Barriers to Fair Access Assessment

Final Protocol

June 5, 2024

Institute for Clinical and Economic Review

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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. In the 2023 report, we expanded our scope to assess the largest and smallest formularies by covered lives from each of the five largest US commercial payers/pharmacy benefit managers (PBMs), and the largest and smallest formularies of state health exchange plans from each of the four geographic regions of the US. In addition, we included exploratory transparency analyses on policies related to continuation of therapy and copay adjustment programs.

Based on the experience with the first three reports, and with ongoing input from our multi-stakeholder Working Group, our 2024 report will be modified from prior reports as summarized below. A more detailed explanation of these methods is provided in the body of this research protocol.

We will continue to evaluate coverage policies for drugs reviewed by ICER two years ago. This year, we will apply our criteria for fair access to the following formularies:

- For each of the ten largest US commercial payers/PBMs, their largest formulary by covered lives that is not associated with a specific employer;
- The single formulary offered by the Veteran's Health Administration (VHA).

In addition, we are considering new exploratory analyses. These analyses may involve a select set of the drugs and formularies in scope, and the research protocol will be updated once the analyses have been determined.

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/PBMs in the United States, expanded for the 2024 report to include the largest formularies of the 10 largest payers/PBMs and the VHA. For each of the drugs reviewed by ICER in 2022 we will perform analyses of the proportion of selected fair access criteria that are met in these formularies, analyzed across drugs, conditions, and payers/PBMs.

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 2024 and the 2024 Barriers to Fair Access Assessment report is scheduled for release in December 2024.

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 2024 ICER Barriers to Fair Access Assessment will assess the concordance of drug coverage policies with fair access criteria for ICER-reviewed drugs in 2022. We will review and abstract data from the coverage policies of the largest formularies by number of covered lives, not associated with a specific employer, of the ten largest commercial payers/PBMs in the US. We will also review the formulary of the VHA. In addition to core analyses of concordance with fair access criteria for cost sharing and the content of prior authorization policies, the 2024 report will also include exploratory analyses on a select set of drugs and formularies.

2.3. Timeline

Please see the figure below for an overview of the timeframe for the 2024 Barriers to Fair Access Assessment to be released later this year.

Timeline 2024	
Research Protocol Posted	June
Draft Report Review Period for Payers and PBMs	October – November
Draft Report Review Period for Working Group Members	October – November
Final Report Posted	December
Public Webinar	January

Payers/PBMs 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:

- **Alan Balch,** PhD, Chief Executive Officer, Patient Advocate Foundation
- **Erica Cischke**, MPH, Vice President, Government Affairs, Alliance for Regenerative Medicine
- **Omar Escontrias,** DrPH, MPH, Senior Vice President, Equity, Research & Programs, National Health Council
- **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
- **Rick Kelly,** FSA, SVP & National Pharmacy Practice Leader, Marsh McLennan Agency
- **Rebecca Kirch**, JD, Executive Vice President, National Patient Advocate Foundation
- **M. Kay Scanlan,** JD, Sr. Policy Advisor, Haystack Project
- **Gail Ryan,** PharmD, Director of Pharmaceutical Transformation, Point32Health
- **Carl Schmid,** Executive Director, HIV+Hepatitis Policy Institute
- **Bari Talente,** Executive Vice President, Advocacy, National Multiple Sclerosis Society
- **Diana Thiara,** MD, DABOM, Assistant Clinical Professor of Medicine and Medical Director, UCSF Weight Management Clinic
- **Kimberly Westrich,** MA, Chief Strategy Officer, National Pharmaceutical Council (NPC)

4. List of Included Drugs

Drugs eligible for consideration are those reviewed by ICER in 2022 and that are currently FDA approved for an indication consistent with the ICER review (Table 4.1.). One drug reviewed by ICER in 2022, plinabulin [BeyondSpring Inc.] for prevention of chemotherapy-induced neutropenia, received a complete response letter from the FDA and has yet to gain approval. Another drug, AMX0035 [Relyvrio™, Amylyx Pharmaceuticals] for amyotrophic lateral sclerosis, was granted FDA approval but a subsequent failed readout from the Phase 3 trial prompted the manufacturer to withdraw the product from the market. As such, both drugs will be excluded from the report. In addition, the agents for treating COVID-19 that were reviewed in 2022 will not be included in this analysis as those drugs were part of a "special assessment" and not subject to a traditional ICER review, and because the treatment landscape for COVID-19 has evolved significantly since 2022.

