Barriers to Fair Access Assessment

Final Protocol

May 23, 2022

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 in to 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. ICER intends to repeat these assessments each year going forward. Based on the experience with the first report, and with ongoing input from our multi-stakeholder Working Group, we have modified our methods for the 2022 report to expand the scope of fair access criteria to be evaluated, increase the number of payer formularies in the assessment, and shift the process for identifying the set of the drugs whose coverage policies will be evaluated so that it includes all drugs reviewed by ICER during the calendar year 2020, with future reports continuing, in a rolling fashion, to evaluate coverage policies for all ICER-reviewed drugs in the calendar year two years ago. More detailed explanation of these methods changes is provided in the body of this research protocol.

In the main, however, the goals and basic approach of the report remains 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 2022 report to include the Veterans Health Administration (VHA) and the two largest state ACA exchange

health plans. For each of the drugs reviewed by ICER in 2020 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 2022, and the 2022 Barriers to Fair Access Assessment report is scheduled for release in November 2022.

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 2022 ICER Barriers to Fair Access Assessment will assess the concordance of drug coverage policies with fair access criteria for ICER-reviewed drugs in 2020. The coverage polices to be evaluated will be those of the leading formularies of large payers in the United States, including the largest 15 commercial payers, the VHA, and the two largest state health exchange plans. In addition to core analyses of concordance with fair access criteria for cost sharing and the content of prior authorization policies, the 2022 report will also evaluate concordance on a select set of drugs and formularies on criteria related to the relative burden of prior authorization and the transparency of cost sharing and clinical eligibility criteria to prospective plan enrollees.

2.3 Timeline

Please see the figure below for an overview of the timeframe for the 2022 Barriers to Fair Access Assessment to be released later this year.

Timeline 2022	
Research Protocol Posted	May
Draft Report Review Period for Payers and PBMS	Late July – Late August
Draft Report Review Period for Working Group Members	Mid - September to Early October
Final Report Posted	November
Public Webinar	To Be Announced

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
- **Sharon Phares,** PhD, Chief Scientific Officer, National Pharmaceutical Council
- **Carl Schmid,** Executive Director, HIV+Hepatitis Policy Institute
- **Saira Sultan,** President, Connect4Strategies (representing The Haystack Project)
- **Bari Talente,** Executive Vice President, Advocacy, National Multiple Sclerosis Society
- **Douglas White,** MD, PhD, Treasurer, American College of Rheumatology

4. List of Included Drugs

Drugs eligible for consideration are those reviewed by ICER in 2020 and that are currently FDA approved for an indication consistent with the ICER review (Table 4.1.). The 2020 ICER review of remdesivir evaluated its use for in-patient treatment of COVID-19. Given that remdesivir for in-patient use is typically reimbursed as part of a bundled payment, and therefore coverage policies and cost-sharing specific to remdesivir are unlikely, we have removed it from this review.

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 2020 report at the $150,000 per evLYG 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, 2021-December 31, 2021), 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 same price data that was used in the report, which consists of the WAC price plus a markup.

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 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 2022 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†	Annual Net Price Estimated Above or Below ICER HBPB *
Ubrogepant	Ubrelvy	Migraine: Acute	Oral	$4,687	Below
Rimegepant	Nurtec	Migraine: Acute	Oral	$4,697	Below
Lasmiditan	Reyvow	Migraine: Acute	Oral	$3,189	Above
Crizanlizumab	Adakveo	Sickle Cell Disease	IV	$35,046	Above
Voxelotor	Oxbryta	Sickle Cell Disease	Oral	$23,668	Above
L-glutamine	Endari	Sickle Cell Disease	Oral	$19,568	Above
Lumacaftor/Ivacaftor	Orkambi	Cystic Fibrosis	Oral	$61,750	Above
Tezacaftor/Ivacaftor	Symdeko	Cystic Fibrosis	Oral	$70,760	Above
Ivacaftor	Kalydeco	Cystic Fibrosis	Oral	$74,303	Above
Elexacaftor/Tezacaftor/ Ivacaftor	Trikafta	Cystic Fibrosis	Oral	$86,552	Above
Vedolizumab	Entyvio	Ulcerative Colitis	IV	$11,844	Above
Infliximab	Remicade	Ulcerative Colitis	IV	$11,034	Below
Infliximab-dyyb	Inflectra	Ulcerative Colitis	IV	$11,034	Below
Infliximab-abda	Renflexis	Ulcerative Colitis	IV	$11,034	Below
Adalimumab	Humira	Ulcerative Colitis	SC	$6,985	Above
Golimumab	Simponi	Ulcerative Colitis	SC	$7,693	Above
Tofacitinib	Xeljanz	Ulcerative Colitis	Oral	$15,488	Above
Ustekinumab	Stelara	Ulcerative Colitis	SC	$16,804	Above
Emicizumab	Hemlibra	Hemophilia A	SC	Cost saving	Cost saving

HBPB: Health Benefit Price Benchmark

*Average prices net of all discounts and rebates, for the year of 2021, obtained from SSR Health. For prices not available or deemed unreliable, prices taken from Federal Supply Schedule (FSS).

† ICER health benefit price benchmarks for the higher of the $150,000 per QALY or $150,000 per evLYG threshold, inflated to 2021 prices.

