Barriers to Fair Access Assessment

Final Protocol

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Institute for Clinical and Economic Review

Table of Contents

Table of Contents i
1. Executive Summary 1
2. Background 3
2.1 Background 3
2.2 Objectives 3
2.3 Timeline 3
3. Role of the Working Group 4
4. List of Included Drugs 5
4.1 Determining Whether Drugs Are Fairly Priced 5
4.2 Drugs in Scope 7
5. List of Payers and Identification of Relevant Coverage Policies 8
6. Determination of Concordance of Coverage Policies with Fair Access Criteria 10
6.1. Scope of Fair Access Criteria 10
6.2 Criteria for the Exploratory Transparency Analyses 13
7. Analytic Plan 16
7.1 Process for Comparing Coverage Policies to Fair Access Criteria 16
8. Payer and Patient Organization Review Prior to Public Release 18

1. Executive Summary

The national debate about drug pricing has focused great attention on methods to determine whether the price of a drug is "fair" or "reasonable." A question far less examined is how to determine whether insurance coverage is providing fair access to that drug. It appears widely agreed that cost sharing and drug coverage criteria serve everyone's interest when they steer patients toward evidence-based use of treatments that achieve equal or better outcomes at lower costs. But this level of conceptual agreement does little to help advance thinking on how to assess and judge specific cost-sharing provisions and prior authorization protocols. Is it fair to have patients pay at the highest cost-sharing level when there is only a single drug available in a drug class? What are the circumstances in which step therapy is a reasonable approach to limiting coverage? When is it appropriate for the clinical criteria required for coverage to be narrower than the Food and Drug Administration (FDA) labeled indication? And for all of these questions, how should the pricing of a drug factor into whether certain strategies to limit or steer patient access are appropriate?

To answer these questions, ICER worked with stakeholders and the member organizations of the ICER Policy Leadership Forum to develop a set of appropriateness criteria for cost-sharing and for prior authorization protocols for pharmaceutical coverage. These criteria are described in the white paper *Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals,* published on September 28, 2020. The appropriateness criteria are based on analysis of prior policy and ethical research, with active deliberation and revision following a December 2019 ICER Policy Summit with representatives from patient groups, clinical specialty societies, private payers, and the life science industry.

Applying these criteria to judge the coverage policies of leading payers, ICER performed the first Barriers to Fair Access Assessment in 2021. In the 2022 report, we modified our methods to include a threshold of a maximum of 3 steps for the step therapy and included two exploratory analyses on transparency and prior authorization burden. Based on the experience with the first two reports, and with ongoing input from our multi-stakeholder Working Group, we have modified our methods for the 2023 report.

This year, we will review the following formularies:

- For the five largest US commercial payers, the largest and smallest formularies by covered lives that are not associated with a specific employer;
- For state health exchange plans, the largest and smallest formularies by covered lives in each of the four geographic regions of the US;
- The single formulary offered by the Veteran's Health Administration (VHA).

In addition, we will also conduct two new exploratory transparency analyses on 1) so-called "grandfathering" policies that provide continuous coverage of therapies for patients who switch health plans and 2) copay adjustment programs. We will continue to evaluate coverage policies for

drugs reviewed by ICER two years ago and plan to continue this approach, in a rolling fashion, in future reports. A more detailed explanation of these methods is provided in the body of this research protocol.

In the main, however, the goals and basic approach of the report remain consistent with the 2021 report. We will continue to leverage the MMIT Analytics Market Access Database for formulary information on a set of the largest commercial payers in the United States, expanded for the 2023 report to include the largest and smallest formularies of the 5 largest payers/PBMs, the VHA and the largest and smallest state ACA exchange health plans for the four geographic regions of the United States as defined by the U.S. Census. For each of the drugs reviewed by ICER in 2021 we will perform analyses of the proportion of selected fair access criteria that are met in these formularies, analyzed across drugs, conditions, and payers.

As noted earlier, to help provide important guidance on this assessment, the Barriers to Fair Access Assessment will continue to benefit from ongoing input from a multi-stakeholder Working Group consisting of representatives from leading patient advocacy groups, clinical societies, private payers/ pharmacy benefit managers, and the life sciences industry. The Working Group will advise ICER on the application of the fair access criteria to coverage policies, provide insight into the patient experience with prescription drug coverage and access, and advise on important nuances in the interpretation of payer coverage policies. Work on this project will begin during April 2023 and the 2023 Barriers to Fair Access Assessment report is scheduled for release in October 2023.

