



The Utility of ICER Reports for Private Payer Drug Coverage Decision-Making: Cost-Effectiveness Assessments

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EXECUTIVE SUMMARY

BACKGROUND

U.S. private health care payers, including insurers and self-insured employers, provide health insurance to more than 200 million people. These private payers face relentless medical inflation in an environment where many other business expenses have been constrained. Drug spending has received much scrutiny, partly because of the high prices of some drugs. The nature of the drug supply chain creates challenges for private payers who need to decide which drugs to cover, for which patients, and under what circumstances. New drug approvals, approved indications, price changes, and the introduction of generic alternatives to brands are among the operational and financing challenges payers must address.

The Institute for Clinical and Economic Review (ICER) has emerged as a prominent source of cost-effectiveness assessments (CEAs) and budget impact analyses (BIAs) for drugs and other medical interventions. ICER proposes that its CEAs “establish a ‘value-based price benchmark’ reflecting how each drug should be priced to appropriately reflect long-term improved patient outcomes.”¹ We note that there is already a large body of cost-effectiveness research to which payers have access. In our opinion, CEAs can offer value if adapted to payers’ real-world situations and may be a useful point in negotiations between payers and pharmaceutical companies, but we believe that private payers will likely find ICER’s price benchmarks inadequate for their on-going pharmaceutical decision-making.

This report identifies several disconnects between ICER’s work and its potential use by private payers, which could help explain why private payers make little use of ICER assessments when making coverage decisions. These include:

- ICER’s use of a total U.S. population and health care system perspective, even though no payer—private or public—serves the total U.S. population or pays national average costs.
- ICER’s reliance on quality-adjusted life years (QALYs), an intangible measure that has no applicability in private payers’ financial realities.
- ICER’s use of proprietary models, which prevents payers from modifying or customizing the models to reflect their unique circumstances.

FINDINGS

ICER DOES NOT CONSIDER THAT PRIVATE PAYERS HAVE DIVERSE POPULATIONS AND COSTS

- **Private payers serve distinct subpopulations of the U.S. population.** ICER uses the perspective of the entire U.S. population, but a coverage decision for one subpopulation may not be appropriate for another subpopulation. A Medicare Advantage plan will have a very different population to manage than an employer plan—the ages and comorbidities will be different—so coverage decisions may be different.
- **Different private payers have different prices—and these differences can lead to different decisions.** Discounts and rebates are negotiated at the payer and drug level and are not the same across the class. There is significant variability in drug prices due to these discounts and rebates across payers, which can lead different payers to make different decisions. However, ICER assessments assume a common price.

ICER’S ASSESSMENTS RELY ON QALYS, WHICH ARE NOT TYPICALLY A FACTOR IN PRIVATE PAYER DECISION-MAKING

- **QALYs may be a helpful academic tool, but have limited practical use in real-world decision-making.** While QALY metrics provide a measure of value that may be useful for academic research, their intangibility does not fit well with private payer decision-making, which must be based on expected financial impact and expected outcomes of standard performance metrics (such as HEDIS).

- **QALYs assign diminished value to the elderly and disabled and do not put a premium value on preservation of life.** QALYs show lower values for elderly and disabled people, but private payers are responsible for all of their insureds.
- **ICER's approach to Quality of Life is not necessarily consistent from report to report.** ICER must often combine available data sources to develop measures for a condition. The lack of consistent sources suggests that private payers should exercise caution in comparing ICER reports for different conditions.

ICER'S ASSESSMENTS LACK ALIGNMENT WITH PRIVATE PAYER DECISIONS

- **Private payers can best use assessments that support nuanced decisions.** ICER's cost per QALY assessments are best-suited for a binary—cover/do not cover—environment. However, people with private payer insurance expect wide access to treatments that provide good health outcomes, so insurers rarely completely exclude particular drugs or services.
- **ICER often uses a lifetime horizon, but private payers' time horizons are seldom the lifetime of the population.** Most private payers will not see the full impact of QALYs gained, because their insureds will switch to other plans during their lifetimes.
- **ICER may overstate the certainty of their assessments.** There is inherent uncertainty when using short-term clinical trials for long-term projections, applying RCT findings for one product to other products, testing assumptions individually, and using inconsistent data to produce comparisons. These issues all add to uncertainty in applying ICER assessments, especially when payers compare individual products.
- **ICER does not prioritize the use of information that is relevant to private payers.** ICER's preferred source of information for both outcomes and costs is data from randomized controlled trials or dated peer-reviewed publications, not recent real-world evidence that is preferred by payers.
- **Private payers vary in their concern with non-drug (medical) costs.** Clearly differentiating the services that generate costs or savings in its assessments would help payers adapt the assessments to their specific situations.

ICER RELIES UPON PROPRIETARY, NON-TRANSPARENT MODELS, WHICH ARE DIFFICULT FOR PAYERS TO UNDERSTAND AND CUSTOMIZE

- **ICER models are proprietary and do not accommodate customization by payers to reflect their own circumstances and needs.** Many of the details of ICER's cost-effectiveness models are proprietary and are not made public, which makes it difficult for payers to adapt to their circumstances or to reproduce ICER's results.