5. List of Payers and Identification of Relevant Coverage Policies

We will review and abstract data from the coverage policies of the leading formulary, by number of enrollees, of the 15 largest commercial payers in the US. We will also review the formulary of the VHA and the two largest state Health Exchange plan formularies 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 leverage the MMIT Analytics Market Access Database to identify relevant prior authorization forms, documents, and formulary tiering information. As needed, we will also supplement this database with targeted outreach to payers to obtain additional information to clarify coverage policies. 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
CVS Health (Aetna)	CVS Caremark Performance Standard w/ Advanced Specialty Control	Commercial
Express Scripts PBM	Express Scripts National Preferred with Advantage Plus	Commercial
UnitedHealth Group, Inc.	UnitedHealthCare Advantage Three Tier	Commercial
OptumRx	OptumRx Select Standard	Commercial
Cigna Corporation	Cigna Standard Three Tier	Commercial
Kaiser Foundation Health Plans, Inc.	Kaiser Permanente Southern California	Commercial
Anthem, Inc.	Anthem Essential 4 Tier	Commercial
Health Care Service Corporation	BCBS of Illinois Basic 6 Tier	Commercial
MedImpact Healthcare Systems, Inc.	MedImpact Portfolio High Formulary	Commercial
Blue Shield of California	Blue Shield of California Plus Formulary	Commercial
Blue Cross Blue Shield of Michigan	BCBS of Michigan Custom 3 Tier	Commercial
Blue Cross Blue Shield of Massachusetts	BCBS Massachusetts Three Tier	Commercial
Premera, Inc.	Premera Preferred 3-Tier – B3	Commercial
Highmark, Inc.	Highmark Blue Cross Blue Shield 3 Tier	Commercial
Elixir PBM	Elixir Standard Formulary	Commercial
Veterans Health Administration (VHA)	VHA National Formulary	Federal
Florida Blue	Florida Blue Care Choices HIX	State Exchange
Kaiser Foundation Health Plans, Inc.	Kaiser Permanente California HIX	State Exchange

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

As with the 2021 report, the 2022 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.	**Yes**
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.	**Yes**
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**

6.3 Step Therapy Fair Design Criteria

For the 2022 report we will be introducing a new element in our evaluation of the fair design of step therapy policies. 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 will 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 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 – new 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.	No
• 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.	**Yes**

[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 when payers explicitly affirm 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**

6.5 Transparency and Documentation Burden Criteria

For the 2022 report we will add evaluation of fair access criteria from the 2020 white paper related to 1) the **transparency** of cost sharing (i.e. tiering) and of clinical eligibility criteria for prospective plan enrollees; and 2) prior authorization **documentation burden**. Transparency criteria are shown in Table 6.5. and documentation burden criteria are described below.

Given that we have not attempted before to evaluate these domains of fair access, we are going to use a more targeted approach and have selected to evaluate coverage policies for the migraine and ulcerative colitis treatments in the data set.

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 do an internet search of individual payers to determine if prior authorization forms and tiering information are publicly available. We are aware that payers and plan sponsors (e.g. employers) may have specialized procedures through which prospective plan enrollees can obtain this information, so we will invite each payer to provide any guidance on its approach. 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.

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. 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.	**Yes**
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

Documentation Burden

With prior authorization there may be a risk of delayed or abandoned care that could harm patients.[2] For example, a 2018 Physician Survey conducted by the AMA on prior authorization found that 65% of providers had to wait, on average, at least one business day within the past week

[2] Stuart BC, Tom SE, Choi M, et al. Placement of selected new FDA-approved drugs in Medicare Part D formularies, 2009-2013. The American journal of managed care. 2018;24(6):e175-e182.

before receiving a prior authorization decision from a health plan and 26% of providers waited three business days or more.[3] It should also always be remembered that prior authorization protocols impose an administrative burden on patients and clinicians that can, by itself, pose a risk to fair access.

The 2020 white paper included an ethical goal that "the administrative burden of documenting clinical eligibility should be streamlined and transparent to avoid creating a significant barrier to appropriate care." To evaluate this element as part of this 2022 report, where applicable, we will use the material available in the MMIT database to record the number of questions on the prior authorization form for an individual payer and note any additional documentation requirements that could create additional burden, such as when medical records are explicitly required to be sent to the payer. We will also contact all payers to inquire if they have a "gold card" approach for clinicians within their prior authorization procedures. There will be no set threshold for how many questions or additional documentary requirements would qualify as appropriate or not appropriate. Instead, we will present findings on the range and variation across payers to provide insight and suggest avenues for determining what level of documentation burden might be accepted as "best practice" under different circumstances.

[3] American Medical Association. 2018 AMA prior authorization (PA) physician survey. 2018; https://www.ama-assn.org/system/files/2019-02/prior-auth-2018.pdf.

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 2020 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.

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 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

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 and prior authorization documentation burden has been presented above. This approach will have some quantitative elements, e.g. the median and range of the number of questions on prior authorization forms for migraine drugs. 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 and clinical specialty societies to provide context to the quantitative analyses. The methods by which this information will be gathered is yet to be determined, but could include submission of published and 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. All payers will also be offered the opportunity to provide a written comment for inclusion with the material posted publicly when the report is released.

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, and they will be given the opportunity to provide written comment for inclusion with the material posted publicly when the report is released.