
Assessment of Barriers to Fair Access: Evaluating Coverage Policies in 2023

Findings and Reflections

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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

Acknowledgements

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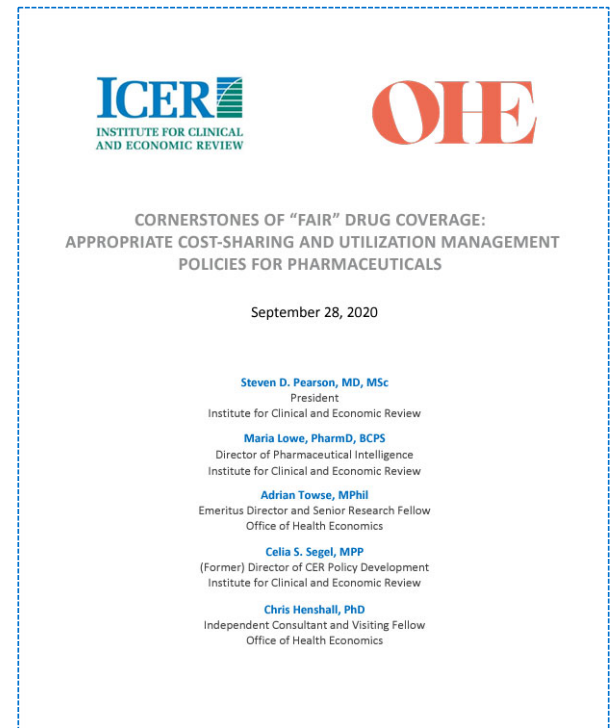
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- Serina Herron-Smith, BA, Former Associate Research Manager
- Steven D. Pearson, MD, MSC, President

- *Barriers to Fair Access Working Group Members**
- *Patient Groups**

- *MMIT Analytics Market Access Database*

Background

- 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

How we did our analysis (1/2)

- Using MMIT Analytics Market Access Database, ICER selected **19 formularies** including
 - The largest and smallest formularies by numbers of covered lives offered by the **5 largest commercial payers in the US**,
 - The single formulary of the **Veteran's Health Administration**,
 - The largest and smallest **state health exchange plan formularies** offered in the **four geographic regions** of the US (Northeast, Midwest, South, West)
- All payers were contacted to obtain tiering and prior authorization documentation. If needed, details were supplemented with information from MMIT Analytics Market Access Database.
- Focus was **18 drugs** across the **8 therapeutic areas** reviewed by ICER in 2021

How we did our analysis (2/2)

- Evaluated specific criteria within **cost sharing, clinical eligibility, step therapy, and provider restrictions**
- Requested **stories and information from leading patient advocates** from the eight therapeutic areas
- **Exploratory analysis on transparency** of each formulary regarding availability of information on cost-sharing, tiering structure, clinical eligibility, copay adjustment programs, and continuation of coverage policies from the perspective of individuals shopping for health insurance.

Results

Concordance by Fair Access Criterion

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

Fair Access Criterion	Drug-Formulary Combinations with Relevant Policies Available* out of Applicable Policies, n/N (%)	Concordant Policies, n/N (%)
Cost sharing	37/38 (97%)	23/37 (62%)
Clinical eligibility	260/266 (98%)	257/260 (99%)
Step therapy	264/266 (99%)	261/264 (99%)
Prescriber restrictions	262/267 (98%)	262/262 (100%)

*No policies were provided by Quartz Health Solutions for the Quartz Health Solutions Standard Choice Four Tier. We were able to locate partial information on Quartz's policies for 5 drugs through MMIT.

Step Therapy

Number of Steps Required for Prior Authorization by Drug

Drug Brand Name (Formulary type)	Most Common # of Steps	Range	Formularies with Non-Concordant Number of Steps (≥ 4 Steps)
Soliris (Medical)	3	0-4	Cambia BridgeSpan Metallic Formulary HIX, Horizon BlueCross BlueShield of NJ HIX
Vyvgart (Medical)	2	0-4	Cambia BridgeSpan Metallic Formulary HIX

- All other drugs required 3 or fewer steps.