This report evaluates whether ICER-produced findings would assist private payers who make detailed drug coverage decisions based on financial outcomes, premium rates, competitiveness, or contractual reimbursement. The report does not assess whether a payer would benefit from publicizing its adherence with ICER recommendations, nor does it contemplate ICER obtaining statutory authority or the U.S. adopting features of single-payer systems.

The authors of this paper are actuaries with extensive experience with private and public insurance and with health care provider systems. This report describes the research and opinions of the authors and should not be interpreted as the opinion of Milliman, Inc. Bruce Pyenson, Tia Goss Sawhney, and Eric Buzby are members of the American Academy of Actuaries and meet its qualification standards for this work. Our review is from a private payer perspective and for ICER's cost-effectiveness assessments only. The Pharmaceutical Research and Manufacturers of America, an industry group representing many brand drug companies, commissioned this work.

BACKGROUND

CONTEXT FOR PRIVATE PAYER DRUG COVERAGE DECISIONS

U.S. private payers, including insurance companies, Health Maintenance Organizations, and self-insured employers, provide health insurance to more than 200 million people, as shown in Table 1. This paper focuses on these private payers.

Table 1: 2016 Enrollment by Private Payer Market Segment

Private Payer Program ^a	Millions of People
Employer-sponsored plans ²	157
Individual market ³	13
Medicare Advantage Prescription Drug plans (MA-PDs) ⁴	14
Medicare Part D Plans (PDPs—drugs only) ⁵	25
Total	209

Within boundaries set by federal and state law and regulation, each U.S. private health care payer may make its own coverage decisions. The context for these decisions includes many factors specific to its business, including the characteristics of its insureds, the details of its contracts with physicians, hospitals, pharmacies and other providers, the demands of its market and pressure from competitors, as well as its financial goals and constraints. Private payers operate in an environment where many of these factors may be uncertain due to changing technology, epidemics and other disruptive events, changing regulations, and the actions of other parties in the health care system. Best practices for managing private payer business in this risky environment include the use of the actuarial control cycle, through which emerging results and information inform forecasts and decisions.

For private health care payers who cover comprehensive benefits, the cost of care (medical and prescription drug services) is typically over 80% of total plan spending, with administrative cost, contribution to surplus, and profit typically under 20% (Table A1^b). Depending on whether the plan offers medical benefits, prescription drugs may represent a small component or the only component of the cost of care. Each component of total cost of care, not just drugs, gets scrutinized by a typical private payer as part of its on-going business operations.

One way that private payers manage cost is by negotiating contracts for services with providers, including prices, rebates, and other financial terms. These contracts can specify prices for tens of thousands of services or drugs. Some contracts deal with commonplace but relatively inexpensive services, such as routine laboratory tests. Although individual laboratory tests may be low price, their high volume makes managing their cost important. Other contracts focus on rare services with very high prices, such as organ transplants. For services across the spectrum of price and frequency, private payers must decide whether and how to manage care and costs.

^a In addition to the programs listed in Table 1, tens of millions of people receive Medicaid benefits through private managed care organizations, but we do not examine that population in this paper because of the complex federal-state funding and rules for Medicaid

^b Table A1 shows a national average, high-level categorization of cost for private payers

A payer's decisions about which drugs to manage involves considering the administrative effort required, the potential to improve health, customer demand, and the impact on spending. There are thousands of different prescription drugs that a private payer can cover. Some drugs, such as orphan drugs, have very high prices but are rarely used. Other drugs have low prices and may be used by many people. Managing prescription drug spending, as with other categories, also involves decisions about member cost-sharing, medical management, network, and negotiated contracts.

Coverage decisions are often more nuanced than a binary, "covered" or "not covered," decision. Some drugs may be assigned lower cost-sharing and others higher cost-sharing, which is accomplished through drug "tiers." Some drugs may be covered as first-line drugs and some as second- or third-line drugs via "step therapy," which require a patient to try certain drugs, typically lower-priced, before trying more expensive drugs. Some drugs are covered through "prior authorization" by the payer, who may consider the patient's clinical condition before approving coverage. Sometimes drugs that are not explicitly covered may be covered after an appeal by the patient's physician. In addition, a private payer's cost-sharing policies, market competition, the role of Part D financing (reinsurance, low income subsidies, coverage gap discounts), and whether the payer is responsible for both the medical and drug coverage or only drug coverage may influence the private payer's decision.

