



The Utility of ICER Reports for Private Payer Budgeting: Budget Impact Analyses

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EXECUTIVE SUMMARY

BACKGROUND

U.S. private healthcare payers, including insurers and self-insured employers, provide health insurance to more than 200 million people. These private payers face complex budget challenges caused by medical inflation, new technology, shifts in practice patterns, and many other factors. These factors can change continuously, but most payers set budgets annually well in advance of the plan year. Insurers' strategic decisions, such as whether to remain in markets or enter new markets, require multi-year budgets. Unexpected variance in healthcare costs compared to budget affects the private payer's bottom line and may undermine profitability or solvency. Changes in healthcare costs that appear suddenly, such as the introduction of expensive but easy-to-take cures for hepatitis C, can require the private payer to make difficult decisions that may impact their long-term financial health.

The Institute for Clinical and Economic Review (ICER) publishes value assessments for new drugs that include a "potential budget impact." ICER believes that including the potential budget impact will help relevant parties, including payers, understand whether the costs of a new drug represent such a significant impact to budgets that short-term cost management actions are required, such as "a lower price, prioritization of treatment for certain patients, or re-allocation of resources from other health services."¹ ICER budget impact analyses may provide negotiating points that some payers can use when contracting for certain drugs. However, this report identifies several disconnects between ICER's work and its potential use by private payers to analyze the impact of new drugs on their budgets. These include:

- ICER's budget impact threshold calculation methodology is highly variable, ignores important dynamics of the drug marketplace, and uses ICER's national spending targets as benchmarks rather than private payers' goals.
- ICER's national-level analysis ignores many of the financial, operational, and clinical realities of today's healthcare system that strongly affect the impact of new drugs on private payer's budgets.

KEY FINDINGS

ICER'S METHODOLOGY DOES NOT ALIGN WITH PRIVATE-PAYER BUDGETING PROCESSES

- **ICER's budget threshold serves to create a single, national list of new drugs to further evaluate, but different payers can come to different decisions about the impact of a new drug based on their own circumstances.** Each individual private payer is responsible for its own population. Different payers may place different values on a drug as they make decisions based on their own populations and other circumstances, not just the average population.
- **Payers have varied techniques to manage costs to a budget.** Private payers have an array of strategies such as prior authorization and cost-sharing to manage their budgets, rather than simply deciding whether or not to cover a drug. Which techniques a private payer chooses to employ, if any, depend on its own particular circumstances including its insured population.
- **ICER does not consider the potential impact of a new drug on prices for existing drugs.** Due to marketplace competition and financial forces, the entrance of a new drug can cause the prices of other drugs to increase or decrease.
- **ICER anticipates medical savings and nets them against drug costs.** Payers that are responsible for only drug costs will not benefit from any associated medical savings.

- **ICER calculates the average annual budget impact for a drug across five years without providing yearly detail.** Private payers typically update their budgets annually, making a five-year average number difficult to apply as new drugs typically increase in cost and expand in use over several years.
- **A national budget impact threshold does not consider risk to payers.** A low-priced and widely used drug can have a much larger national budget impact than a very high-priced and very rare drug. However, a small payer could be hurt financially if it insures someone who needs the very high-priced drug. Assuming that rare events are spread evenly over the entire healthcare system does not work well for rare events that are expensive and happen to a small payer.
- **ICER does not consistently use real-world data and assumptions in their incremental cost calculations.** ICER does not consider price offsets, such as cost-sharing, or the current market share of existing drugs, making the budget impact analyses inappropriate for private payer utilization.
- **ICER does not present detailed models that would enable payers to make adjustments for their own circumstances.**

