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Health Policy Analysis

Are Drugs Priced in Accordance With Value? A Comparison of Value-Based and Net Prices Using Institute for Clinical and Economic Review Reports

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ABSTRACT

Objectives: The Institute for Clinical and Economic Review (ICER) is an independent organization that reviews drugs and devices with a focus on emerging agents. As part of their evaluation, ICER estimates value-based prices (VBP) at $50 000 to $150 000 per quality-adjusted life-year (QALY) gained thresholds. We compared actual estimated net prices to ICER-estimated VBPs.

Methods: We reviewed ICER final evidence reports from November 2007 to October 2020. List prices were combined with average discounts obtained from SSR Health to estimate net prices. If a drug had been evaluated more than once for the same indication, only the more recent VBP was included.

Results: A total of 34 ICER reports provided unique VBPs for 102 drugs. The net price of 81% of drugs exceeded the $100 000 per QALY VBP and 71% exceeded the $150 000 per QALY VBP. The median change in net price needed to reach the $150 000 per QALY VBP was a 36% reduction. The median decrease in net price needed was highest for drugs targeting rare inherited disorders (n = 15; 62%) and lowest for cardiometabolic disorders (n = 6; 162% price increase). The reduction in net prices needed to reach ICER-estimated VBPs was higher for drugs evaluated for the first approved indication, rare diseases, less competitive markets, and if the drug approval occurred before the ICER report became available.

Conclusion: Net prices are often above VBPs estimated by ICER. Although gaining awareness among decision makers, the long-term impact of ICER evaluations on pricing and access to new drugs continues to evolve.

Keywords: cost-effectiveness, cost-utility analysis, health economics, Institute for Clinical and Economic Review, model-based economic evaluation.

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Introduction

Pharmaceutical innovation has resulted in the availability of novel therapies, sometimes at considerable added cost to patients and payers.[1] One area of ongoing discussion is how the high prices for new therapies relate to gains in outcomes. In the United States, the Institute for Clinical and Economic Review (ICER) is an independent research organization that evaluates the clinical and economic value of healthcare interventions.[2] As part of this review, ICER estimates a value-based price (VBP) for drugs based on cost-effectiveness modeling and then publishes these reports online.[3] The VBP is the price of the drug at which the cost per quality-adjusted life-year (QALY) gained is at or below a specific threshold. ICER-estimated VBPs are based on thresholds of $50 000, $100 000, and $150 000 per QALY gained.[4] A few noteworthy examples exist where ICER evaluations may have impacted drug pricing. For example, significant price cuts occurred for Praluent (alirocumab), from $14 600 per year at market entry to within the range recommended by ICER ($4500 to $8000 per year).[5] Another example is the similarity of the Aimovig (erenumab) market entry list price to ICER-estimated VBP thresholds.[6] Sanofi and Regeneron Pharmaceuticals Inc. were reported to have engaged with ICER regarding pricing prior to launch of Dupixent (dupilumab), ultimately pricing dupilumab within ICER's VBP range.[7] Most recently, the $2.125 million per treated patient entry price for Zolgensma (onasemnogene abeparvovec-xioi), while being the highest drug price ever recorded, fell within the bounds of the ICER-estimated VBP and well below initial analyst estimates of up to $5 million per treated patient.[8]

Other than these isolated examples, the system-wide magnitude of the impact of ICER VBPs on drug pricing and the degree of deviation between the ICER VBPs and actual prices is currently unknown. With the first ICER reports dating back to 2007, sufficient data are emerging to allow for comparisons across drugs that have been evaluated by ICER. There is limited published literature that explores how ICER-estimated VBPs have compared with prices and what factors may contribute to alignment or misalignment of actual price with ICER-estimated VBP. We sought to

review published ICER Final Evaluation Reports comprehensively to explore the relationship between the ICER-estimated VBPs and estimated net prices, which is the price paid after negotiating discounts and rebates that could be influenced by the existence of a published ICER-estimated VBP. Comparing ICER-estimated VBPs to net pricing across therapeutic areas may provide a valuable insight to decision makers on comparative value and serve as a basis for future analyses of trends over time.