2. Background

2.1 Background

The design and implementation criteria for fair access are taken from the September 28, 2020 white paper, *Cornerstones of "Fair" Drug Coverage: Appropriate Cost-Sharing and Utilization Management Policies for Pharmaceuticals*. These criteria represent requirements that must be met in order for the prior authorization protocol to be appropriate, or, in other words, to ensure fair access. The criteria are based on analysis of prior policy and ethical research, and have undergone active deliberation and revision following a December 2019 ICER Policy Summit with representatives from patient groups, clinical specialty societies, private payers, and the life science industry.

2.2 Objectives

The 2023 ICER Barriers to Fair Access Assessment will assess the concordance of drug coverage policies with fair access criteria for ICER-reviewed drugs in 2021. We will review and abstract data from the coverage policies of the largest and smallest formularies by number of covered lives, not associated with a specific employer, of the five largest commercial payers in the US. We will also review the formulary of the VHA and the largest and smallest state health exchange plan formularies in each geographic region of the US (Northeast, Midwest, South, West) as identified in the MMIT Analytics Market Access Database. In addition to core analyses of concordance with fair access criteria for cost sharing and the content of prior authorization policies, the 2023 report will also include exploratory analyses on a select set of drugs and formularies on criteria related to the transparency of cost sharing, clinical eligibility criteria, continuation of therapy, and the use of accumulators prior to plan enrollment.

2.3 Timeline

Please see the figure below for an overview of the timeframe for the 2023 Barriers to Fair Access Assessment to be released later this year.

Timeline 2023	
Research Protocol Posted	April
Draft Report Review Period for Payers and PBMs	August – September
Draft Report Review Period for Working Group Members	August – September
Final Report Posted	November
Public Webinar	November

Payers who are part of this assessment will receive updates with specific dates within the timeline as part of the process.

3. Role of the Working Group

To help provide important guidance on this project, the Barriers to Fair Access Assessment benefits from ongoing input from a multi-stakeholder Working Group consisting of representatives from leading patient advocacy groups, clinical societies, private payers/ pharmacy benefit managers, and the life sciences industry. The Working Group advises ICER on the application of the fair access criteria to coverage policies; provides insight into the patient experience with prescription drug coverage and access, including real-world examples; and advises on important nuances in the interpretation of payer coverage policies. The Working Group members are:

- **Cat Davis Ahmed,** MBA, Vice President of Policy and Outreach, Familial Hypercholesterolemia Foundation
- **Alan Balch,** PhD, Chief Executive Officer, Patient Advocate Foundation
- **Patrick Gleason,** PharmD, Assistant Vice President of Health Outcomes, Prime Therapeutics
- **Leah Howard**, JD, Chief Operating Officer, National Psoriasis Foundation
- **Cliff Hudis,** MD, FACP, FASCO, Chief Executive Officer, American Society of Clinical Oncology
- **Anna Hyde,** Vice President of Advocacy and Access, Arthritis Foundation
- **Rebecca Kirch**, JD, Executive Vice President, National Patient Advocate Foundation
- **Robert Nordyke,** PhD, Vice President of Research, National Pharmaceutical Council (NPC)
- **Carl Schmid,** Executive Director, HIV+Hepatitis Policy Institute
- **M. Kay Scanlan,** JD, Sr. Policy Advisor, Haystack Project
- **Bari Talente,** Executive Vice President, Advocacy, National Multiple Sclerosis Society
- **Sean Fahey,** MD, Board of Directors, American College of Rheumatology

4. List of Included Drugs

Drugs eligible for consideration are those reviewed by ICER in 2021 and that are currently FDA approved for an indication consistent with the ICER review (Table 4.1.). Several drugs reviewed by ICER in 2021 were not approved by the FDA (roxadustat [AstraZeneca and FibroGen, Inc.] for anemia in chronic kidney disease) or were withdrawn from the market (belantamab mafodotin [Blenrep™, GlaxoSmithKline] for multiple myeloma) and will not be included in this assessment. In addition, ICER has elected not to include aducanumab (Aduhelm™, Biogen) for the treatment of Alzheimer's in the assessment, as many payers have excluded it from coverage.[1]

