Assessment of Barriers to Fair Access:
Findings and Reflections

December 3, 2021
Today’s Speakers

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ICER
ICER: Who Are We?

- Independent, non-profit health technology assessment (HTA) group founded in 2006

- Use evidence in a transparent way to align prices with the benefits for patients and families

- Improve access and affordability while retaining the incentives necessary for future innovation
Background/ Purpose

• Input from members of ICER’s Policy Leadership Forum (life sciences companies, health plans, and PBMs), clinical societies and patient groups led to:

  • 2020 White Paper *Cornerstones of “Fair” Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals* introduced full set of criteria

  • Goal: To serve as a starting point for dialogue and action to achieve fair access.
Methods

- Identified **28 drugs** that were reviewed by ICER between 2015 and 2020 and are within $100-150K/QALY/evLYG cost-effectiveness range

- MMIT Analytics Market Access Database utilized to identify **15 formularies** in the United States with most covered lives and to obtain tiering and prior authorization documentation

- Evaluated specific criteria within **cost sharing, clinical eligibility, step therapy, and provider qualifications**

- **Multi-Stakeholder Working Group** consisting of Patient Advocacy Groups, Clinical Society, Private Payer, Pharmacy Benefit Manager, and Life Sciences Group
## Fair Access Criteria in Scope (abbreviated)

<table>
<thead>
<tr>
<th>Cost Sharing</th>
</tr>
</thead>
<tbody>
<tr>
<td>• At least one drug in every class should be covered at the lowest relevant cost-sharing level.</td>
</tr>
<tr>
<td>• If all drugs in a class are priced so that they represent a fair value, it remains reasonable for payers to use preferential formulary placement with tiered cost sharing to help achieve lower overall costs.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clinical eligibility criteria that complement the FDA label language may be used only in specific ways.</td>
</tr>
<tr>
<td>• Clinical eligibility criteria should not deviate from the FDA label language in a manner than would narrow coverage.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The first-step therapy is clinically appropriate for all or nearly all patients and does not pose a greater risk of any significant side effect or harm.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Provider Qualifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Restrictions of coverage to specialty prescribers are reasonable with only certain justifications.</td>
</tr>
<tr>
<td>• Requiring a non-specialist clinician attest they are caring for the patient in consultation with a relevant specialist is a reasonable option in certain circumstances.</td>
</tr>
</tbody>
</table>
Key Limitations

- Many fair access criteria cannot be assessed from viewing insurance coverage and tiering information alone
  - We assessed 7 out of 20 specific criteria across the four domains

- Between 21%-28% of relevant insurance coverage policies for each domain were not available to us through the database

- Appropriate implementation of coverage could not be assessed

- Tiering is a rough surrogate for cost sharing amount; 4-tier vs. 3-tier formulary issues

- Assessment of step therapy policies evaluates each step on clinical criteria but does not include a threshold for the number of steps that equate with unreasonable burden

- It is possible that the 15 formularies selected provide superior -- or inferior -- coverage than formularies covering fewer individuals offered by the same payers
Final Results
## Concordance by Fair Access Criterion

### Number of Coverage Policies Available and Overall Rate of Concordance with Fair Access Criteria

<table>
<thead>
<tr>
<th>Fair Access Criterion</th>
<th>Drug-formulary combinations with relevant policies available out of maximum possible of 420, n (%)</th>
<th>Concordant Policies, n/N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost sharing</td>
<td>332 (79%)</td>
<td>254/332 (77%)</td>
</tr>
<tr>
<td>Clinical eligibility criteria</td>
<td>302 (72%)</td>
<td>290/302 (96%)</td>
</tr>
<tr>
<td>Step Therapy</td>
<td>317 (75%)</td>
<td>313/317 (99%)</td>
</tr>
<tr>
<td>Prescriber restrictions</td>
<td>311 (74%)</td>
<td>311/311 (100%)</td>
</tr>
</tbody>
</table>
## Concordance by Fair Access Criterion

### Number of Coverage Policies Available and Overall Rate of Concordance with Fair Access Criteria

<table>
<thead>
<tr>
<th>Fair Access Criterion</th>
<th>Concordant, n (%)</th>
<th>Discordant, n (%)</th>
<th>Not Applicable, n (%)</th>
<th>No Policy Available, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost sharing</td>
<td>254 (60%)</td>
<td>78 (19%)</td>
<td>79 (19%)</td>
<td>9 (2%)</td>
</tr>
<tr>
<td>Clinical eligibility criteria</td>
<td>290 (69%)</td>
<td>12 (3%)</td>
<td>19 (5%)</td>
<td>99 (24%)</td>
</tr>
<tr>
<td>Step Therapy</td>
<td>313 (75%)</td>
<td>4 (1%)</td>
<td>20 (5%)</td>
<td>83 (20%)</td>
</tr>
<tr>
<td>Prescriber restrictions</td>
<td>311 (74%)</td>
<td>0 (0%)</td>
<td>19 (5%)</td>
<td>90 (21%)</td>
</tr>
</tbody>
</table>
## Concordance by drug