Objective

The objective of this study was to estimate the relationship between ICER's estimated VBPs and net prices, overall and stratified by characteristics such as therapeutic classification, year of evaluation, population size, novel therapies versus established markets, and timing of approval relative to ICER evaluation.

Methods

ICER final evidence reports posted from November 2007 to October 2020 were reviewed for the availability of an ICER-estimated VBP for one or more drugs. Data such as date of ICER report publication, therapeutic area, ICER-estimated VBP and year of approval were captured for each drug with an ICER-estimated VBP.

Nondrug interventions, drugs without a current list price, and drugs which did not ultimately receive approval by the Food and Drug Administration for the indication under review were excluded. If a drug was evaluated by ICER more than once for the same indication (eg, drug appears in the class evaluation for psoriasis in both 2016 and 2018), the more recent update was included in our sample. As some drugs have been evaluated for multiple indications and have different VBPs based on the indication, a drug may contribute more than one observation in our dataset.

For the primary analysis, ICER-estimated VBPs at $100 000 and $150 000 per QALY gained were compared with current estimated net prices, calculated by applying average discounts for the most recent 2 quarters for each drug obtained from SSR Health to the wholesale acquisition cost (WAC) as of October 2020.[9] If no discount was available from SSR Health, we assumed a discount of 27% off the list price in alignment with the ICER reference case methodology.[10] A series of subanalyses were conducted to assess trends in the discordance of ICER-estimated VBP and net price. These included year of ICER final evidence report publication, original drug approval date for any indication, drug approval date for the indication evaluated by ICER, whether the drug is used to treat a rare disease, therapeutic area, presence of market competition, and whether the ICER-estimated VBP was publicly available before the date of drug approval. Because drugs in different therapeutic areas may be priced differently relative to value, we established classifications to group drugs based by indication evaluated. These classifications were chosen to allow for sufficient sample size to make robust comparisons between groups and consisted of autoimmune disorders, inherited disorders, oncologic disorders, cardiometabolic disorders, and other disorders. To explore whether drugs for rare diseases are priced differently relative to value compared with drugs to treat nonrare disease, we used the budget impact model section of the ICER final evidence report to estimate the number of patients per year who would be eligible for treatment. Drugs with an eligible patient population size of less the 10 000 per year in the United States were classified as drugs to treat rare diseases in alignment with ICER's modified value assessment framework for drugs to treat ultra-rare conditions.[10]

Market competition may influence alignment of net prices and ICER-estimated VBPs. Highly competitive markets may push drugs toward the VBP due to competition or availability of generics and biosimilars while net price for drugs in noncompetitive markets may be based on market forces unrelated to VBP. On the contrary, drugs may be priced based on established market price benchmarks in highly competitive markets whereas in a less competitive market, the availability of an ICER VBP may drive alignment of a drug price with VBP where no established price benchmark is available (eg, a novel treatment for a rare disease with little precedent to inform an appropriate list price). We stratified our sample into classifications of more and less competitive markets based on the availability of alternatives for the same indication. Drugs were considered to be in a highly competitive market if established guidelines listed multiple different treatment options for a given indication and were otherwise classified as a less competitive market if no alternative treatment options were cited.

Lastly, manufacturers may be more likely to align net price with the ICER-estimated VBP if the VBP is known before product approval. To investigate this possibility, we compared drugs with first FDA approval dates before the date of publication of the draft ICER evidence report to those with approval dates after publication of the draft report. For this analysis, the date of the draft evidence report was used rather than the date of the final evidence report as the draft represents the first time the ICER-estimated VBP is publicly available and, while still draft, this date was hypothesized to more closely inform pricing strategy.