4.1 Determining Whether Drugs Are Fairly Priced

Whether the price for a drug is considered "fair" or "not fair" will be determined according to whether the most recent net price of a drug falls at or below ICER's cost-effective price calculated in the relevant 2021 report at the $150,000 per evLY or QALY threshold (whichever produces a higher price). Net drug prices will be obtained from SSR Health, LLC, the health care division of SSR, LLC, an independent investment research firm. To derive a net price, SSR Health combines data on unit sales with publicly disclosed US sales figures. Discounts, rebates, concessions to wholesalers and distributors, and patient assistance programs are subtracted from gross sales to derive a net price.

To estimate the most recent average net price in the US market, we will average net price data across the four most recently available quarters for which SSR data is available (January 1, 2022-December 31, 2022), to account for seasonal or other sources of annual price fluctuations. To confirm the validity of the SSR net prices, we will compare them to the Wholesale Acquisition Cost (WAC) and the Federal Supply Schedule Service (FSS). In cases where we deem the SSR net prices to be unreliable (such as the net prices being higher than the WAC), or where SSR prices are not available, we will use price estimates from FSS. If no data are available in either SSR or FSS, we will use list prices reported in Redbook. For physician administered drugs we will use the ASP price plus 6%, if available.

SSR reports net prices on a per unit basis. We will convert the unit prices as listed in SSR to annual prices using the dosing assumptions used in the economic evaluation of our reports. For drugs with loading doses or dose-escalation regimens, we will use the maintenance dose to calculate annual costs (i.e., second year costs) for consistency. Drugs that require weight-based dosing will use the same weight assumptions as described in the economic evaluation section of our reports. The

[1] Adams K. https://www.beckershospitalreview.com/pharmacy/insurers-won-t-pay-for-aduhelm-until-they-know-it-works.html. https://www.beckershospitalreview.com/pharmacy/insurers-won-t-pay-for-aduhelm-until-they-know-it-works.html. Published 2021. Accessed March 30, 2023.

remainder of partially used vials will be counted as medical waste. Pricing calculations and assumptions will be independently validated by another member of the research team and discrepancies will be resolved via a consensus process.

4.2 Drugs in Scope

The drugs to be included in the 2023 report are those shown below in Table 4.1.

Table 4.1. Drug List

Generic Drug Name	Brand Drug Name	Indication	Route of Administration	ICER Health Benefit Price Benchmark[ǂ]	Annual Net Price Estimated Above or Below ICER HBPB [*]
Tezepelumab	Tezpire®	Asthma	SC	$12,590	Above
Mavacamten	Camzyos™	Hypertrophic Cardiomyopathy	Oral	$15,608	Above
Eculizumab	Soliris®	Myasthenia Gravis	IV	$20,186	Above
Efgartigimod	Vyvgart™	Myasthenia Gravis	IV	$29,550	Above
Lanadelumab	Takhzyro™	Hereditary Angioedema	SC	$228,749	Above
C1 esterase Inhibitor	Haegarda®	Hereditary Angioedema	SC	$258,856	Above
C1 esterase Inhibitor	Cinryze®	Hereditary Angioedema	IV	$146,243	Above
Abrocitinib	Cibingo®	Atopic Dermatitis	Oral	$43,493	Above
Tralokinumab	Adbry®	Atopic Dermatitis	SC	$36,418	
Baricitinib	Olumiant®	Atopic Dermatitis	Oral	$34,649	Below
Upadacitinib	Rinvoq®	Atopic Dermatitis	Oral	$43,181	Above
Ruxolitinib	Opzelura™	Atopic Dermatitis	Topical	NC[‡]	NA
Idecabtagene vicleucel	Abecma®	Multiple Myeloma	IV	$275,734	Above
Ciltacabtagene autoleucel	Carvykti™	Multiple Myeloma	IV	$324,638	Above
Voclosporin	Lupkynis™	Lupus Nephritis	Oral	$104,988	Above
Belimumab	Benlysta®	Lupus Nephritis	IV, SC	$63,684	Below
Inclisiran	Leqvio®	High Cholesterol	SC	$6,243	Above
Bempedoic acid	Nexletol®	High Cholesterol	Oral	NC[‡]	NA
Bempedoic acid/ezetimibe	Nexlizet™	High Cholesterol	Oral	$2,705	Below

