

Assessment of Barriers to Fair Access: Findings and Reflections

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Today's Speakers



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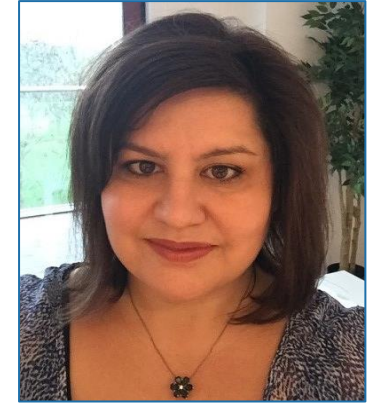
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ICER: Who Are We?

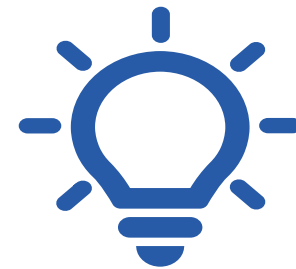
- Independent, non-profit **health technology assessment (HTA) group** founded in 2006
- Use **evidence** in a **transparent** way to **align prices with the benefits** for patients and families
- **Improve access and affordability** while retaining the incentives necessary for future innovation



Fair Price



Fair Access



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)

Cost Sharing

- At least one drug in every class should be covered at the lowest relevant cost-sharing level.
- 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.

Clinical Eligibility

- Clinical eligibility criteria that complement the FDA label language may be used only in specific ways.
- Clinical eligibility criteria should not deviate from the FDA label language in a manner that would narrow coverage.

Step Therapy

- 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.

Provider Qualifications

- Restrictions of coverage to specialty prescribers are reasonable with only certain justifications.
- 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.

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

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

Concordance by Fair Access Criterion

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

Fair Access Criterion	Concordant, n (%)	Discordant, n (%)	Not Applicable, n (%)	No Policy Available, n (%)
Cost sharing	254 (60%)	78 (19%)	79 (19%)	9 (2%)
Clinical eligibility criteria	290 (69%)	12 (3%)	19 (5%)	99 (24%)
Step Therapy	313 (75%)	4 (1%)	20 (5%)	83 (20%)
Prescriber restrictions	311 (74%)	0 (0%)	19 (5%)	90 (21%)

Concordance by drug

	Cost Sharing	Clinical Eligibility	Step Therapy	Prescriber Restrictions
Drug (Indication)	<i>Concordant Policies, n/N (%)</i>	<i>Concordant Policies, n/N (%)</i>	<i>Concordant Policies, n/N (%)</i>	<i>Concordant Policies, n/N (%)</i>
Dupilumab (Atopic Dermatitis)	9/15 (60%)	14/14 (100%)	13/15 (87%)	15/15 (100%)
Emicizumab (Hemophilia A)	7/13 (54%)	8/11 (73%)	9/11 (82%)	11/11 (100%)
Plasma-Derived C1-INH (Hereditary Angioedema)	8/15 (53%)	10/10 (100%)	10/10 (100%)	10/10 (100%)
Rimegepant (Acute Migraine)	9/15 (60%)	8/8 (100%)	10/10 (100%)	10/10 (100%)
Afatinib (NSCLC)	12/15 (80%)	11/11 (100%)	11/11 (100%)	11/11 (100%)

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

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

Concordance by formulary

	Cost Sharing	Clinical Eligibility	Step Therapy	Prescriber Restrictions
Three Tier Formularies				
CVS Health/Aetna	20/21 (95%)	22/22 (100%)	22/22 (100%)	22/22 (100%)
Express Scripts PBM	26/28 (93%)	15/15 (100%)	16/16 (100%)	16/16 (100%)
UnitedHealthcare	18/22 (82%)	21/22 (95%)	21/22 (95%)	22/22 (100%)
CIGNA Health Plan	19/22 (86%)	19/20 (95%)	20/20 (100%)	20/20 (100%)
BCBS of Massachusetts	19/21 (90%)	18/19 (95%)	20/20 (100%)	20/20 (100%)
Florida Blue	19/22 (86%)	25/26 (96%)	26/27 (96%)	26/26 (100%)
Highmark	17/21 (81%)	24/26 (92%)	26/26 (100%)	26/26 (100%)
MC-RX PBM	18/20 (90%)	4/4 (100%)	8/9 (89%)	5/5 (100%)
MedImpact	21/23 (91%)	6/6 (100%)	11/11 (100%)	10/10 (100%)
BCBS of Minnesota	19/22 (86%)	21/22 (95%)	23/23 (100%)	22/22 (100%)
Four-Tier Formularies				
Anthem	5/22 (23%)	23/27 (85%)	27/27 (100%)	27/27 (100%)
Elixir PBM	9/25 (36%)	12/12 (100%)	15/15 (100%)	15/15 (100%)
BS of California	6/21 (29%)	28/28 (100%)	28/28 (100%)	28/28 (100%)
Other				
Health Care Service Corp	18/22 (82%)	25/26 (96%)	26/26 (100%)	26/26 (100%)
Kaiser	20/20 (100%)	27/27 (100%)	24/25 (96%)	26/26 (100%)

Changes to Formularies After June 30, 2021

- 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>