The Evolving Role of Independent Drug Value Assessments

By Steven Pearson, M.D., MSc

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

CEPAC
Comparative Effectiveness Public Advisory Council

MIDWEST CEPAC
Comparative Effectiveness Public Advisory Council

NEW ENGLAND CEPAC
Comparative Effectiveness Public Advisory Council
ICER Policy
Funding Sources - %

- Government grants and contracts
- Non-profit foundations
- Contributions from health plans and provider groups
- Manufacturer grants and contributions

Sources of Funding, 2019
Goal: Fair Price, Fair Access, Future Innovation

- Long-Term Value for Money
  - Comparative Clinical Effectiveness
  - Incremental cost-effectiveness
  - Other Benefits or Disadvantages
  - Contextual Considerations

- Short-Term Affordability
  - Potential Budget Impact
ICER’s Value-based Price Benchmarks
Determining value-based price benchmarks

Cost ($)

Effectiveness (QALYs)

Cost-effectiveness Threshold

Even more effective
Higher cost

More effective
Higher cost

Effectiveness (QALYs)
# ICER's Value-based Price Benchmarks (2018)

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

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

*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

<table>
<thead>
<tr>
<th>Annual price to achieve...</th>
<th>$50,000/QALY</th>
<th>$100,000/QALY</th>
<th>$150,000/QALY</th>
<th>$200,000/QALY</th>
<th>$300,000/QALY</th>
<th>$500,000/QALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual cost at WAC</td>
<td>$272,886</td>
<td>$58,790</td>
<td>$83,193</td>
<td>$95,394</td>
<td>$119,797</td>
<td>$168,604</td>
</tr>
</tbody>
</table>

- 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
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

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