HBPB: Health Benefit Price Benchmark, IV: Intravenous, NC: not calculated, SC: Subcutaneous

*Average prices net of all discounts and rebates, for the year of 2022, obtained from SSR Health. For prices not available or deemed unreliable, prices are taken from the Federal Supply Schedule (FSS). For physician administered drugs we will use the ASP price plus 6%, if available.

ǂ ICER health benefit price benchmarks for the higher of the $150,000 per QALY or $150,000 per evLY threshold, inflated to 2022 prices.

‡ NC indicates instances where ICER did not calculate a benchmark price. Since we did not calculate a benchmark price any item with this categorization will be exempt for the cost sharing analysis.

5. List of Payers and Identification of Relevant Coverage Policies

We will review and abstract data from the coverage policies of the largest and smallest formularies by number of covered lives, not associated with a specific employer, of the five largest commercial payers in the US. We will also review the formulary of the VHA and the largest and smallest state health exchange plan formularies in each geographic region of the US (Northeast, Midwest, South, West) as identified in the MMIT Analytics Market Access Database. The entity (payer or PBM) that controls the coverage decision is assigned the covered life. We will obtain the necessary coverage policies such as relevant prior authorization forms, documents, and formulary tiering information through targeted outreach to payers, and as needed, supplement any additional information needed by leveraging the MMIT Analytics Market Access Database. The list of payer formularies in scope is listed below in Table 5.1.

Table 5.1. Payer Formularies in Scope

Payer/PBM	Formulary	Plan Type	Reason for Inclusion
CVS Health (Aetna)	Largest Formulary	Commercial	Largest CVS formulary by covered lives, not specific to an employer
CVS Health (Aetna)	Smallest Formulary	Commercial	Smallest CVS formulary by covered lives, not specific to an employer
Express Scripts PBM	Largest Formulary	Commercial	Largest Express Scripts formulary by covered lives, not specific to an employer
Express Scripts PBM	Smallest Formulary	Commercial	Smallest Express Scripts formulary by covered lives, not specific to an employer
UnitedHealth Group	Largest Formulary	Commercial	Largest UnitedHealth formulary by covered lives, not specific to an employer
UnitedHealth Group	Smallest Formulary	Commercial	Smallest UnitedHealth formulary by covered lives, not specific to an employer
OptumRx	Largest Formulary	Commercial	Largest OptumRx formulary by covered lives, not specific to an employer
OptumRx	Smallest Formulary	Commercial	Smallest OptumRx formulary by covered lives, not specific to an employer
Cigna Corporation	Largest Formulary	Commercial	Largest Cigna formulary by covered lives, not specific to an employer
Cigna Corporation	Smallest Formulary	Commercial	Smallest Cigna formulary by covered lives, not specific to an employer
Veterans' Health Administration (VHA)	VHA National Formulary	Federal	Federally managed formulary used at all VA facilities
Centene Corporation	Fidelis Care Essential Plan	Health Exchange (NY)	Largest state exchange formulary from the Northeast region
UnitedHealth Group, Inc.	UnitedHealthcare MA 3 Tier HIX	Health Exchange (MA)	Smallest state exchange formulary from the Northeast region
Health Care Service Corporation	Blue Cross Blue Shield of Illinois Marketplace 6 Tier HMO-HIX	Health Exchange (IL)	Largest state exchange formulary from the Midwest region
Quartz Health Solutions	Quartz Health Solutions Standard Choice Four Tier	Health Exchange (IL)	Smallest state exchange formulary from the Midwest region
Florida Blue	Florida Blue Care Choices HIX	Health Exchange (FL)	Largest state exchange formulary from the South region
CVS Health (Aetna)	Aetna Health Exchange Plan Innovation Health	Health Exchange (VA)	Smallest state exchange formulary from the South region
Kaiser Foundation Health Plans, Inc.	Kaiser Permanente California HIX	Health Exchange (CA)	Largest state exchange formulary from the West region
Cambia Health Solutions	BridgeSpan Metallic Formulary HIX	Health Exchange (UT)	Smallest state exchange formulary from the West region