ICER'S NATIONAL BUDGET IMPACT APPROACH SUFFERS FROM SEVERAL TECHNICAL CHALLENGES

- **ICER's budget threshold can vary greatly from year to year.** ICER's budget threshold for a drug approved in a particular year is tied to the number of FDA approvals in the prior two years. Since the number of FDA approvals varies significantly from year to year, the per-drug cost threshold has the potential to vary significantly each year.
- **ICER focuses disproportionately on novel drugs, but novel drugs might not have the most important budget impacts.** Existing drugs usually have a greater impact to payer's budgets than new drugs, but ICER focuses on new drugs.
- **An unintended consequence of ICER's budget impact approach could be to set a price floor for some drugs.** By providing a cost benchmark in its analysis, some manufacturers may set their price at the benchmark, which could be higher than they otherwise would have chosen.
- **The allowable spending increase that ICER uses for the budget impact threshold calculation is arbitrary.** GDP growth plus 1% is not consistent with either historical experience or expected future pharmacy cost growth.

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, Eric Buzby, and Tia Goss Sawhney 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 potential budget impact analyses only. The Pharmaceutical Research and Manufacturers of America, an industry group representing many brand drug companies, commissioned this work.

BACKGROUND

PRIVATE PAYER BUDGETING OVERVIEW

U.S. private payers, including insurance companies, Health Maintenance Organizations, and self-insured employers, provide health insurance to more than 200 million people (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

Budgets

Budgeting is an annual, concrete exercise that uses estimates based on real-world data. Each U.S. private health care payer sets its own budget and makes its own budget-related decisions. The budget process occurs in the context of an organization’s business, financial goals, constraints, the demands of its market, pressure from competitors, the characteristics of its insureds, and the details of its health care coverage including financial arrangements with providers and drug suppliers. If the private payer is an insurer, the revenues are member or policyholder premium and other revenue (such as CMS revenue for Medicare Advantage plans), and the expenditures are healthcare and administrative costs. If the private payer is a self-insured employer, the employer receives employee payroll contributions and pays for health care and administrative costs. For both insurers and employers, budgets always consider expenditures net of cost-sharing. While there is often some degree of conservatism built into the budget, budgets must align with real-world financial resources.

For private payers that cover comprehensive benefit plans, the cost of care (medical and prescription drug services) is typically more than 80% of total plan expenditures, with administrative cost, contribution to surplus, and profit typically under 20% (Table A1). Prescription drugs may represent a small component or the only component of the cost of care; for example, Medicare Part D plans cover only drugs. Each component of total cost of care gets scrutinized by a typical private payer as part of its budgeting process.

^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

Budgets and Risk

The most important budgeting metric is the year-over-year trend in total healthcare costs. The U.S. has had persistent medical inflation for decades, so the change in cost is almost always an increase. If the estimated increase in total healthcare costs is greater than the increase in revenues, then management will evaluate how to decrease costs or obtain more revenues to cover healthcare costs.

Private payers do not have standards for what constitutes too big an increase. Instead, payers focus on how the overall budget can be funded and how the overall budget will affect the business. Private payers must consider the competitive consequences of funding—for example, will an insurer lose business if it raises premium rates, or will an employer lose valuable employees if it cuts benefits. Some budget impacts can be funded over time, with losses in some years offset by gains in other years.

When payers face financial scrutiny, tradeoffs become inevitable. For example, large increases in prescription drug costs may result in more vigorous negotiation of hospital contracts to constrain spending in that area. Competition among insurers can constrain premium increases, which may result in tighter budgets for administrative costs or healthcare spending. Financial pressures on employers can lead to reductions in benefits, such as increases in cost-sharing or employee payroll contributions.

Of course, budget forecasts can never predict all risks. Economic slowdowns, new competition, and many other factors can cause significant and unexpected variations from the forecast budget. If an insurer incurs losses in one year, they will often try to recoup those losses in a future period. Sometimes, adverse events coincide with one another, and the adverse effects compound to produce financial losses. Unexpected adverse fluctuations and their impact on solvency is a critical issue for insurers, which has led to regulatory requirements for reserves and surplus. We do not address unexpected fluctuations further than to say that the best budget impact models will not eliminate the need to manage risk.