Statistical Analysis

Means, standard deviations, medians, and interquartile ranges are reported for continuous variables while frequency and percentages are reported for categorical variables. Differences in median change in net price needed to reach the ICER-estimated VBP, year of initial drug approval, and year of drug approval for the indication evaluated by ICER were analyzed using Spearman rank-order correlation coefficient with 2-sided Student's t test or Mann-Whitney U test. χ^2 tests without Yates' continuity correction were used to assess differences in the proportion of drugs with net prices below the ICER-estimated VBP at $150 000 per QALY gained, with Fisher exact test used when expected counts were small in any group ($n < 5$). All statistical analyses were conducted in R.[11]

Results

Overall Sample

A total of 34 ICER reports provided ICER-estimated VBPs for 95 drugs across 35 indications, a total of 102 unique drugs and indications which could be paired with current net prices. The net price of 81% of drugs exceeded the $100 000 per QALY VBP and 71% exceeded the $150 000 per QALY VBP. Median change in net price needed to reach the ICER-estimated VBP at $100 000 per QALY and $150 000 per QALY thresholds are shown in Table 1. Relative to estimated net prices, a median additional reduction of 36% (IQR 61% reduction, 14% increase) was needed to reach the $150 000 per QALY VBP. Figure 1 presents the change in net price required to reach the ICER-estimated VBP at the $150 000 per QALY threshold for the overall sample and by stratified subanalyses.

Results by Therapeutic Class

The proportion of drugs with net prices in alignment with ICER-estimated VBPs differed across therapeutic classes ($P = .04$).

Table 1. Comparison of net prices and ICER-estimated VBPs at $100 000 and $150 000 per QALY (n = 102).

VBP QALY threshold	Net price exceeds ICER VBP n (%)	Mean (SD) reduction in net price needed to reach ICER-estimated VBP	Median (IQR) reduction in net price needed to reach ICER-estimated VBP
$100 000 per QALY	83 (81%)	21% (69%)	56% (15%, 74%)
$15000 0 per QALY	72 (71%)	−11% (137%)	36% (−14%, 61%)

ICER indicates Institute for Clinical and Economic Review; IQR, interquartile range; QALY, quality-adjusted life-year; SD, standard deviation; VBP, value-based price.

The median reduction in net price required to reach the $150 000 per QALY threshold was highest for drugs to treat inherited disorders (n = 15; 62% reduction) and lowest for drugs to treat cardiometabolic disorders (n = 6), where the net price for most drugs could increase to reach the ICER-estimated VBP (162% price increase; P = .70 across classes; Table 2). Within the autoimmune class, 7 targeted immune modulators had been evaluated for at least two different indications: rheumatoid arthritis, psoriasis, and/or ulcerative colitis.[12-14] The annual estimated net price and ICER-estimated VBP at the $150 000 per QALY threshold for drugs evaluated across these three indications is presented in (Table 3). Net prices were consistently more aligned with ICER-estimated VPBs for psoriasis compared with rheumatoid arthritis or ulcerative colitis, with ustekinumab as an extreme example where the net price fell below the ICER-estimated VBP for the psoriasis indication but required a 76% reduction in net price to reach this threshold for the ulcerative colitis indication.