CA: California, FEHBP: Federal Employees Health Benefits Program, FL: Florida, HIX: Health Insurance Exchange, HMO: Health Maintenance Organization, IL: Illinois, MA: Massachusetts, NY: New York, PBM: Pharmacy Benefit Manager, UT: Utah, VA: Virginia

6. Determination of Concordance of Coverage Policies with Fair Access Criteria

6.1. Scope of Fair Access Criteria

As with the 2022 report, the 2023 report will evaluate formulary concordance with fair access criteria related to cost sharing, clinical eligibility, step therapy, and restrictions on prescriber qualifications. All of the criteria in these domains from the original 2020 white paper are shown in the Tables below. The criteria that will be in scope for this review are those that we believe we can reliably judge through review of available coverage documents.

Table 6.1. Cost Sharing Fair Design Criteria

Cost Sharing	
Fair Access Criteria	**In Scope for this Review?**
Patient cost sharing should be based on the net price to the plan sponsor, not the unnegotiated list price.	No
All medications identified by the IRS as high-value therapies should receive pre-deductible coverage within high deductible health plans.	No
At least one drug in every class should be covered at the *lowest relevant* cost-sharing level unless all drugs are priced higher than an established fair value threshold.	Yes
If all drugs in a class are priced so that there is not a single drug that represents a fair value as determined through value assessment, it is reasonable for payers to have all drugs on a higher cost-sharing level.	Yes
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.	Yes
As part of economic step therapy, when patients try a lower cost option with a lower cost sharing level but do not achieve an adequate clinical response, cost sharing for further therapies should also be at the lower cost sharing level as long as those further therapies are priced fairly according to transparent criteria.	No

IRS: Internal Revenue Service

Table 6.2. Clinical Eligibility Fair Design Criteria

Clinical Eligibility	
Fair Design Criteria	**In Scope for this Review?**
Payers should offer alternatives to prior authorization protocols such as programs that give feedback on prescribing patterns to clinicians or exempt them from prior authorization requirements ("gold carding") if they demonstrate high fidelity to evidence-based prescribing.	No
Payers should document at least once annually that clinical eligibility criteria are based on high quality, up-to date evidence, with input from clinicians with experience in the same or similar clinical specialty.	No
Clinical eligibility criteria should be developed with explicit mechanisms that require payer staff to document that they have: • Considered limitations of evidence due to systemic under-representation of minority populations; and • Sought input from clinical experts on whether there are distinctive benefits and harms of treatment that may arise for biological, cultural, or social reasons across different communities; and • Confirmed that clinical eligibility criteria have not gone beyond reasonable use of clinical trial inclusion/exclusion criteria to interpret or narrow the FDA label language in a way that disadvantages patients with underlying disabilities unrelated to the condition being treated.	No

For all drugs: Clinical eligibility criteria that complement the FDA label language may be used to:
• Set standards for diagnosis; and/or
• Define indeterminate clinical terms in the FDA label (e.g., "moderate-to-severe") with explicit reference to clinical guidelines or other standards; and/or
• Triage patients by clinical acuity when the payer explicitly documents that triage is both reasonable and necessary because:
  • The size of the population included within the FDA label is extremely large, and there is a reasonable likelihood that many patients would seek treatment in the short term; AND
  • The clinical infrastructure is not adequate to treat all patients seeking care and/or broad coverage would create such substantial increases in short-term insurance premiums or other financial strain that patients would be harmed through loss of affordable insurance; AND
  • Acuity can be determined on objective clinical grounds and waiting for treatment will not cause significant irremediable harm.
	Yes

For drugs with prices that have been deemed reasonable: Except for the three purposes outlined above, clinical eligibility criteria should not deviate from the FDA label language in a manner than would narrow coverage.	Yes
For drugs with prices that have been deemed reasonable: Documentation that patients meet clinical eligibility criteria should represent a light administrative burden, including acceptance of clinician attestation in lieu of more formal medical record documentation unless documentation is critical to ensure patient safety.	Yes
For drugs with prices that have been deemed unreasonable: Clinical eligibility criteria may narrow coverage by applying specific eligibility criteria from the pivotal trials used to generate evidence for FDA approval if implemented with reasonable flexibility and supported by robust appeals procedures as described in the implementation criteria.	Yes