<table>
<thead>
<tr>
<th>Drug (Indication)</th>
<th>Cost Sharing</th>
<th>Clinical Eligibility</th>
<th>Step Therapy</th>
<th>Prescriber Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dupilumab (Atopic Dermatitis)</td>
<td>9/15 (60%)</td>
<td>14/14 (100%)</td>
<td>13/15 (87%)</td>
<td>15/15 (100%)</td>
</tr>
<tr>
<td>Emicizumab (Hemophilia A)</td>
<td>7/13 (54%)</td>
<td>8/11 (73%)</td>
<td>9/11 (82%)</td>
<td>11/11 (100%)</td>
</tr>
<tr>
<td>Plasma-Derived C1-INH (Hereditary Angioedema)</td>
<td>8/15 (53%)</td>
<td>10/10 (100%)</td>
<td>10/10 (100%)</td>
<td>10/10 (100%)</td>
</tr>
<tr>
<td>Rimegepant (Acute Migraine)</td>
<td>9/15 (60%)</td>
<td>8/8 (100%)</td>
<td>10/10 (100%)</td>
<td>10/10 (100%)</td>
</tr>
<tr>
<td>Afatinib (NSCLC)</td>
<td>12/15 (80%)</td>
<td>11/11 (100%)</td>
<td>11/11 (100%)</td>
<td>11/11 (100%)</td>
</tr>
</tbody>
</table>
Concordance by drug

• Hypothesis: concordance with tiering/cost sharing criterion will be lower for “fairly priced” drugs that have higher net prices

• Median annual net price for the 28 drugs = $27,000

• Cost sharing concordance:
  • Below median annual net price: 81%
  • Above median annual net price: 72%
## Step Therapy

<table>
<thead>
<tr>
<th>Drug (Generic)</th>
<th>Most Common # of Steps</th>
<th>Range</th>
<th>Formularies with Highest Number of Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apremilast</td>
<td>1</td>
<td>0-2</td>
<td>Blue Shield of CA</td>
</tr>
<tr>
<td>Axicabtagene ciloleucel</td>
<td>2</td>
<td>0-2</td>
<td>CVS, UnitedHealthcare, Anthem, Blue Shield of CA, HCSC, Florida Blue, BCBS MN</td>
</tr>
<tr>
<td>Brodalumab</td>
<td>3</td>
<td>1-10</td>
<td>Elixir</td>
</tr>
<tr>
<td>Dupilumab</td>
<td>2</td>
<td>1-4</td>
<td>Kaiser</td>
</tr>
<tr>
<td>Fremanezumab</td>
<td>3</td>
<td>0-3</td>
<td>Blue Shield of CA</td>
</tr>
<tr>
<td>Guselkumab</td>
<td>1</td>
<td>0-6</td>
<td>Elixir</td>
</tr>
<tr>
<td>Infliximab</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plaque Psoriasis</td>
<td>1</td>
<td>0-3</td>
<td>BCBS MA, Elixir</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>1</td>
<td>0-3</td>
<td>BCBS MA</td>
</tr>
<tr>
<td>Ixekizumab</td>
<td>1</td>
<td>0-10</td>
<td>Elixir</td>
</tr>
<tr>
<td>Olaparib</td>
<td>2</td>
<td>0-3</td>
<td>Anthem, BCBS MA, Blue Shield of CA, Florida Blue, Highmark</td>
</tr>
<tr>
<td>Rivaroxaban</td>
<td>0</td>
<td>0</td>
<td>All identical</td>
</tr>
<tr>
<td>Sacubitril/valsartan</td>
<td>0</td>
<td>0-1</td>
<td>Express Scripts, UnitedHealthcare</td>
</tr>
<tr>
<td>Tisagenlecleucel</td>
<td>2</td>
<td>0-4</td>
<td>HCSC, Florida Blue, Highmark</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>1</td>
<td>0-2</td>
<td>UnitedHealthcare and Blue Shield of CA</td>
</tr>
</tbody>
</table>
## Concordance by Formulary

