or effectiveness
    - Patient-level burden of illness
    - Patient preference (ease of administration)
    - Proportion of eligible patients currently being treated
    - Primary care vs. specialty clinician prescribing/use
    - Presence or emergence of competing treatments of equal or superior effectiveness

Potential Budget Impact of Unmanaged Utilization



- *Unmanaged* cumulative 5-year uptake patterns
  - Very high uptake pattern
    - 75% of eligible patients assumed to use the intervention
  - High uptake pattern
    - 50% of eligible patients assumed to use the intervention
  - Intermediate uptake pattern
    - 25% of eligible patients assumed to use the intervention
  - Low uptake pattern
    - 10% of eligible patients assumed to use the intervention

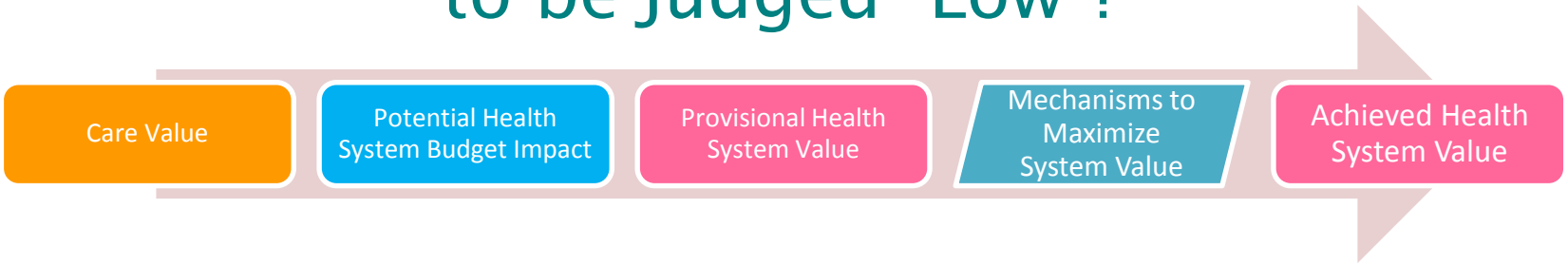
Potential Budget Impact Threshold

- How much potential budget impact is “too much”?
- Theoretical basis of the potential budget impact threshold
  - 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 greater scrutiny and for efforts to maximize health system value

Summary of 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

What if Potential Budget Impact causes Provisional Health System Value to be Judged "Low"?



- Maximizing health system value 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 ICER "Value-Based Price Benchmarks"

- The ICER value-based price benchmark represents the price at which patients in the population being considered could be treated with reasonable long-term value at the individual patient level *and* with added short-term costs that would not outstrip growth in the national economy.

- ICER value-based price benchmark
  - DRAFT VBPB = $100-150K/QALY (care value price range), limited by the $904 million per year budget impact threshold if applicable
  - FINAL VBPB depends on voting of appraisal committees, with the care value price being either $100K/QALY or $150K/QALY

From Value Assessment to "Value-Based Price Benchmarks"

	Price to Achieve $100K/QALY	Price to Achieve $150K/QALY	Max Price at Potential Budget Impact Threshold
PCSK9 Drugs *List price $14,350* *(n=2,636,179)*	*$5,404*	*$7,735*	*$2,177*
	46%-62%		85%

	Price to Achieve $100K/QALY	Price to Achieve $150K/QALY	Max Price at Potential Budget Impact Threshold
Entresto *List price $4,560* *(n=1,949,400)*	*$9,480*	*$14,472*	*$4,168*
	2-3x higher!		9%