FDA: U.S. Food and Drug Administration

The original 2020 white paper definition of the fair access criteria did not include a threshold for the number of steps, each appropriate in itself, that would cumulatively represent a failure to meet reasonable standards for fair access. After reviewing data from our 2021 evaluation, and examining clinical policy statements from other groups, we decided to use a threshold of 3 steps, meaning that any step therapy policy requiring 4 or more steps will be judged to fail concordance with step therapy fair access criteria. In a recent analysis of step therapy protocols, the vast majority of payers required 1-3 steps and minority (3%) required more than 3.[2]

Table 6.3. Step Therapy Fair Design Criteria

Step Therapy and Required Switching	
Fair Access Criteria	**In Scope for this Review?**
In order to justify economic step therapy policies extending beyond FDA labeling as appropriate, payers should explicitly affirm or present evidence to document all of the following: • Use of the first-step therapy reduces overall health care spending, not just drug spending	No
• 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. • Patients will have a reasonable chance to meet their clinical goals with first-step therapy. • Failure of the first-step drug and the resulting delay in beginning the second-step agent will not lead to long-term harm for patients. • Patients are not required to retry a first-line drug with which they have previously had adverse side effects or an inadequate response at a reasonable dose and duration.	Yes – threshold of a maximum of 3 steps even if all include appropriate first-line therapies
In order to justify required switching policies as appropriate, payers should explicitly affirm or present evidence to document all of the following: • Use of the required drug reduces overall health care spending. • The required switch therapy is based on the same mechanism of action or presents a comparable risk and side effect profile to the index therapy. • The required switch therapy has the same route of administration or the difference in route of administration will create no significant negative impact on patients due to clinical or socio-economic factors. • Patients are not required to switch to a drug that they have used before at a reasonable dose and duration with inadequate response and/or significant side effects, including earlier use under a different payer.	No

FDA: U.S. Food and Drug Administration

[2] Lenahan KL, Nichols DE, Gertler RM, Chambers JD. Variation in Use and Content of Prescription Drug Step Therapy Protocols, Within and Across Health Plans. *Health Affairs.* 2021; 40 (11): 1749-1757.

Table 6.4. Provider Qualifications Fair Design Criteria

Provider Qualifications	
Fair Access Criteria	**In Scope for this Review?**
Restrictions of coverage to specialty prescribers are reasonable with one or more of the following justifications: • Accurate diagnosis and prescription require specialist training, with the risk that non-specialist clinicians would prescribe the medication for patients who may suffer harm or be unlikely to benefit. • Determination of the risks and benefits of treatment for individual patients requires specialist training due to potential for serious side effects of therapy. • Dosing, monitoring for side effects, and overall care coordination require specialist training to ensure safe and effective use of the medication.	Yes
Requiring that non-specialist clinicians attest they are caring for the patient in consultation with a relevant specialist is a reasonable option when the condition is frequently treated in primary care settings but some elements of dosing, monitoring for side effects, and/or overall coordination of care would benefit from specialist input for many patients.	Yes

6.2 Criteria for the Exploratory Transparency Analyses

For the 2023 report we will add evaluation of fair access criteria from the 2020 white paper related to transparency: 1) the availability of **cost sharing** (i.e. tiering), and of **clinical eligibility criteria** for prospective plan enrollees, 2) the availability of policies prior to enrollment on the **continuation of therapy** after switching to a new plan; and 3) the availability of policies prior to enrollment describing whether a drug is subject to **copay adjustment programs** (e.g., copay accumulators and maximizers). Transparency criteria are shown in Table 6.5. and the continuation of treatment and accumulator criteria are described below.

In order to evaluate these domains of fair access, we will use a targeted approach and have elected to evaluate coverage policies for efgartigimod (myasthenia gravis), upadacitinib (atopic dermatitis), and bempedoic acid (high cholesterol).