<table>
<thead>
<tr>
<th>Cost Sharing</th>
<th>Clinical Eligibility</th>
<th>Step Therapy</th>
<th>Prescriber Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Three Tier Formularies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CVS Health/Aetna</td>
<td>20/21 (95%)</td>
<td>22/22 (100%)</td>
<td>22/22 (100%)</td>
</tr>
<tr>
<td>Express Scripts PBM</td>
<td>26/28 (93%)</td>
<td>15/15 (100%)</td>
<td>16/16 (100%)</td>
</tr>
<tr>
<td>UnitedHealthcare</td>
<td>18/22 (82%)</td>
<td>21/22 (95%)</td>
<td>21/22 (95%)</td>
</tr>
<tr>
<td>CIGNA Health Plan</td>
<td>19/22 (86%)</td>
<td>19/20 (95%)</td>
<td>20/20 (100%)</td>
</tr>
<tr>
<td>BCBS of Massachusetts</td>
<td>19/21 (90%)</td>
<td>18/19 (95%)</td>
<td>20/20 (100%)</td>
</tr>
<tr>
<td>Florida Blue</td>
<td>19/22 (86%)</td>
<td>25/26 (96%)</td>
<td>26/27 (96%)</td>
</tr>
<tr>
<td>Highmark</td>
<td>17/21 (81%)</td>
<td>24/26 (92%)</td>
<td>26/26 (100%)</td>
</tr>
<tr>
<td>MC-RX PBM</td>
<td>18/20 (90%)</td>
<td>4/4 (100%)</td>
<td>8/9 (89%)</td>
</tr>
<tr>
<td>MedImpact</td>
<td>21/23 (91%)</td>
<td>6/6 (100%)</td>
<td>11/11 (100%)</td>
</tr>
<tr>
<td>BCBS of Minnesota</td>
<td>19/22 (86%)</td>
<td>21/22 (95%)</td>
<td>23/23 (100%)</td>
</tr>
<tr>
<td><strong>Four-Tier Formularies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anthem</td>
<td>5/22 (23%)</td>
<td>23/27 (85%)</td>
<td>27/27 (100%)</td>
</tr>
<tr>
<td>Elixir PBM</td>
<td>9/25 (36%)</td>
<td>12/12 (100%)</td>
<td>15/15 (100%)</td>
</tr>
<tr>
<td>BS of California</td>
<td>6/21 (29%)</td>
<td>28/28 (100%)</td>
<td>28/28 (100%)</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health Care Service Corp</td>
<td>18/22 (82%)</td>
<td>25/26 (96%)</td>
<td>26/26 (100%)</td>
</tr>
<tr>
<td>Kaiser</td>
<td>20/20 (100%)</td>
<td>27/27 (100%)</td>
<td>24/25 (96%)</td>
</tr>
</tbody>
</table>
Six payers changed policies and/or tiering in ways that brought their coverage into concordance with fair access criteria:

1. Removed prior authorization entirely for sacubitril/valsartan
2. Added rimegepant to its formulary in a preferred brand position
3. Added ubrogepant to its formulary in a preferred brand position
4. Updated step therapy criteria for alirocumab to no longer require additional trials of statins for patients who are stable on a high-potency statin in combination with ezetimibe
5. Updated clinical eligibility criteria for brodalumab and other non-preferred drugs to broaden coverage to “moderate-to-severe” plaque psoriasis (previously only “severe” plaque psoriasis)
6. Moved elagolix from specialty tier to Tier 2 (Preferred Brand)
7. Moved dupilumab from Tier 3 (Non-Preferred Brand) to Tier 2 (Preferred Brand)
8. Moved ubrogepant from Tier 3 (Non-Preferred Brand) to Tier 2 (Preferred Brand)
9. Moved rimegepant from Tier 3 (Non-Preferred Brand) to Tier 2 (Preferred Brand)
10. Removed criteria that differentiates between symptomatic infantile onset and later onset SMA
Summary/ Conclusion
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• A comprehensive assessment was not possible given limitations to the available data and therefore this report represents an exploratory analysis intended to chart a roadmap for future research.

• In our assessment of fairly priced drugs, we found that most of the payer policies available to us were structured appropriately in a way to support many key elements of fair access; six payers changed tiering or coverage policies following sharing of draft results in ways that met fair access criteria.

• Perhaps the most salient conclusion that can be drawn at this time is that there should be greater transparency regarding how insurers frame and implement their coverage policies.
Barriers to Fair Access

Final Report

https://icer.org/policy-papers/fair-access-2021/#timeline