Budget Impact of a New Drug

In order to estimate the budget impact of a new drug within a drug class, the budgeters need to know or estimate, *for the population that the payer insures*,

- 1) The use and cost of existing drugs within the class during the base period
- 2) The expected use and cost of the new drug
- 3) How the new drug will (or will not) impact the existing users of the drug class, the relative use of drugs within the class, and costs of other drugs within the class
- 4) Any impacts on spending on medical services or drugs outside the class

Illustration 1 in the Appendix shows a simplified budget impact calculation for an employer-sponsored plan of 100,000 members for a new drug.

Budget Management—and Managing to a Budget

One way private payers manage budgets is by negotiating financial terms, which can span several years, such as unit prices, discounts, and rebates with providers or drug suppliers. These contracts can specify prices for tens of thousands of services or drugs. Some drugs, such as orphan drugs, have very high prices but are rarely used, but others have low prices and may be more commonly used. A payer's decisions about targeting specific drugs for active negotiation involves considering the administrative

effort required and the potential to reduce spending. Managing prescription drug budgets, as with other categories of services, requires information about member cost-sharing, medical management, provider and/or pharmacy network arrangements, and negotiated contracts.

Coverage decisions, which include which drugs to cover (and member cost-sharing) also have cost impact and are integral to budgeting. For example, Sovaldi was introduced in 2014 as a cure for hepatitis C, and it had a significant impact on healthcare spending, even though its price was close to that of existing therapy.^{6,7} New drugs can also have small consequence when compared to the background inflation relative to drugs that are already covered.

ICER OVERVIEW

Organization and Goals

The Institute for Clinical and Economic Review 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.⁸ ICER’s work is from the perspective of the U.S. healthcare system and is, generally speaking, forward-looking to the healthcare system that it desires for tomorrow and therefore not necessarily aligned with the multi-payer realities of today’s healthcare system.

Value Assessment Framework

ICER’s core products are “Evidence Reports.” Each evidence report examines a class of treatments, often but not exclusively drug treatments. 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 it assesses the US “health care system” from a “population perspective,” with the health care system and population viewed as a whole entity. In keeping with this perspective, ICER does not differentiate between public and private payers and does not differentiate the populations that public and private payers serve. ICER refers to this as a “full societal perspective.”⁹

ICER’s Thresholds (Limits) for Budget Impact

ICER’s evidence reports typically focus on drugs that have recently entered or are soon to enter the market. An important component of these reports is comparing the potential budget impact of a drug to a nationwide spending threshold. ICER develops its estimate of the percentage of the total population needing treatment that would be able to be treated before hitting their threshold at various price points for the treatment. The calculations use price points of Wholesale Acquisition Cost (WAC) and discounted WAC, and also calculate the prices that produce \$50,000-\$150,000 per quality-adjusted life year (QALY), leveraged from ICER’s own cost-effectiveness assessments. The implication is that if fewer than 100% of the treatable population can be treated at a given price, then that price is too expensive. However, ICER acknowledges that its budget assessments are not aligned with payer budgets and that payers set annual (not five-year) budgets by type of service (and do not net drug and hospital costs) and that the misalignments reduce the utility of their assessments for most payers.

The ICER framework document says that “...the perverse influence of an undiluted focus on budget impact cannot be overstated. A narrow short-term [budget] perspective blinds policy makers, insurers, and providers to the need to forge efforts to reshape the delivery system and reframe payment mechanisms to ‘make room’ for new, and potentially expensive interventions that will help patients and pay off in the end. Therefore, if an economic analysis of new interventions is focused only on the short term, relying solely on budget impact estimates, patients and the health care system will be the ultimate losers.”⁹

The ICER threshold is calculated so that the contribution of new drugs to total healthcare spending will be consistent with historical levels. An annual aggregate threshold for U.S. healthcare spending is calculated as the prior year’s spending increased at the rate of GDP growth plus 1%. New drug spending is determined for the entire U.S. healthcare system based on the historical percentage attributed to drug spend and then converted to a per drug amount threshold by dividing the aggregate threshold by the number of new drugs approved by the FDA in recent years. The per-drug amount is then doubled to produce ICER’s ultimate budget threshold. Table 2 is ICER’s calculation of the 2017-2019 annual threshold for budget impact—\$915 million for 2017-2018 and \$991 million for 2018-2019.