Table 6.5. Transparency Fair Design Criteria

Transparency	
Fair Access Criteria	**In Scope for this Review?**
Cost-sharing policies should be presented clearly to consumers prior to health plan selection, allowing all individuals to understand what cost sharing they will face for treatments they are currently taking or are considering.	Yes
Any significant change to formulary or cost sharing structures should not occur mid-cycle unless plan sponsors include this as a qualifying event allowing plan enrollees to switch plans.	No
At the point of care, clinicians and patients should be able to rapidly determine the cost-sharing requirements for any treatment along with cost sharing for other alternatives.	No
Individuals considering health plan enrollment should be presented with clear information allowing them to understand whether they meet the insurers' clinical criteria for the treatments they are currently taking. The policies should also set out the rationale behind them and be readily understandable.	Yes
Clinicians and patients should be able to rapidly determine the clinical criteria for any treatment and view the clinical rationale supporting these criteria. The referenced clinical information should be readily available to the prescribing/ordering provider and the public.	No
Individuals considering health plan enrollment should be presented with clear information allowing them to understand whether the treatments they currently take or envision taking will be subject to non-medical step therapy or switching policies.	Yes
Clinicians, pharmacists, and patients should be able to rapidly determine the requirements related to step therapy and switching policies and be able to easily view a full justification from the insurer.	No
Individuals considering health plan enrollment should be able to easily find information related to coverage criteria, including prescriber qualifications, for drugs that they or family members are currently taking.	Yes
Clinicians and patients should be able to rapidly determine whether there is a restriction on prescribing for any treatment. Insurers should provide ready assistance to primary care clinicians seeking connection with a relevant specialist for consultation as needed.	No

Transparency

For the evaluation of transparency criteria, we will identify the extent to which formulary tiering and clinical eligibility information is available to consumers prior to health plan selection. Specifically, we will perform an internet search of each payer to determine if formulary tiering information with cost-sharing details and policies describing clinical eligibility criteria are publicly available. We will not evaluate transparency of this information to enrolled plan members during the process of care.

Continuation of Therapy

To further investigate transparency, we will conduct an exploratory analysis of whether plans make information on policies related to "grandfathering" or continuation of therapy available prior to plan enrollment. The 2020 white paper notes that "individuals considering health plan enrollment should be presented with clear information allowing them to understand whether they meet the insurers' clinical criteria for the treatments they are currently taking." Another criterion notes that payers should offer a minimum 60-day grace period for any prior authorization protocols if a patient is already stabilized on a particular treatment upon plan enrollment. To evaluate whether continuation of therapy policies are available, we will perform an internet search of each plans' website, drug policies, and drug lists for the three drugs noted above as if we were a prospective plan enrollee to see if there are any descriptions of when a patient would be allowed to continue taking a non-preferred drug. As there may be alternative terms for "grandfathering" used across the health care space, we will search for additional terms such as "exception request", "continuation of therapy/coverage", "maintenance of medical coverage" etc. as needed.

Use of Accumulators

Copay adjustment programs may lead to higher out-of-pocket costs and lower adherence or higher discontinuation of treatment for patients.[3] Programs like these are also widely used – in an analysis of 35 plans and PBMs, representing 121.5 million commercially insured individuals, MMIT found that 39% and 41% of plan members are enrolled in plans that have implemented copay accumulators and maximizers, respectively.[4] Due to the potential financial impact to patients and our criteria requiring that cost-sharing information be made available to patients prior to plan enrollment, we will evaluate whether prospective plan members can determine if the three drugs in our transparency analysis are subject to copay adjustment programs. As with the other transparency analyses, we will conduct an internet search of the health plans' websites to emulate the experience of an individual shopping for health coverage.

[3] Sherman BW, Epstein AJ, Meissner B, Mittal M. Impact of a co-pay accumulator adjustment program on specialty drug adherence. Am J Manag Care. 2019 Jul;25(7):335-340. PMID: 31318506.
[4] Fein A. Copay Accumulator and Maximizer Update: Adoption Plateaus as Insurers Battle Patients Over Copay Support. https://www.drugchannels.net/2023/02/copay-accumulator-and-maximizer-update.html. Published 2023. Accessed March 30, 2023.