4.1. Determining Whether Drugs Are Fairly Priced

Whether the price for a drug is considered "fair" will be determined according to whether the most recent net price of a drug falls at or below ICER's Health Benefit Price Benchmark (HBPB) calculated in the relevant 2022 report at the $150,000 per evLY or QALY threshold (whichever produces a higher price). Each HBPB will be inflated to 2023 dollars to reflect current year US dollars using the price index for health care personal consumption expenditures from the Bureau of Economic Analysis. To determine the most recent net price of the included drugs, we will follow the methods outlined in the ICER Reference Case.

For drugs that do not require physician administration, the net price will be calculated using the Wholesale Acquisition Cost (WAC) of the relevant formulation from RED BOOK, multiplied by the most recent four-quarter rolling average gross-to-net discount percentage from SSR Health, LLC, the health care division of SSR, LLC, an independent investment research firm. To confirm the validity of calculated net prices, we will compare them to prices reported in the Federal Supply Schedule Service (FSS). In cases where data from SSR are not available or deemed to be unreliable (such as no recent or inconsistently available gross-to-net discount data), we will use price estimates from FSS. For the gene therapies included in our review, we will prioritize using RED BOOK WAC pricing over FSS pricing because it is unlikely that the lower prices captured in FSS apply to the broader market. Upfront discounts for chronic treatments are less common with cell and gene therapies which are more likely to be managed with downstream outcomes-based agreements. For drugs that require physician administration, the net price will be calculated using the published average sales price (ASP) without the 6% mark-up.

RED BOOK reports WAC prices on a per package basis. We will convert the package prices as listed in RED BOOK to the unit of analysis used in the ICER report (e. g., annual price, one-time

administration price, or price per vial) 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 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 2024 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‡	Estimated Net Price* Above or Below ICER HBPB
Tirzepatide	Mounjaro™	Diabetes: Type 2	SC	$5,833	Below
Trilaciclib	Cosela™	Chemotherapy-Induced Neutropenia	IV	$512 per vial	Above
Betibeglogene autotemcel	Zynteglo™	Beta Thalassemia	IV	$2,497,082 per administration	Above
Oral Edaravone	Radicava ORS®	Amyotrophic Lateral Sclerosis	Oral	$3,275	Above
Semaglutide	Wegovy®	Obesity Management	SC	$10,029	Below
Liraglutide	Saxenda®	Obesity Management	SC	$4,912	Above
Phentermine/Topiramate	Qsymia®	Obesity Management	Oral	$4,912	Below
Naltrexone/Bupropion	Contrave®	Obesity Management	Oral	$2,456	Above
Etranacogene dezaparvovec	Hemgenix®	Hemophilia B	IV	$3,027,200 per administration	Above
Valoctocogene roxaparvovec	Roctavian™	Hemophilia A	IV	$2,006,876 per administration	Above
Fezolinetant	Veozah™	Menopause: Vasomotor Symptoms	Oral	$2,661	Above

HBPB: Health Benefit Price Benchmark, IV: Intravenous, SC: Subcutaneous

*Average prices net of all discounts, rebates, and mark-ups for the year of 2023

ǂ ICER HBPBs for the higher of the $150,000 per QALY or $150,000 per evLY threshold, inflated to 2023 prices. HBPBs represent annual prices unless otherwise indicated.