Table 2: ICER’s Calculation of the 2017-2019 Annual Threshold for Budget Impact

Item	Parameter	2017-2018	2018-2019	Source
1	Growth in US GDP (est.) +1%	3.2%	3.5%	World Bank (2017, 2018)
2	Total personal medical health care spending	\$2.71 trillion	\$2.88 trillion	CMS NHE (2017, 2018)
3	Contribution of drug spending to total health care spending	17.7%	17.0%	CMS NHE (2017, 2018); Altarum Institute (2014, 2017)
4	Contribution of drug spending to total health care spending	\$479 billion	\$481 billion	(2) x (3)
5	Annual threshold for net health care cost growth for ALL drugs	\$15.3 billion	\$16.8 billion	(1) x (4)
6	Average annual number of new molecular entity approvals ^b	33.5	34	FDA (2015/16, 2016/17)
7	Annual threshold for average cost growth per individual new molecular entity	\$457.5 million	\$495.3 million	(5) / (6)
8	Annual threshold for estimated potential budget impact for each individual new molecular entity	\$915 million	\$991 million	(7) x 2

Source: ICER^{9,10}

^b See Appendix Table A3 for listing of new molecular approvals by year

FINDINGS

ICER compares the incremental cost of a new drug to a macro-economic threshold and implies a pass-fail choice for drug coverage. However, the ICER budget threshold calculation suffers from several critical technical challenges and ICER's approach does not allow its results to be used for quantitative input by payer budget processes.

LACK OF ALIGNMENT WITH PAYER BUDGETING PROCESSES

ICER states that its evidence reports support “population-level decisions and policies, such as broad guidelines on appropriate care, pricing, insurance coverage determinations, and payment mechanisms.”⁹ However, the population-level perspective (e.g., total U.S. population) does not support private payer budgeting processes, because all private payers have populations that differ in important ways from the national average. The decisions made by private payers take into account the characteristics of the population they are insuring, their responsibilities to those insured populations, and the competitiveness of their coverage relative to peers. Furthermore, private payers' outcomes are in no way tied to national outcomes. There is no mechanism for a private payer create an accounting entry or financial asset associated with ICER's national-level goals. The discrepancies between the population-level perspective and a private payer's perspective are highlighted below.

1. **ICER's budget threshold serves to create a single, national list of new drugs to further evaluate, but different payers can come to different decisions about the impact of a new drug based on their own circumstances.** A private payer's decision will vary depending on the value of the drug to their organization. For example, a payer heavily affected by behavioral illness (perhaps a special needs plan) may have a different perspective than a large commercial payer on whether to be concerned about a new drug for patients with mental health conditions.
2. **Payers have varied techniques to manage costs to a budget.** Payer decisions may be to cover or to not cover a drug, but, more often, the decisions involve ways to manage the use of a new drug, such as prior-authorization, or ways to manage the cost of the drug, such as limited networks or cost-sharing. While drugs that exceed ICER's threshold set off an “affordability and access alert,”⁹ the extent to which this is needed and what utilization management techniques are then used will depend on the payer's circumstances and the disease burden of its population. This flexibility is not part of ICER's budget impact analysis.
3. **ICER does not consider the potential impact of a new drug on prices for existing drugs.** Some drugs compete against other drugs, so the entrance of a new drug can affect other drug prices. Historically, the prices of existing drugs may go up or down after competitors are launched depending on the competitive response and negotiations with payers. These changes can have an important impact.
4. **ICER anticipates medical savings and nets them against drug costs.** The budget impact analysis assumes that a new drug may replace current therapies' costs and generate incremental savings in other parts of the healthcare system (such as hospital costs) during the 5-year period. While some payers may benefit from medical savings, other payers, such as Part D plans, do not benefit from medical savings, so offsetting the cost of new therapies will understate the true budget impact.
5. **ICER calculates the average annual budget impact for a drug across five years, without providing yearly detail.** Private payer budgets are typically focused on the next year—and budgets

are updated annually. A five-year average calculation is difficult to apply in relevant annual increments, because new drugs typically increase in cost and expand in use over several years. Private payers focus on their plan's liability at the expected cost and uptake rate for the next year, not in future years, so this budget impact is likely overstated for the period of concern. Additionally, ICER's average annual incremental cost calculation assumes there will be no future price changes (for the drug, the comparative drug(s), or any other part of the healthcare system), unless there is anticipation with "high likelihood of a major change to pricing" in the next 12-24 months.⁹