Concordance by Drug

Drug (Indication)	Predominant Benefit Plan Type (Number of formularies with predominant plan type/number of all formularies)	Cost Sharing Concordant Policies, n/N* (%)	Clinical Eligibility Concordant Policies, n/N* (%)	Step Therapy Concordant Policies, n/N* (%)	Prescriber Restrictions Concordant Policies, n/N* (%)
Adbry (Atopic Dermatitis)	Pharmacy (19/19)	N/A	13/16 (81)	16/16 (100)	16/16 (100)
Benlysta (Lupus Nephritis)	Pharmacy (19/19)	9/19 (47)	17/17 (100)	17/17 (100)	17/17 (100)
Nexlizet (High Cholesterol)	Pharmacy (19/19)	14/18 (78)	13/13 (100)	13/13 (100)	13/13 (100)
Soliris (Myasthenia Gravis)	Medical (13/19)	N/A	18/18 (100)	16/18 (89)	18/18 (100)
Vyvgart (Myasthenia Gravis)	Medical (15/19)	N/A	16/16 (100)	15/16 (94)	16/16 (100)

All other drugs had high concordance ratings

Concordance by Formulary

- No significant variation by formulary size (number of covered lives)
- No significant variation by geographic region (Northeast, Midwest, South, West)
- Most variation was for cost-sharing, but small denominator (N=2)

Concordance by Condition

Rate of Concordance by Condition

	Cost Sharing	Clinical Eligibility	Step Therapy	Prescriber Restrictions
Condition	Concordant Policies, n/N* (%)	Concordant Policies, n/N* (%)	Concordant Policies, n/N* (%)	Concordant Policies, n/N* (%)
Atopic Dermatitis	N/A	56/58 (95)	59/59 (100)	59/59 (100)
Lupus Nephritis	9/19 (47)	29/29 (100)	29/29 (100)	29/29 (100)
High Cholesterol	14/18 (78)	41/41 (100)	41/41 (100)	41/41 (100)
Hereditary Angioedema	N/A	43/43 (100)	46/46 (100)	43/43 (100)
Multiple Myeloma	N/A	26/26 (100)	27/27 (100)	27/27 (100)
Myasthenia Gravis	N/A	34/34 (100)	31/34 (91)	34/34 (100)
Hypertrophic Cardiomyopathy	N/A	14/14 (100)	14/14 (100)	15/15 (100)
Asthma	N/A	14/14 (100)	14/14 (100)	14/14 (100)

N/A: not applicable

*The total N for each fair access criteria represents whether the specific criterion is applicable for the drug and formulary combination within each condition.

Transparency

- Exploratory analysis focused on **three drugs**: Nexletol, Rinvoq, and Vyvgart across **14 formularies** (PBMs were excluded).
- Simulated experience of individuals shopping for health plans

Summary of Results for Exploratory Transparency Analyses

	Transparency of Cost-Sharing and Tier Information	Transparency of Copay Adjustment Programs	Transparency of Clinical Criteria	Transparency of Continuation of Coverage
Nexletol	10/10 (100%)	8/14 (57%)	7/10 (70%)	5/14 (36%)
Rinvoq	13/13 (100%)	8/14 (57%)	12/13 (92%)	9/14 (64%)
Vyvgart	3/3 (100%)	8/14 (57%)	13/14 (93%)	9/14 (64%)

Changes to Payer Policies After June 1, 2023

- **One** payer changed a policy in a way that brought their coverage into concordance with fair access criteria

Formulary	Drug	Policy Change	Concordance with Policy Change Included
Cigna National Preferred	Adbry	Effective October 1, 2023, the Cigna National Preferred formulary no longer defines moderate to severe atopic dermatitis as having an affected body surface area of $\geq 10\%$, regardless of involvement of crucial body areas.	Clinical Criteria 18/18 (100%)

Key Limitations

- Many fair access criteria cannot be assessed from viewing insurance coverage and tiering information alone
- Implementation of policies could not be assessed
- Tiering is an imperfect surrogate for cost sharing experienced by patients
- Average net prices across all payers used in cost-sharing analysis, will not represent one particular payer's price
- It is likely that the formularies selected are not completely representative of the entire US payer landscape

Summary

Conclusion

- Among criteria able to be assessed, most payers are abiding by fair access criteria, with the notable exception of cost-sharing
- Continuing to improve transparency of policies benefits current and prospective members.
 - Greater transparency related to clinical coverage criteria, copay adjustment programs, and continuation of coverage policies would be especially helpful.
- Work beginning now for the 2024 report that will cover drugs reviewed in 2022, such as those for Type 2 Diabetes, Obesity, and Hemophilia A & B.

Questions from the Audience

Barriers to Fair Access

Final Report

<https://icer.org/policy-papers/fair-access-coverage-policies-in-2023/#timeline>

CALL FOR FEEDBACK

*We want to hear your suggestions for expanding ICER's
fair access work*

Email ideas to info@icer.org