The U.S. does not rely on direct government regulation to establish national prices and coverage decisions. Private payers of all kinds, including Medicare Part D and Medicare Advantage (MA) plans, negotiate their own pharmaceutical contracts and prices. MA plans must follow the coverage requirements set for the Medicare fee-for-service program, but the plans otherwise have flexibility.⁶

As expected in a competitive market, private payers vary in how they consider cost-effectiveness information (e.g., pharmacoeconomic information) when making coverage decisions. Medicare statute and policy recognizes cost-effectiveness as one factor, among many, that Part D plan pharmacy and therapeutics (P&T) committees may consider for coverage and formulary placement decisions.⁷ The dossiers for particular drugs that manufacturers develop using the Academy of Managed Care Pharmacy (AMCP) format or the analytics developed by payers' medical-technology committees may contain cost-effectiveness information.⁸ But, under some circumstances, using certain cost-effectiveness approaches to set coverage could be interpreted as discriminating against people with disabilities.⁹ Certainly, different companies make different decisions—even when they operate in the same market. For Part D, Medicare's Plan Finder,¹⁰ which finds plans in a beneficiary's locale that cover the beneficiary's prescriptions, is designed to help beneficiaries navigate this variability.

Compared to MA and Part D plans, which must meet Medicare standards, employer-sponsored plans have greater variability in what they cover and how they manage their plans. A private payer may offer dozens of health plans in the individual and employer-sponsored market and can vary drug coverage decisions by market segment (for example, individual, small group, large group) and by plan within segment. Plans need to vary certain decisions by market segment to comply with federal (Medicare, ERISA, ACA) or state regulatory requirements.

There are many health plan variations and nuanced coverage decisions across private payers. Payers' decisions vary depending on the needs and characteristics of the populations and markets

they are serving. Thus, national recommendations developed for an average population are difficult for particular payers to use, even if the recommendations are based on fully-transparent analysis and denominated in financial terms.

ICER OVERVIEW

Organization and Goals

The Institute for Clinical and Economic Review (ICER) is a Boston-based non-profit organization, founded in 2006 with the primary goal to “play a pivotal role in creating a future in which collaborative efforts to move evidence into action provide a foundation for a more effective, efficient, and just health care system” with an emphasis on analyzing drugs.¹ A common theme across the goals is that ICER takes a high-level “health system” perspective and seeks to advance health care system change (Table A2). ICER asserts that their value assessment framework and reports should be highly useful for today’s private payer drug coverage decisions (Table A3).

Value Assessment Framework

ICER’s “evidence reports” each examine a set of treatments related to a medical condition. ICER states that the “purpose of the value framework is to form the backbone of rigorous, transparent evidence reports that, within a broader mechanism of stakeholder and public engagement, will help the United States evolve toward a health care system that provides sustainable access to high-value care for all patients.” The value framework is intended to support system change, so the health care system and population are viewed in their entirety. In keeping with this “population perspective,” ICER does not differentiate among the many public and private payers or their differing populations.¹¹

Overview of Cost-Effectiveness Assessments

ICER’s cost-effectiveness assessments typically focus on a drug class and often coincide with the market-entry of a new drug. The core of the assessments is the calculation of the incremental cost per quality-adjusted life year (QALY), a number (scalar) that combines an estimate of an individual’s future life years with an estimate of that individual’s quality of life (QoL). QALYs are typically calculated for particular conditions or treatments. Incremental costs and QALYs are discounted lifetime values, relative to the cost and QALY of a comparator treatment. The comparator may be a single treatment, a combination of treatments, or no treatment. ICER attributes costs and QALYs to a specific treatment on an intent-to-treat basis, meaning that even if the patient uses the treatment for a short time before switching to another treatment (or to no treatment), the patient’s lifetime costs and QALYs are attributed to the first treatment.

ICER estimates incremental costs using estimated current average health-system-wide prices. When a treatment is not yet on the market, ICER estimates prices or price ranges based on information the drug manufacturer has provided, or estimates the drug prices that will produce costs per incremental QALY of \$50,000 to \$150,000. All costs are in current dollars with no estimates of future price changes unless they are reasonably anticipated in the next 12-24 months.¹¹ ICER discounts both costs and QALYs at 3% per year.

ICER prefers to use clinical evidence from randomized controlled trials (RCTs) and relies exclusively on data from peer-reviewed publications unless a necessary data element is found only in grey literature. Grey literature includes technical reports from recognized governmental authorities such as regulators and health technology assessment agencies, “conference proceedings and/or

abstracts, manufacturer submissions to regulators, technical briefs, and other online reports.”¹² ICER will also, when necessary, use unpublished, confidential data from pharmaceutical companies and other sources. ICER preserves the data confidentiality for up to 18 months after they release a final report.¹³

ICER has concluded that the break-point between a high-value and low-value treatment is generally between \$100,000 and \$150,000 per incremental QALY. ICER classifies treatments with costs less than \$50,000 per QALY as “high-value” and treatments with costs more than \$175,000 per QALY as “low-value.” Treatments with values \$50,000 to \$175,000 per QALY are classified as either high- or low- value through a vote of one of ICER’s review committees. The voting committee may consider factors not captured in the cost per QALY calculation, such as life-years gained.^{11, c}

^c QALYs assign a fractional value to an additional life year if the life year is lived in less than perfect health. Many argue that this unjustly diminishes life value for people with disabilities and chronic conditions.¹⁴

FINDINGS

We find that ICER cost-effectiveness assessments have little utility for private payer drug coverage decisions. The reasons for our conclusion include:

- ICER’s use of a total U.S. population and health care system perspective, even though no payer—private or public—serves the total U.S. population or pays national average costs.
- ICER’s reliance on QALYs, an intangible measure that currently has no applicability in private payers’ financial realities.
- ICER’s use of proprietary models, which prevents payers from modifying or customizing the models to reflect their circumstances.