6. **The national budget impact does not consider risk to payers.** Sales of Tylenol from 2014 through 2016 exceeded \$915 million annually,¹¹ which is above the ICER threshold set for 2017-2018. Even if Tylenol were covered by insurance, its use and low per-unit cost is spread throughout the entire healthcare system, so the impact would be relatively evenly spread across many payers. However, Voretigene Neparovec, a treatment for Biallelic RPE65-mediated retinal disease at its \$107,080 cost could have a significant impact on a small, self-insured employer if several covered lives were affected, even though ICER's evidence report indicates that the healthcare system, as a whole, can sustain the budget impact of this treatment.¹²
7. **ICER does not consistently use real world data and assumptions in their incremental cost calculations.** Budgeting is a real world exercise. The base year needs to use real world data, some of which is confidential and/or unique to particular payers and plans.
 - a. **Price offsets.** ICER does not consider patient cost-sharing or Part D reinsurance and coverage gap discounts in its calculations. Cost-sharing is specific to a health plan and is used to steer patients from one drug to another, to competitively position plans, and to offset costs. The impact of patient cost-sharing and plan design are important.
 - b. **Other data and assumptions.** ICER does not consider current market share when discussing the incremental cost of a new drug. For example, in ICER's multiple sclerosis (MS) report, they used natalizumab as a reference for daclizumab, but ignored that natalizumab is not the current or even dominant treatment for all people with relapsing-remitting MS. In the analysis, they assumed all treated MS patients would switch from natalizumab to daclizumab. Of course, it is impossible for more people to switch from natalizumab than are currently prescribed that treatment, so this simplification produced an inappropriate budget impact.
8. **ICER does not present detailed models that would enable payers to make adjustments for their own circumstances.** A model similar to Illustration 1 would be very useful to payers, but we could not reproduce ICER's budget impact calculations from the material that they present in their evidence reports. The ICER reports show only the average incremental annual cost over a five-year period.

TECHNICAL CHALLENGES WITH ICER'S NATIONAL BUDGET IMPACT APPROACH

ICER's updated value assessment framework overview states that a goal is to "provide mechanisms through which all stakeholders and the general public can engage in discussions...for a more effective and sustainable health care system."⁹ However, as described below, ICER's budget impact approach relies on a volatile metric which missteps on real-world costs and historical trends.

9. **ICER's budget threshold can vary greatly from year to year.** To determine the threshold per new molecular entity (NME), ICER divides the national threshold amount (total maximum drug cost growth) by the average number of FDA approvals for the prior two years. In its updated budget threshold calculation for 2017-2018, ICER used 33.5 approvals, which was the average of 45 approvals in 2015 and 22 approvals in 2016. This method will be volatile, because the number of FDA approvals is

volatile. Based on the number of FDA approvals from 1996 to 2017 the two-year-averaged approvals ranged from a minimum of 19 (2002-2003) to a maximum of 46 (1996-1997). See Table A3 for the number of Center for Drug Evaluation and Research new molecular entity approvals since 1994. Since 2010, the minimum two-year average number of approvals was 23.5 (2009-2010) and the maximum was 43 (2014-2015). Using ICER's budget threshold calculation, we created two alternative scenarios, replacing the number of FDA approvals (33.5) used in ICER's 2017-2018 threshold with the minimum (23.5) and the maximum (43) historical figures. The results of the two scenarios show that the threshold for 2017-2018 would have been either 20% lower or 40% higher using the maximum and minimum, respectively, of recent approvals. See Table A2 of the Appendix for details of this calculation. This analysis shows that a drug that exceeds the threshold in its year of approval might have fallen below the threshold if its approval had simply been delayed to the next calendar year.