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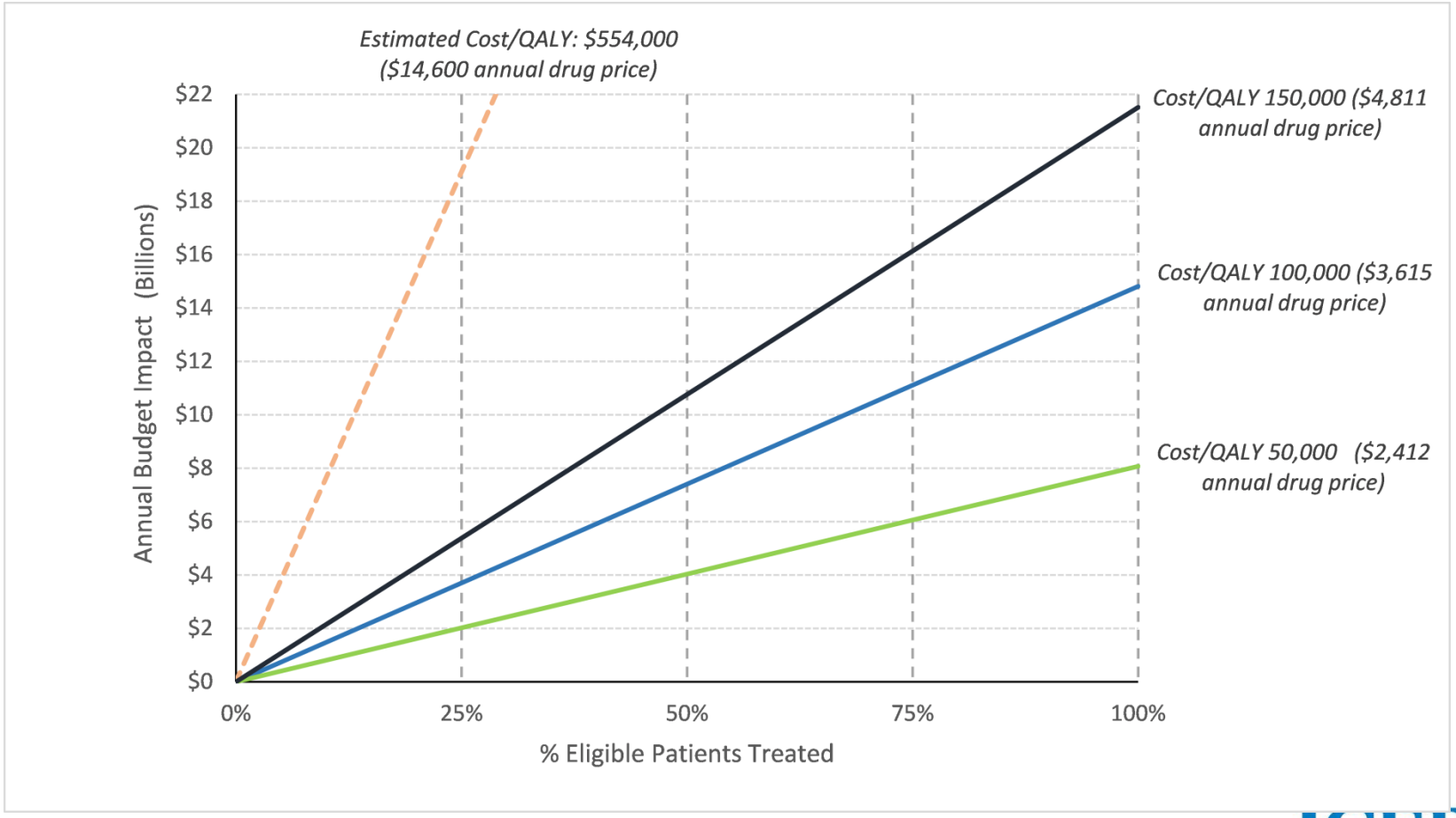
ICER value graph: PCSK9 drugs