In this section we discuss our findings and provide examples from recent ICER evidence reports.

PRIVATE PAYERS HAVE DIVERSE POPULATIONS AND COSTS

1. **Private payers serve distinct subpopulations of the U.S. population.** The same coverage decision may not be appropriate for all populations. Age and comorbidities may be important factors in appropriate care. A drug that is high value for a pediatric and working-age adult population with employer-sponsored coverage may not be appropriate for an elderly and disabled population with MA-PD coverage.¹⁵ The RCTs from which ICER prefers to gather clinical evidence sometimes underrepresent pediatric and elderly populations (and may also underrepresent people with multiple comorbidities, people of various races and ethnicities, and women).^{16, 17, 18}
2. **Different private payers have different prices—and these differences can lead to different decisions.** In the U.S., each large private payer can negotiate its own drug discounts and rebates, and there is significant variability. Private payers also have variable cost-sharing arrangements with their insureds. However, ICER uses common drug prices, net of assumed rebates and discounts. Rebates are typically connected to tier placement; a drug manufacturer can pay a higher rebate than competitors to obtain lower cost-sharing or reduced utilization management scrutiny for its product relative to competitors. ICER does not model the member cost-sharing impact. The interplay of these factors can mean that for one payer, drug A may be more expensive than drug B, but the opposite may be true for a different payer. Considering such factors means that different payers can come to different decisions.

Example: In the rheumatoid arthritis evidence report, ICER assumes that all drugs in a class have the same discount and rebates. This may not reflect an individual private payer’s net cost for each drug, as prices are negotiated at the drug-level, particularly for high-priced drugs.

Example: In the ovarian cancer evidence report, ICER assumes a common net price of 90% of Wholesaler Average Cost (WAC), to account for discounts and rebates, for all drugs evaluated. However, each drug likely has a negotiated net cost and the drugs may be placed on different formulary tiers. Thus, even if ICER’s estimate is good on average, the price paid by a specific payer for a specific drug may be quite different than ICER’s estimate.

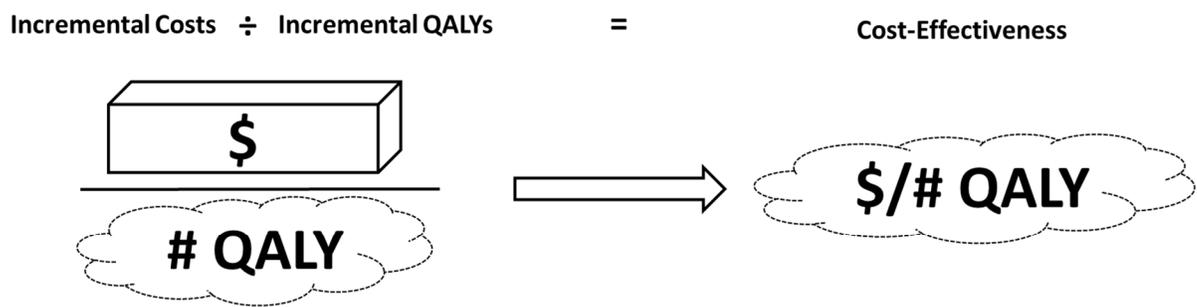
The peer-reviewed publications from which ICER prefers to gather data for non-drug costs typically reflect out-of-date prices for just one private payer or subpopulation. The widespread availability of large real-world data on medical prices and utilization patterns makes it puzzling that ICER prefers older published figures.

Example: In the osteoporosis evidence report, ICER’s sources for the cost of fracture treatment include a report that used MarketScan data from 2005 to 2007. Changes in treatments and prices since 2005 make this data less than ideal for determining the cost of treating fractures.

RELIANCE ON QALYS

- 3. QALYs may be a helpful academic tool, but are of limited practical use in real-world decision-making.** QALYs were developed as a method to include the QoL in economic modeling. QALYs combine the intangible, QoL, and tangible, the number of years of life, into a single theoretical numeric value.

Figure 1: Cost-Effectiveness using QALYs produces an intangible ratio



 brick = tangible (hard) value
 cloud = intangible (ethereal) value

Source: Milliman graphic

Dividing the dollar costs of an intervention by the QALYs associated with the intervention produces a ratio denominated in dollars, but this ratio does not appear in the financial accounting or forecasting by private payers (Figure 1). Private payers’ success depends on managing revenue, expense and capital, as summarized in payers’ audited financial statements. Thus, while QALY metrics provide a common, simplified measure of value that is useful from an academic perspective, they are of limited practical use for private payer real-world decision making.