10. **ICER focuses disproportionately on novel drugs, but novel drugs might not have the most important budget impacts.** ICER analyses focus exclusively on new drugs. ICER acknowledges this limitation in its updated overview of the value assessment framework, stating that it “[assumes] all net health budget impact for drug spending can be allocated to new drugs alone, requiring an assumption that the background spending on existing drugs is net neutral.”⁹ Existing drugs far exceed new drugs in both quantity and spending.^{13,14}
11. **An unintended consequence of ICER's budget impact approach could be to set a price floor for some drugs.** While manufacturers could reduce very high prices to meet the budget threshold, manufacturers could also set the price of a new drug at a level just below the budget threshold instead of a lower price and cite ICER reports for support. One example of such unintended consequences occurred with Medicaid Best Price rules in the early 1990s. Under the Omnibus Reconciliation Act of 1990, Medicaid was to pay for drugs the lower of the best price offered to any private payer or 15% off the list price. Manufacturers reacted to this new legislation by reducing discounts given to private payers rather than decreasing the amounts charged to Medicaid, so Medicaid received no savings and private payers were charged more than they were prior to this legislation.¹⁵
12. **The allowable spending increase that ICER uses for the budget impact threshold calculation is arbitrary.** ICER limits growth due to new drugs to the rate of U.S. GDP growth plus 1% “based on an underlying assumption that health care costs should not grow much faster than growth in the overall national economy.”¹⁶ Since 2001, health care cost growth has not come within 1% of the US national GDP growth—coming closest in 2010 when health care cost growth was 1.4% greater. The average health care cost growth over this period was 4% higher than GDP growth.^{17,18} Pharmacy cost trends should not be expected to follow GDP trends as they are subject to new drug approvals and patent expirations. Since 2010, nominal pharmacy per capita retail drug spending has ranged from -0.7% in 2010 to 11.5% in 2014.¹⁹

METHODOLOGY

Our approach to evaluating ICER's budget impact component of the value assessment framework was to consider whether ICER information would assist private payers in setting budgets and making budget-related decisions—within the realities and constraints of today's healthcare system.

Our approach is largely from an actuarial perspective, and we focus on whether ICER budget analyses would influence private payer budgets and, in particular, financial forecasts, premium rates, contractual reimbursement, or drug coverage decisions. We evaluated the methodology of the budget threshold calculation by first validating the threshold calculation and then determined whether the threshold itself was applicable to the decision-making process of private payers.

To support our investigation, we reviewed the general overview of the framework and description of the 2017 update to the framework,⁹ examined the ICER budget impact analyses from the evidence reports as noted in this paper, leveraged the information in the pharmaceutical data warehouse, *EvaluatePharma*, and compared the assumptions in ICER's budget threshold calculation to historical trends.

