Evaluating the Value of New Drugs and Devices
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 advantage for ICER
  – Public HTA program “laboratories” for the application of a value framework in deliberation and voting
What is the Overall Structure?
A Value Assessment Flowchart

Comparative Clinical Effectiveness

Incremental cost per clinical outcomes achieved

Other benefits or disadvantages

Contextual Considerations

“Care Value”
Discussed and voted upon during public meetings
High Intermediate Low

“Care Value”
Discussed and voted upon during public meetings
High Intermediate Low

Potential Short-Term Health System Budget Impact

Provisional “Health System Value”
Discussed and voted upon during public meetings
High Intermediate Low

Mechanisms to Maximize Health System Value
Discussed during public meetings; included in final ICER reports

Achieved “Health System Value”
Not evaluated by ICER or voted upon by public panels

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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 ICER’s EBM matrix to describe the scientific staff’s judgment of comparative clinical effectiveness.

  - Judgments of the magnitude of net health benefit should consider not just average outcomes but potential significant differences in the pattern of patient response to treatment, e.g. significantly greater numbers of patients with long-term response despite overall equivalent mean response.

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.

- Examples include (but are not limited to)
  - 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) that have demonstrated low rates of response to currently available treatments

- The relative importance of other benefits or disadvantages in an overall determination of care value will be judged not by ICER but by one of its independent public appraisal committees.
• Contextual considerations include ethical, legal, or other issues that influence the relative priority of illnesses and interventions.

• Specific issue to be considered:
  – Is there a particularly high burden/severity of illness?
  – Do other acceptable treatments exist?
  – Are other, equally or 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?

• The relative importance of contextual considerations in an overall determination of care value will be judged not by ICER but by one of its independent public appraisal committees.
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 utilization is unmanaged.
- If the potential budget impact of unmanaged introduction of a new intervention would contribute to an increase in overall health care costs at a trend far greater than growth in the overall national economy, health system value would be threatened.
- Therefore, if the provisional health system value of a new intervention is low, manufacturers, insurers, providers, and policymakers should consider mechanisms to achieve improved health system value through changes to price, payment mechanisms, and/or patient eligibility.
Potential Budget Impact of Unmanaged Utilization

- **Potential Budget Impact:**
  - 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 drugs, i.e. without estimating potential payer or provider group actions that might modulate uptake
  - New drugs will be assigned to one of 4 uptake patterns – very high, high, intermediate, and low – based on consideration of 6 drug/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
    - Presence or emergence of competing treatments of equal or superior effectiveness
Potential Budget Impact of Unmanaged Utilization

- **Unmanaged 5-year drug uptake patterns**
  - Very high uptake pattern
    - Assumption is that 75% of eligible patients take the drug
  - High uptake pattern
    - Assumption is that 50% of eligible patients take the drug
  - Intermediate uptake pattern
    - Assumption is that 25% of eligible patients take the drug
  - Low uptake pattern
    - Assumption is that 10% of eligible patients take the drug
Potential Budget Impact Threshold: Drugs

- **Theoretical basis of the potential budget impact threshold for new drugs**
  - The amount of net cost increase per individual new drug that would contribute to growth in overall health care spending greater than the anticipated growth in national GDP + 1%

- **Calculating the threshold for individual new drugs**
  - World Bank estimates 2015-16 US GDP growth at an average of 2.75%, so GDP + 1% = 3.75%
  - National health care expenditures for 2014 were estimated by CMS at $3,080,100,000,000
  - Contribution of drug spending in 2014 to total national health care costs = 13.3% ($409,653,300,000 out of total NHE)
  - If we assume that the net health care cost impact for existing drugs does not change, and allow only new drugs to account for growth in net health costs related to drugs, then all new drugs combined should not contribute to net health care cost growth more than 3.75% over current drug spending ($409,653,300,000): 3.75% x $409,653,300,000 = $15,361,998,750
  - $15,361,998,750 is therefore the budget impact threshold for NET costs due to new drugs for 2015-16
  - To calculate the budget impact threshold for each *individual* new drug, we divide the total maximum budget impact for all new drugs by the 2-year running average of the number of new drugs approved in the US. For 2013 and 2014 the average number of new drugs approved was (27 + 41) ÷ 2 = 34
  - The average net budget impact threshold for each new drug can then be calculated:
    - Total net budget impact for all drugs of $15,361,998,750 ÷ 34 = $452 million average net budget impact per new drug
  - If $452 million is the average budget impact threshold, then in order to identify those new drugs whose potential budget impact is significantly higher than the average, ICER will set its potential budget impact threshold at 2x the level of the “average” drug: $452 million x 2 = $904 million NET health care cost increase.
  - The 2015-16 ICER threshold for NET budget impact of individual new drugs = $904 million. This figure represents net additional costs to the health care system, including cost offsets of switching from other treatments as well as any potential reductions in hospitalizations or changes in other health care costs.
Potential Budget Impact Threshold: Devices

- **Theoretical basis of the potential budget impact threshold for new drugs**
  - The amount of net cost increase per individual new device that would contribute to growth in overall health care spending greater than the anticipated growth in national GDP + 1%

- **Calculating the potential budget impact threshold for individual new devices**
  - World Bank estimates 2015-16 US GDP growth at an average of 2.75%, so GDP + 1% = 3.75%
  - National health care expenditures for 2014 were estimated at ~$3,080,100,000,000
  - Contribution of device spending in 2014 to total national health care costs ≈ 6.0% ($184,806,000,000 out of total NHE)
  - If we assume that the net health care cost impact for existing devices does not change, and allow only new devices to account for growth in net health costs related to devices, then all new devices combined should not contribute to net health care cost growth more than 3.75% over current device spending ($184,806,000,000): 3.75% × $184,806,000,000 = $6,930,225,000
  - $6,930,225,000 is therefore the budget impact threshold for NET costs due to new devices for 2015-16
  - To calculate the budget impact threshold for an *individual* new device, we divide the total budget impact cap for all new devices by the 2-year running average of the number of new devices approved in the US. For 2013 and 2014 the average number of new devices approved was (21 + 25) ÷ 2 = 23
  - The average net budget impact threshold for each new device can then be calculated:
    - Total net budget impact for all devices of $6,930,225,000 ÷ 23 = $301 million average net budget impact per new device
  - If $301.3 million is the *average* budget impact threshold, then in order to identify those new devices whose potential budget impact is significantly higher than the average, ICER will set its potential budget impact threshold at 2x the level of the “average” device: $301 million × 2 = $602 million NET health care cost increase.
  - The 2015-16 ICER threshold for NET budget impact of individual new devices = $602 million. This figure represents net additional costs to the health care system, including cost offsets of switching from other treatments as well as any potential reductions in hospitalizations or changes in other health care costs.

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## Connecting care value and provisional health system value: Drugs

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What if the Provisional Health System Value is 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 overall short-term costs to the health care system that would not be so large as to be likely to contribute to faster growth in health care spending than growth in the national economy.
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---|---|---|---|---|---
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