5. List of Payers/PBMs and Identification of Relevant Coverage Policies

We will review and abstract data from the coverage policies of the largest formularies by number of covered lives, not associated with a specific employer, of the ten largest commercial payers/PBMs in the US. We will also review the formulary of the VHA. 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/PBMs, and as needed, supplement any additional information needed by leveraging the MMIT Analytics Market Access Database.

For this analysis, the formularies marketed under Express Scripts and Cigna Corporation will remain separate even though the companies are merged because each company continues to make formulary decisions independently. Formularies for OptumRx and UnitedHealthcare will also be evaluated separately because even though they use the same underlying template, UnitedHealthcare has the discretion to design its own coverage policies, which can differ from those in the OptumRx formulary. The list of payer/PBM formularies in scope is listed below in Table 5.1.

Table 5.1. Payer Formularies in Scope

Payer/PBM	Formulary Name	Plan Type
CVS Health (Aetna)	CVS Caremark Performance Standard Control w/ Advanced Specialty Control	Commercial
Express Scripts PBM	Express Scripts National Preferred Formulary	Commercial
UnitedHealth Group, Inc.	UnitedHealthcare Advantage Three Tier	Commercial
Cigna Corporation	Cigna Standard Three Tier	Commercial
OptumRx	OptumRx Premium Formulary	Commercial
Kaiser Foundation Health Plans, Inc.	Kaiser Permanente Southern California 3 Tier HMO	Commercial
Elevance Health, Inc.	Anthem Essential 4 Tier	Commercial
Health Care Service Corporation	BCBS of Illinois Basic 6 Tier	Commercial
Highmark, Inc.	Highmark Blue Cross Blue Shield 3 Tier	Commercial
Blue Shield of California	Blue Shield California Plus Formulary	Commercial
Veterans' Health Administration (VHA)	VHA National Formulary	Federal

BCBS: Blue Cross Blue Shield, HMO: Health Maintenance Organization, PBM: Pharmacy Benefit Manager

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

6.1. Scope of Fair Access Criteria

As with the 2023 report, the 2024 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.[1]

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

[1] 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 Analysis

For the 2024 report we will add evaluation of fair access criteria from the 2020 white paper related to the transparency of **cost sharing** (i.e. tiering) and of **clinical eligibility criteria** for prospective plan enrollee.

In order to evaluate these domains of fair access, we will use a targeted approach and have elected to evaluate coverage policies for the three gene therapies in scope this year: betibeglogene autotemcel (beta thalassemia), etranacogene dezaparvovec (hemophilia B), and valoctocogene roxaparvovec (hemophilia A).

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

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 do an internet search of individual payers to determine if prior authorization forms and tiering information are publicly available. We will focus on availability of this information for prospective enrollees prior to joining a health plan; we will not evaluate transparency of this information during the process of care.

6.3. Assessment of Cost-Sharing and Prior Authorization Analytics

New for this year, ICER is partnering with IQVIA, a leading healthcare data and analytics provider, to gain insights into national level cost-sharing and prior authorization metrics from real-world claims data. We will evaluate measures illustrating average *'consumer accessibility'* for a subset of the 11 drugs in scope for the past 2 years in the commercial line of business. We will not report any identifiable information at the payer or plan level. The data points we will access are listed below:

Prior authorization burden measures

- Total written commercial prescriptions
- Total dispensed commercial prescriptions
- Total dispensed New to Brand commercial prescriptions
    - % filled on first attempt
    - % filled after multiple attempts
    - % of prescriptions rejected
        - % rejections due to prior authorization or step therapy
        - % rejections due to another reason (e.g., not covered, fill limit, etc.)
        - % reversals

Patient cost-sharing measures

- % of claims by out-of-pocket cost, ranges
- %/# cash pay
    - Amount of cash pay transaction, in categories

Note: This is based on insights licensed from IQVIA's Market Access Analytic Solutions (LAAD Data): for the period of most recent two data years reflecting estimates of real-world activity. All rights reserved.

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 2022 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 senior project staff at ICER, including a clinician. 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 (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 (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 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 2022 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.