- 4. QALYs assign diminished value to the elderly and disabled and do not put a premium value on preservation of life.** QALYs show lower values for elderly and disabled people, because QALYs consider future life span, which is lower for older or disabled people. Furthermore, ICER’s practice of discounting QALYs diminishes the importance of the later years of people who are not yet elderly.¹⁹ Since people who are disabled or near the end of life would have lower QALYs, a system that evaluates private payers based on their actual QALY performance could reward payers who avoid such patients.

Example: While most people, including people with paraplegia, value full mobility as desirable, people with paraplegia do not necessarily feel that their life is less valuable or less worthy of health service investment.

5. **ICER’s approach to QoL is not necessarily consistent from report to report.** ICER must often combine available data sources to develop QoL measures for a particular condition. The data sources and their quality vary by condition. The lack of consistent sources suggests that private payers should exercise caution in comparing ICER reports for different conditions.

Example: For the rheumatoid arthritis report, ICER used assumptions developed from two rheumatoid arthritis RCT studies to estimate Health Assessment Questionnaire (HAQ) scores from clinical outcomes as measured by the American College of Rheumatology (ACR) improvement criteria. They then used a formula from another study to estimate EQ-5D QoL values based on HAQ scores, age, duration of disease, and other parameters.

In contrast, for the osteoporosis report, ICER estimated the QoL impact of fractures by taking baseline EQ-5D QoL values for elderly women as reported by one study and multiplying these “by utility multipliers” for fractures. Depending on the type of fracture and the time since the fracture, the multiplier was developed from one or two of four studies of different populations, deploying different methodologies. In the absence of long-term data, ICER assumed women with hip or vertebral fractures lose a constant utility for the remainder of their post-recovery lives.

LACK OF ALIGNMENT WITH PRIVATE PAYER DECISIONS

6. **Private payers can best use assessments that support nuanced decisions.** Assessments that classify drugs as “low-value” and “high-value” imply that payers can, and should, cover high-value drugs and not cover low-value drugs. ICER’s assessments are best-suited for this binary environment. However, plans typically have very few drugs that are not covered under any circumstance, because people with private payer insurance expect wide access to treatments that provide good health outcomes. Instead, private payers prioritize drug choice using factors such as price, consumer demand, safety, and side-effects. Payers also have a variety of techniques for managing drug choice and utilization such as prior authorization, quantity limits, choosing first-line therapies, step therapy, and varied cost-sharing.²⁰ ICER’s single cost-effectiveness measure—cost per QALY—is not sufficient to guide these nuanced decisions.

Example: Safety considerations figure into payers’ formulary decisions, but the weight of safety considerations in ICER’s approach may not align with other’s views. In ICER’s cost-effectiveness analysis of disease-modifying therapies for multiple sclerosis, the drug ICER identified as the highest-value drug is one that the FDA does not recommend for first-line therapy use, because of its potential for adverse events. While ICER adjusted the cost per QALY for each treatment based on the average likelihood of the adverse events, the FDA views the risk associated with the product as too great for first-line use.

7. **ICER often uses a lifetime horizon, but private payers’ time horizons are seldom the lifetime of the population.** ICER uses a lifetime horizon to “reflect the chronic nature” of some diseases. A private payer’s financial responsibility for most of its insureds will end before the insureds’ lives end. This is particularly true for people covered under commercial insurance, which typically ends when an individual (or their spouse) changes employers, selects another plan during open enrollment, or enrolls in Medicare. Most payers will not see the full impact of QALYs gained, because their insureds will switch to other plans during their lifetimes. We see no reason for payers to unilaterally adopt a lifetime approach.

Example: The target population for ICER’s rheumatoid arthritis population has a mean age of 55 years. Since most people retire and switch to Medicare by age 65, an employer-sponsored plan covering a non-disabled 55 year old would plan to have responsibility for the patient’s costs for 10 years at most. This is particularly relevant for patients with rheumatoid arthritis as these patients may become disabled and eligible for Medicare well before age 65.²¹

8. **ICER may overstate the certainty of their assessments.**

a. **Short-term results applied to long-term projections.** Analyses that extrapolate from short-term results to long-term projections have inherent uncertainty. Long-range projections for aggregates, such as health care spending, are likely to be more accurate than projections for individual therapies, partly because fluctuations can affect individual therapies much more than aggregates. Long-term outcomes data is simply not available for many drugs, particularly newer drugs that have been approved based on short-term RCTs.

b. **RCT findings for one product applied to other products.**

Example: In the ovarian cancer evidence report, ICER extrapolates a significant relationship—the relationship between progression-free and overall survival—from one study to other studies, but the relationship may not hold in other circumstances. Although this extrapolation is noted in the limitations section of the report, the methodology calls into question the overall findings.

c. **Assumption testing.** While ICER tests the impact of some of the assumptions individually, they do not test the cumulative impact of the multiple assumptions and therefore overstate the certainty of their estimates.

d. **Use of inconsistent data to produce comparisons.**

Example: In its ovarian cancer report, ICER states that because of inconsistent data from RCTs for different PARP inhibitors, they “did not attempt to conduct any explicit or implied comparisons across PARP inhibitors,” but in comparing each drug to the same comparator (e.g., a placebo) and calculating a cost-effectiveness measure that is comparable across inhibitors, they appear to do just that. ICER’s warning not to compare across inhibitors is not included in the same section of the evidence report as the cost-effectiveness values, so we expect that readers will make this comparison.