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 budget impact analyses for private payer budgeting. 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, Eric Buzby, and Tia Goss Sawhney 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, [FAQ](#). 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.
- ⁵ Kaiser Family Foundation, [Medicare Prescription Drug Plans: Stand Alone PDP Enrollment](#). Accessed 20 Feb. 2018.
- ⁶ Managed Care Magazine, [Payers Consider Waiting Out Budget-Busting Hepatitis C Drug](#). Accessed 7 Nov. 2018.
- ⁷ United States Senate, Committee on Finance. [The Price of Sovaldi and Its Impact on the U.S. Health Care System](#). 114th Cong. 1st sess. S. Prt. 114-20. Washington: GPO, 2015. Accessed 7 Nov. 2018.
- ⁸ Institute for Clinical and Economic Review, [About](#). Accessed 4 Sept. 2018.
- ⁹ Institute for Clinical and Economic Review, 2018: [Overview of the ICER value assessment framework and update for 2017-2019](#). Accessed 21 Jun. 2018.
- ¹⁰ Institute for Clinical and Economic Review, 2017: [Overview of the ICER value assessment framework and update for 2017-2019](#). Accessed 12 Mar. 2018.
- ¹¹ *EvaluatePharma*. Evaluate Group, 2018, <http://www.evaluategroup.com>. Accessed 12 March 2018.
- ¹² Institute for Clinical and Economic Review, [Voretigene Neparvec for Biallelic RPE65-Mediated Retinal Disease: Effectiveness and Value](#). Accessed 12 Mar. 2018.
- ¹³ Department of Health & Human Services. (2016). [Observations on Trends in Prescription Drug Spending](#). Accessed 12 Jan. 2018.
- ¹⁴ Vizient. (2017). [Drug Price Forecast Executive Summary July 2017](#). Accessed 19 Jun. 2018.
- ¹⁵ Congressional Budget Office. (1996). [How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry](#). Accessed 21 Jun. 2018.
- ¹⁶ Institute for Clinical and Economic Review, [Poly ADP-Ribose Polymerase \(PARP\) Inhibitors for Ovarian Cancer: Effectiveness and Value](#). Accessed 20 Nov. 2017.
- ¹⁷ The World Bank, [GDP growth \(annual %\)](#). Accessed 14 Mar. 2018.
- ¹⁸ Centers for Medicare & Medicaid Services, [Historical National Health Expenditure Data](#). Accessed 14 Mar. 2018.
- ¹⁹ Peterson-Kaiser Health System Tracker. (2017). [What are the recent and forecasted trends in prescription drug spending?](#) Accessed 29 Jun. 2018.

APPENDIX

ILLUSTRATIVE BUDGET DEVELOPMENT

The budgeting process typically starts with the revenues and expenditures from a previous, “baseline” year with changes made to account for differences between the baseline experience and expectations for the future year. Expectations for a future year can reflect differences in the covered population or its benefits, changes to spending for medical services or drugs, an existing or a new service (medical or drug), the unit cost of the service, the number of people using the service, or the intensity or mix of services. Healthcare budgets are typically set on a calendar year basis and disaggregated by type of service, such as “inpatient hospital” or “prescription drug.” Prescription drugs may be further separated into generics, brands, and specialty drugs, although large Part D plans will examine individual drugs.

Illustration 1 shows a simplified budget impact calculation for an employer-sponsored plan of 100,000 members for a new drug that costs twice as much as the existing drugs in the class, expands the number of users of the drug class by 10%, and obtains a 30% market share within the class. We also assume an annual cost trend for current treatments of 5%. The 0.2% budget impact (\$1.12 PMPM change to a base year cost of \$450 PMPM) of the illustrative drug is likely sufficient to add this drug to the budgeting radar (along with other significant changes), particularly since the advantages of the new drug will impact only 66 out of 100,000 members ($0.22\% \times 30\% \times 100,000$).

Although the concepts in Illustration 1 are simple, the measurements are not. “Cost per month of treatment” is the negotiated cost of a month of the drug, less rebates, member cost-sharing, and other cost offsets. If this were a Part D plan, the federal reinsurance, coverage gap discount, and low-income subsidies would also apply. The percent of members treated and percent of treatments attributed to each drug is a function of the insured population, drug coverage decisions, member cost-sharing, a host of conditions not under a payer’s control, and the competitive pressures drug companies put on each other.

Illustration 1: Budget Impact Analysis for a New Drug for a Self-Insured Employer
Step 1 -- Average Cost per Month Calculation

		Drug A	Drug B	Drug C (New)	Total	Average	% Change
2016	Average # of Patients per Month	100	100		200		
	Total Cost per Month of Treatment	\$1,200	\$1,200				
	Copay per Month of Treatment	\$100	\$100				
	Plan Cost per Month of Treatment	\$1,100	\$1,100			\$1,100	
2018 W/O New Drug	Average # of Patients per Month	100	100		200		
	Total Cost per Month of Treatment	\$1,323	\$1,323				
	Copay per Month of Treatment	\$100	\$100				
	Plan Cost per Month of Treatment	\$1,223	\$1,223			\$1,223	11.2%
2018 With New Drug	Average # of Patients per Month	77	77	66	220		
	Total Cost per Month of Treatment	\$1,323	\$1,323	\$2,646			
	Copay per Month of Treatment	\$100	\$100	\$100			
	Plan Cost per Month of Treatment	\$1,223	\$1,223	\$2,546		\$1,620	47.3%