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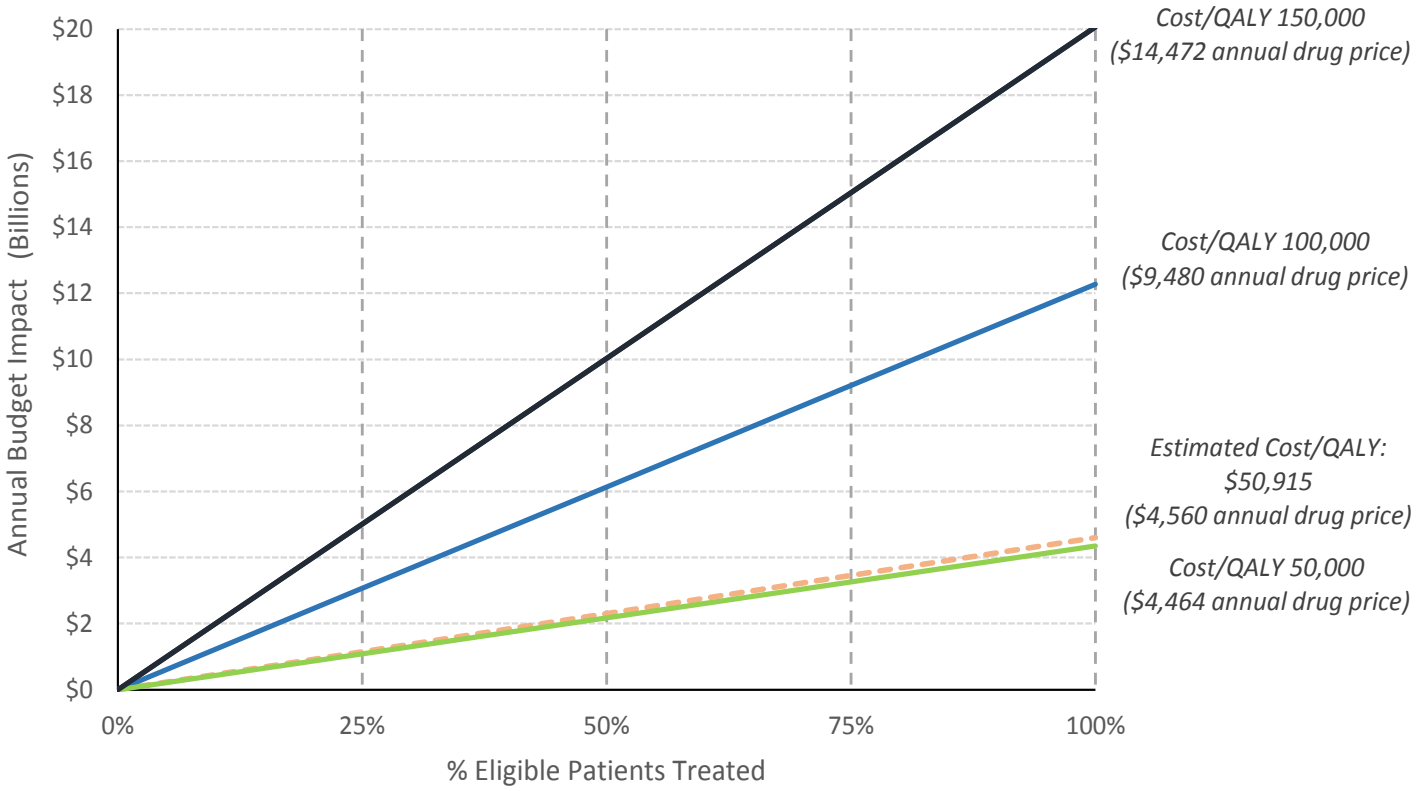
ICER value graph: Entresto