9. **ICER does not prioritize the use of information that is relevant to private payers.** ICER’s preferred source of information is data from RCTs. However, RCTs test the efficacy of drugs for a select group of motivated patients under tightly defined, usually short-term, research protocols. Since RCT protocols may vary from one drug to another, the RCT data for one drug is often not directly comparable to the data for another drug, even within a drug class. In the real world, large numbers of patients take drugs under less-than-ideal circumstances, often over the long-term. Similarly, medicine usage may evolve to demonstrate broader applications than originally seen in trials. Therefore, a private payer that wants to deliver the best outcomes to its insureds often prefers recent real-world efficacy data when available.

Example: In its rheumatoid arthritis evidence report, ICER notes that the methodology is designed to remain consistent with RCT evidence rather than recognizing the real-world data related to dose escalation. Dosing and frequency, however, play a significant role in determining cost and outcomes.

10. **Private payers vary in their concern with non-drug (medical) costs.** ICER’s cost-effectiveness assessments consider the patient’s total cost of care—drug plus medical costs. While this is a basic component of sound value assessment and appropriate for health plans

that cover drug and medical costs, payers making decisions for stand-alone Medicare Part D plans are most concerned with drug costs. Similarly, payers managing HIV-AIDS special needs plans will be more focused on drugs than will payers managing general enrollment plans, because drugs are a mainstay of HIV-AIDS therapy. Clearly differentiating the services that generate costs or savings in its assessments would help payers adapt the assessments to their specific situations.

Example: Older women, generally covered by Medicare, are the primary patients for osteoporosis drugs that prevent fractures and the resulting hospital, surgical, skilled nursing home and other medical costs. ICER includes the medical savings in the cost-effectiveness analysis for osteoporosis drugs. About two-thirds of Medicare beneficiaries with Part D drug coverage, however, are covered under stand-alone Part D plans that do not include medical coverage.^{4,5}

PROPRIETARY, NON-TRANSPARENT MODELING

11. **ICER models are proprietary and do not accommodate customization by payers to reflect their own circumstances and needs.** ICER's cost-effectiveness models are built by contractors at academic institutions. Many of the details of these models are proprietary to the contractors and are not made public. According to ICER, intellectual property concerns prevent ICER from publicly releasing the full models that were used. However, many academic models have been placed in the public domain or are available for third-party use. We are intimately familiar with health care modeling and believe that ICER can choose open-source modelers. While ICER states that "an increasing number of [pharmaceutical] companies have told us that they have been able to replicate our results," ICER acknowledges the significant barriers that its approach presents to organizations trying to reproduce its results.¹¹

METHODOLOGY

We evaluated ICER’s evidence reports and value assessment framework by asking whether the information presented would assist private payers in making detailed drug coverage decisions. We considered that payers manage their particular provider contracts and costs and the health of their particular patient populations within the constraints of today’s health care system. We focused on whether the ICER material would help private payers in a way that would influence financial outcomes, premium rates, competitiveness, or contractual reimbursement. We did not attempt to assess whether a payer would benefit from publicizing its adherence with ICER recommendations.

We reviewed the following material from ICER:

- General overview of ICER’s original value assessment framework and a description of the 2017 updates to the framework¹¹
- Statement of ICER’s Commitment to Economic Model Transparency²²
- ICER Evidence Rating Matrix²³
- Policy on Inclusion of Grey Literature in Evidence Reviews¹²
- Guidelines on ICER’s Acceptance and Use of “In-Confidence” Data from Manufacturers of Pharmaceuticals, Devices, and other Health Interventions¹³
- Several recent final evidence reports (Table 3)

Table 3: ICER Topics Reviewed

Topic	Title	Final Evidence Report Date
Ovarian Cancer* ²⁴	“Poly ADP-Ribose Polymerase (PARP) Inhibitors for Ovarian Cancer”	September 28, 2017
Osteoporosis** ²⁵	“Anabolic Therapies for Osteoporosis in Postmenopausal Women”	July 17, 2017
Rheumatoid Arthritis** ²⁶	“Targeted Immune Modulators for Rheumatoid Arthritis”	April 7, 2017
Multiple Sclerosis** ²⁷	“Disease Modifying Therapies for Relapsing-Remitting and Primary-Progressive Multiple Sclerosis”	March 6, 2017

* Current value assessment framework

** Prior value assessment framework

CAVEATS AND LIMITATIONS

This report describes the research and opinions of the authors and should not be interpreted as the opinion of Milliman, Inc. Our report concerns the utility of ICER cost-effectiveness assessments for private payer drug decisions. We are not opining on the utility of ICER reports for other stakeholders and decisions.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Bruce Pyenson, Tia Goss Sawhney, and Eric Buzby are members of the American Academy of Actuaries and meet the qualification standards for this report.