7. Analytic Plan

7.1 Process for Comparing Coverage Policies to Fair Access Criteria

For each drug, ICER research staff will summarize the policy abstraction data in a policy brief, which will also include details of the FDA label (including clinical trial eligibility criteria), relevant clinical guidelines, and the policy recommendations from the corresponding 2021 ICER Evidence Report. Research staff will make preliminary judgments regarding whether the coverage policy does or does not meet each fair access criterion, and then this judgment will be reviewed by an internist on the ICER staff. If the ICER clinician feels that condition-specific clinical expert input is needed to determine whether a coverage policy meets the fair access criterion, ICER will seek to discuss the question with an expert involved in the original ICER Evidence Report on that drug.

Quantitative analyses of the concordance of coverage policies with fair access criteria will examine:

Table 7.1. Rate of Concordance by Fair Access Criterion

Cost sharing	# of payer policies across all drugs meeting criteria / all payer policies
Clinical eligibility criteria	# of payer policies across all drugs meeting criteria / all payer policies
Step therapy	# of payer policies across all drugs meeting criteria / all payer policies
Prescriber restrictions	# of payer policies across all drugs meeting criteria / all payer policies

Overall concordance will also be presented with policies not available and not applicable split out to emphasize the number of policies that were not available as a separate component of the overall findings. Not applicable refers to the following situations: the cost sharing criteria only applies to drugs deemed cost-effective; and non-formulary drugs are only evaluated for cost-sharing, if applicable.

Table 7.2. Rate of Concordance by Drug

	Cost Sharing	Clinical Eligibility Criteria	Step Therapy	Prescriber Restrictions
Drug 1	# of payer policies meeting criteria/ all payer policies	# of payer policies meeting criteria/ all payer policies	# of payer policies meeting criteria/ all payer policies	# of payer policies meeting criteria/ all payer policies
Drug 2	# of payer policies meeting criteria/ all payer policies	# of payer policies meeting criteria/ all payer policies	# of payer policies meeting criteria/ all payer policies	# of payer policies meeting criteria/ all payer policies

Table 7.3. Rate of Concordance by all Payers

Cost sharing	# of payers with >50% of policies across all drugs meeting criteria/# of payers
Clinical eligibility criteria	# of payers with >50% of policies across all drugs meeting criteria/# of payers
Step Therapy	# of payers with >50% of policies across all drugs meeting criteria/# of payers
Prescriber restrictions	# of payers with >50% of policies across all drugs meeting criteria/# of payers

Table 7.4. Rate of Concordance by Individual Payer

	Cost Sharing	Clinical Eligibility Criteria	Step Therapy	Prescriber Restrictions
Payer 1 (Largest Formulary)	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies
Payer 1 (Smallest Formulary)	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies
Payer 2 (Largest Formulary)	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies
Payer 2 (Smallest Formulary)	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies	# of policies across all drugs meet criteria/all policies

Additional quantitative analyses may be pursued to evaluate whether rates of concordance vary by route of administration, level of competition in the drug category, estimated eligible population, and other factors.

The approach to evaluation of transparency, continuation of therapy, and use of accumulators has been presented above. This approach will have some quantitative elements, however, we will not be performing a systematic evaluation of these elements across all drugs and all payers, so the results will be presented separately from the concordance data on the four areas of coverage policy design shown in the tables above.

In addition, qualitative information will be gathered from patient groups to provide context to the quantitative analyses. Patient groups involved in the relevant ICER review in 2021 will be invited to submit published or unpublished data on barriers to access, examples of barriers to access that may reflect failure to meet fair access criteria, or problems beyond those criteria evaluated directly in this report.

8. Payer and Patient Organization Review Prior to Public Release

For any payer with policies judged not to meet fair access criteria, ICER will provide them with the opportunity to review our judgment and provide comment if they feel the policy has been misinterpreted or misjudged.

Draft results of the evaluation will also be shared with members of the Working Group to get feedback on how the fair access criteria are being judged across different coverage policies. ICER will engage with patient advocacy organizations that were involved in the original assessment of the drugs included in this report, as noted above, and they will be given the opportunity to provide information on barriers to access their communities face for potential inclusion in the report.