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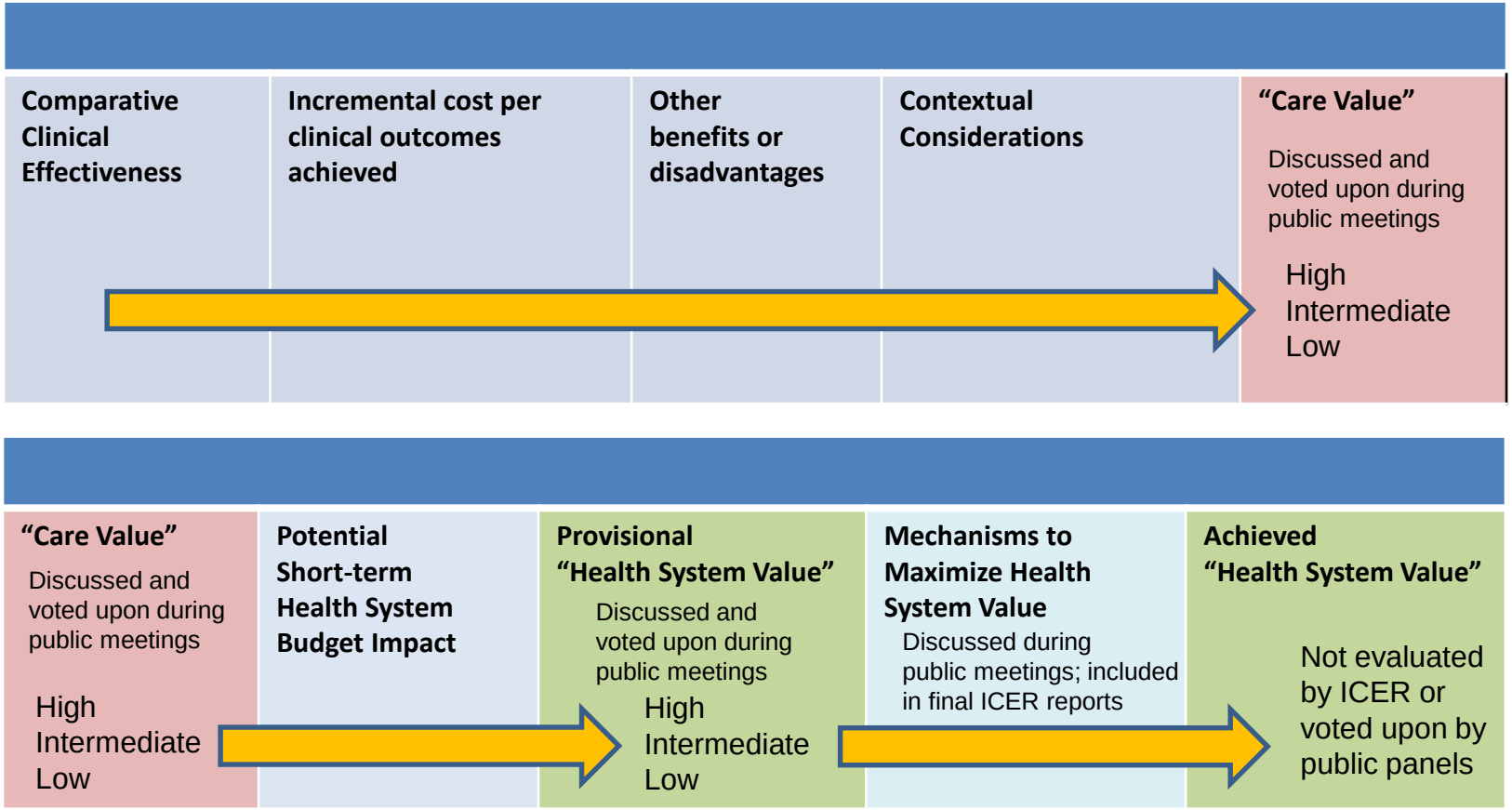
The ICER Value Framework:

Discussion with Robert W. Dubois, MD, PhD
Chief Science Officer and EVP
National Pharmaceutical Council



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Connecting care value and provisional health system value: Drugs

Draft report cost/QALY estimate	Significant benefits or contextual factors	Probable CTAF/CEPAC Care Value votes	Potential Budget Impact	Probable CTAF/CEPAC Provisional Health System Value votes
< $100K/QALY	- sig benefits	High or Intermediate	< $904 million	High or Intermediate
< $100K/QALY	- sig benefits	High or Intermediate	> $904 million	Intermediate or Low
< $100K/QALY	+ sig benefits	High	< $904 million	High
< $100K/QALY	+ sig benefits	High	> $904 million	High, Intermediate or Low
$100-150K/QALY	- sig benefits	Intermediate	< $904 million	Intermediate
$100-150K/QALY	- sig benefits	Intermediate	> $904 million	Low or Intermediate
$100-150K/QALY	+ sig benefits	Intermediate or High	< $904 million	Intermediate or High
$100-150K/QALY	+ sig benefits	Intermediate or High	> $904 million	Low or Intermediate
> $150K/QALY	- sig benefits	Low	< $904 million	Low
> $150K/QALY	- sig benefits	Low	> $904 million	Low
> $150K/QALY	+ sig benefits	Low or Intermediate	< $904 million	Low or Intermediate
> $150K/QALY	+ sig benefits	Low or intermediate	> $904 million	Low