The Pharmaceutical Research and Manufacturers of America, an industry group representing many brand drug companies, commissioned our work.

ENDNOTES

- ¹ Institute for Clinical and Economic Review, [About](#). Accessed 4 Sept. 2018.
- ² Kaiser Family Foundation, [Health Insurance Coverage of the Total Population](#). Accessed 20 Feb. 2018.
- ³ Kaiser Family Foundation, [Marketplace Enrollment](#). Accessed 20 Feb. 2018.
- ⁴ Kaiser Family Foundation, [Medicare Advantage: MA-PD Plan Enrollment](#). Accessed 20 Feb. 2018.
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APPENDIX

Tables

Table A1: 2016 Health Care Costs by Private Payer Market Segment

Approximate Annual Cost of Care	Private Payer Market Segment		
	Individual and Employer-Sponsored	Medicare Advantage-Part D (MA-PD)	Medicare Part D (Drugs Only)
Total Health Plan Revenue per Person per Year [1]	\$5,420	\$12,790	\$2,300
Costs as Percent of Total Revenue			
Administration, Tax, Contribution to Surplus, and Profit	12%	15%	12%
Hospital Services, excluding Outpatient Drugs	41%	35%	n/a
Physician and Other Professional Services	22%	18%	n/a
Drugs Covered as Medical Benefit [2]	5%	5%	n/a
Drugs Covered as Prescription Drug Benefit [3]	18%	17%	88%
Other [4]	2%	10%	n/a

[1] Total health plan (payer) revenue: premiums + federal payments (inclusive of Part D reinsurance, Part D low income subsidy, and ACA subsidies)

[2] Infused and other drugs requiring medically supervised administration, billed by hospitals and physicians

[3] Drug costs shown are after rebate reductions

[4] Skilled nursing facility services, home health care, hospice services, medical equipment and supplies, and more

Source: Milliman estimates using data from the Center for Economic and Policy Research, 2017 Medicare Trustees Report, Kaiser Family Foundation, and Milliman Health Cost Guidelines

Table A2: ICER’s Stated Goals

ICER Goal	Source
“...come up with a more precise [drug price] estimate incorporating average net prices, taking rebates into account, to determine what it [ICER] considers fair value-based pricing.”	Steve Pearson, reported by Reuters ^d
“...move the country toward a more transparent healthcare system that rewards medical innovation while allowing patients to access the treatments they need...”	Steve Pearson, reported by AJMC ^e
“ICER can help stakeholders build a system in which payers, policymakers, drug manufacturers, and others collaborate to bring new drugs to market in a way that allows for optimal patient access, without creating unsustainable strains on health care budgets.”	Kelli Rhee, Arnold Foundation, reported by AJMC ^e
Evaluates “evidence on the value of medical tests, treatments and delivery system innovations and moves that evidence into action to improve the health care system...”	ICER website (“ICER’s Own Words” section below)
Fill “a critical gap by creating sustainable initiatives with all health care stakeholders that can align efforts to use evidence to drive improvements in both practice and policy...”	ICER website (“ICER’s Own Words” section below)
“ICER hopes to create a path toward a future in which prices better mirror how much better a new drug is in improving patients’ lives.”	ICER website (“ICER’s Own Words” section below)

Table A3: ICER “Added-Value” Statements

ICER’s Value for Drug Coverage Decisions	Source
ICER “develops reports...that make it easier to translate evidence into decisions.”	ICER website (“ICER’s Own Words” section below)
“Insurers have always faced the challenge of interpreting evidence on new treatments and deciding if and how to provide coverage for them. ICER offers an independent and objective source of information to support this process.”	ICER website (“ICER’s Own Words” section below)

^d Reuters, [“U.S. Drug Pricing Watchdog Gets Funding to Expand Efforts.”](#) Accessed 4 Sept. 2018.

^e The American Journal of Managed Care, [“ICER Receives \\$13.9 Million Grant, Plans to Assess All New Drugs.”](#) Accessed 4 Sept. 2018.

ICER's Own Words

About ICER^f

ICER is a trusted non-profit organization that evaluates evidence on the value of medical tests, treatments and delivery system innovations and moves that evidence into action to improve the health care system. To accomplish this goal ICER performs analyses on effectiveness and costs; develops reports using innovative methods that make it easier to translate evidence into decisions; and, most distinctively, fills a critical gap by creating sustainable initiatives with all health care stakeholders that can align efforts to use evidence to drive improvements in both practice and policy. Through all its work, ICER seeks to play a pivotal role in creating a future in which collaborative efforts to move evidence into action provide a foundation for a more effective, efficient, and just health care system.

Frequently Asked Questions^g

What is ICER?