Step 2 -- Budget Impact Calculation

Parameter	Amount			
	2016	2018		
		W/O New Drug	With New Drug	Incremental Impact of New Drug
Inputs				
Average total cost per member per month (PMPM)	\$450			
Percent of members treated with drugs from this class	0.20%	0.20%	0.22%	
Average drug treatment plan cost per month (from Step 1)	\$1,100	\$1,223	\$1,620	
Analysis				
Total drug plan cost PMPM	\$2.20	\$2.45	\$3.56	
Change in plan costs for this class of drugs		\$0.25	\$1.36	\$1.12
% Change in plan costs for this class of drugs		11.2%	62.0%	50.8%
% Change in total plan costs		0.1%	0.3%	0.2%

Note: This is a simple illustration. A fuller approach would consider effects over several years, rebates, changes in cost-sharing, and whether changes in therapy generate savings in other areas.

TABLES

Table A1: 2016 Healthcare 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%
Hospitals 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 are shown 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: Impact to Potential Budget Threshold by Adjusting Number of New Molecular Entity (NME) Approvals Using ICER 2017-2018 Estimate

Item	Parameter	ICER Estimate	Low NME Approval Estimate	High NME Approval Estimate
1	Growth in US GDP, 2017 (est.) +1%	3.2%	3.2%	3.2%
2	Total personal medical health care spending	\$2.71 trillion	\$2.71 trillion	\$2.71 trillion
3	Contribution of drug spending to total health care spending	17.7%	17.7%	17.7%
4	Contribution of drug spending to total health care spending	\$479 billion	\$479 billion	\$479 billion
5	Annual threshold for net health care cost growth for ALL drugs	\$15.3 billion	\$15.3 billion	\$15.3 billion
6	Average annual number of new molecular entity approvals	33.5	23.5	43
7	Annual threshold for average cost growth per individual new molecular entity	\$457.5 million	\$652.2 million	\$356.4 million
8	Annual threshold for estimated potential budget impact for each individual new molecular entity	\$915 million	\$1.3 billion	\$712.8 million
(\$)	Difference in threshold due to change in the number of new molecular entity approvals		\$389 million	-\$202 million
(%)			~ +40%	~ -20%

Table A3: New Molecular Entity Approvals by Year, 1994-2017

Year	New Molecular Entity Approvals	Average, Trailing Two Years	Year	New Molecular Entity Approvals	Average, Trailing Two Years
1994	22		2007	18	21
1995	28		2008	24	20
1996	53	25	2009	26	21
1997	39	40.5	2010	21	25
1998	30	46	2011	30	23.5
1999	35	34.5	2012	39	25.5
2000	27	32.5	2013	29	34.5
2001	24	31	2014	41	34
2002	17	25.5	2015	45	35
2003	21	20.5	2016	22	43
2004	36	19	2017	46	33.5
2005	20	28.5	2018		34
2006	22	28			

Source: Center for Drug Evaluation and Research new molecular entity approvals^{c,d}

^c FDA NME approvals, 1994-2011: <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm2006085.htm>. Accessed 21 Jun. 2018.

^d FDA NME approvals, 2012-2017: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm>. Accessed 21 Jun. 2018.

ICER'S OWN WORDS

About ICER^e

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^f

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.

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.

Why look at budget impact?

The potential budget impact of a new drug is analyzed to understand whether the costs over the first five years could represent such a big hit to health care budgets that an "alarm bell" should be rung indicating the need for special attention. Special attention could bring payers, manufacturers, clinicians, and patient groups together to sort out whether managing short-term costs would require actions such as a lower price, prioritization of treatment for certain patients, or re-allocation of resources from other health services.

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.

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

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