ICER's mission is to help provide an independent source of analysis of evidence on effectiveness and value to improve the quality of care that patients receive while supporting a broader dialogue on value in which all stakeholders can participate fully.

Isn't ICER just a mouthpiece for the insurance industry? Doesn't most of your funding come from them?

We do not represent the interests of the insurance industry. Our reports follow the evidence: some have found that the evidence on the comparative effectiveness of a new drug is extremely limited; for other drugs we have judged the evidence to be robust and persuasive. Some of our reports have calculated that the list price of a new drug is much higher than can be justified by how much better it is at helping patients, but other reports have found that the list price of some new drugs are well aligned with patient value, or could even be higher. We have even found that some new drugs save costs overall in the health system and are outstanding values. Our aim is not to support one side in a negotiation; it is to provide what our health care system has lacked for so long: an independent, trustworthy source of information that can bring all voices into the discussion on value.

Why is this work important?

We need prices that make sense. Right now, it's often a black box: we don't know if we are getting good value with new drugs at the prices that are being charged. ICER hopes to create a path toward a future in which prices better mirror how much better a new drug is in improving patients' lives. This will help reward innovation that makes a difference for patients while making the overall costs of drugs in the health care system a better value.

What is in your reports?

Each report includes a full analysis of how the drugs work (comparative effectiveness), and the value the treatments represent to patients and the health care system (cost-effectiveness and the potential budget impact). The reports support the goal of getting excellent drugs to market quickly at a price that is affordable to patients and the health system, without hindering the development of new and effective drugs.

How does ICER fit in the movement to make care more patient-centered?

The ICER value framework is deeply patient-centered: it is explicitly structured to capture what patients feel is important in their care. It was developed with the primary intent of helping bring more transparency to the negotiations between the life science industry and insurers over the coverage and prices of new health care interventions.

Won't ICER's reports be used to limit needed care?

Insurers have always faced the challenge of interpreting evidence on new treatments and deciding if and how to provide coverage for them. ICER offers an independent and objective source of information to support this process.

^f Institute for Clinical and Economic Review, [About](#). Accessed 20 Feb. 2018.

^g Institute for Clinical and Economic Review, [Frequently Asked Questions](#). Accessed 20 Feb. 2018.

Perspective from Surveys of Payer Decision Makers

Several organizations have conducted surveys of private payers' use of ICER's cost-effectiveness assessments and have results showing that payers rarely rely on ICER's recommendations. These results are consistent with our findings that these assessments have little utility for private payer drug coverage decisions. We did not perform a systematic literature search for surveys, and it is possible that other surveys may show different results.

- Xcenda, a pharmaceutical consulting firm, collected data in November 2016 from 55 survey respondents, mostly representing managed care organizations and pharmacy benefit managers. The majority (51%) reported that ICER recommendations do not influence decisions and only 5% reported that ICER recommendations often influenced decisions. 44% reported that ICER recommendations occasionally influence decisions. The respondents felt that the comparative clinical effectiveness (clinical benefit, patient-centered outcomes, and clinical harm) portion of the ICER assessments were by far the most influential portion of the assessment.^h
- Precision for Value, a pharmaceutical and life sciences consulting firm, collected data in August 2016 from 28 medical and pharmacy director respondents representing approximately 160 million privately-insured people. They found that ICER is not used for any purpose by 75% of respondents.ⁱ
- Avalere Health, a health care consulting firm, interviewed 11 payers in the summer of 2016. The interviewees were primarily medical and pharmacy directors. Avalere found that none of the payers actively used ICER assessments, but that some anticipated the possibility of using ICER in the future (but none of them felt the possibility was “very likely”).^j
- Argenta Advisors, a health care consulting firm, interviewed the medical director of a major national health plan in early 2015. He mentioned ICER reports as one of many sources used to develop an evidence “dossier.” He listed considerations weighed during the decision-making process, including ethical, legal, political, and social considerations that are not part of ICER's analysis.^k
- Dymaxium, a firm specializing in data exchange between payers and life sciences companies and data support for reimbursement decisions, presented the results of a survey of 99 decision makers in managed care, pharmacy benefit organizations, hospitals, and other organizations in December 2015. The survey found that 59% had used ICER reports or their organizations had used ICER reports. The most common use was during the evidence collection phase of the decision-making process. The next most common use was to inform or validate the organization's own analysis.^l

^h Xcenda, [“Payer Perceptions and Utilization of ICER Value Assessment Framework.”](#) Accessed 4 Sept. 2018.

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^j Avalere, [“Most Health Plans Do Not Use Existing Value Frameworks to Make Coverage Decisions.”](#) Accessed 4 Sept. 2018.

^k MedTechIntelligence, [“A Major National Health Plan Medical Director Shares Insights on How Coverage Decisions are Made.”](#) Accessed 4 Sept. 2018.

^l Dymaxium. (2015). “Developing and Using Value Frameworks Part II” [Video webinar]. Retrieved from <http://www.amcp.org/Newsletter.aspx?id=20457> on 4 Sept. 2018.