Year of ICER Final Evidence Report Publication

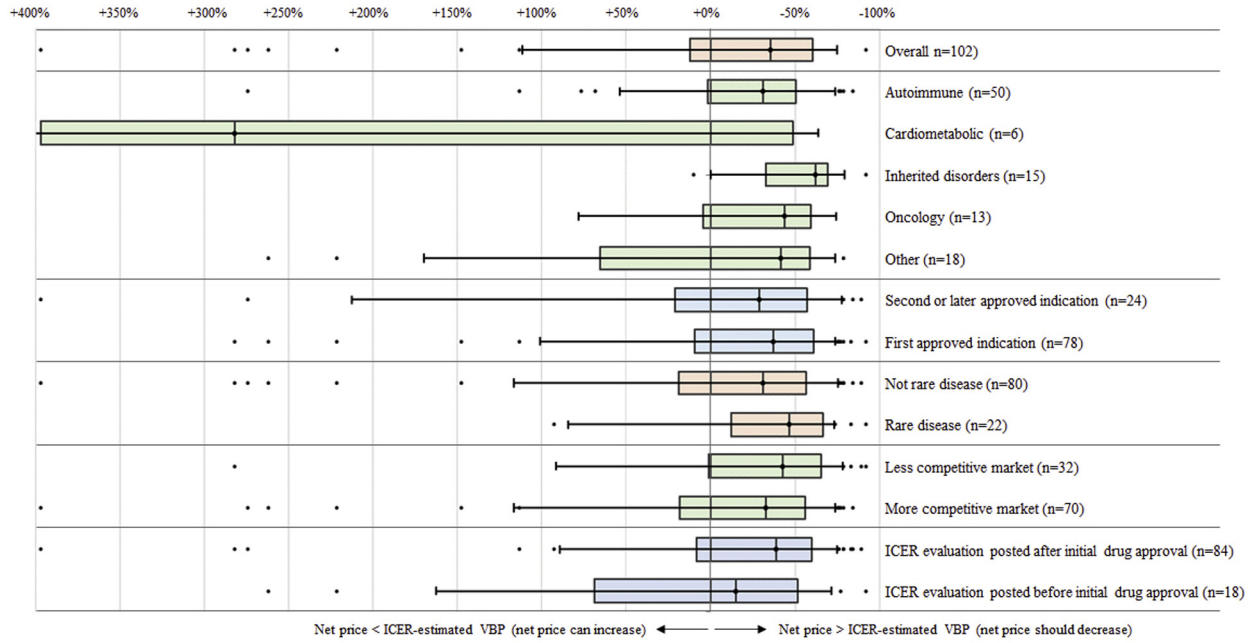
Correlation of net prices and ICER-estimated VBPs by year of publication of the ICER final evidence report was explored to investigate trends in pricing toward or away from the VBP over time. No notable trends were observed in the proportion of drugs with net prices exceeding ICER-estimated VBPs or the reduction in net price needed to reach the ICER-estimated VBP across years of ICER review.

In addition, it was hypothesized that newer drugs may be priced differently relative to ICER-estimated VBP than older drugs. To investigate this possibility, we assessed the relationship between median reduction in net price needed to reach the ICER-estimated VBP at $150 000 per QALY gained by the year of first approval by the Food and Drug Administration for any indication. No statistically significant trends were observed regarding alignment of net price and ICER-estimated VBP by year of initial drug approval or by year of approval for the specific indication evaluated.

First Versus Subsequent Indication

Because each indication has an ICER-estimated VBP based on a cost-effectiveness model created for that specific indication, it was hypothesized that drugs evaluated by ICER for the original approved indication may be priced more in accordance with value. In other words, the manufacturer would have the opportunity to price the drug based on the indication of interest rather than based on market access for an earlier approved indication. However, results showed that fewer drugs evaluated for the first indication had net prices at or below ICER-estimated VBPs than drugs with prior approvals, with the net price for 56 of 78 drugs

Figure 1. Change in net price required to reach ICER-estimated VBP at the $150 000 per QALY threshold.



ICER indicates Institute for Clinical and Economic Review; QALY, quality-adjusted life-year; VBP, value-based price.

Table 2. Subgroup analysis of list price and ICER-estimated VBP at $150 000 per QALY.

Subgroup	List price exceeds ICER VBP		Reduction in net price needed to reach ICER VBP		
	n (%)	*P* value	Mean (SD)	Median (IQR)	*P* value
Year of ICER final evidence report					
2015 (n = 1)	0 (0%)	.11	+282%*	+282%*	.25
2016 (n = 7)	7 (100%)		51% (27%)	57% (40%, 73%)	
2017 (n = 36)	32 (89%)		22% (93%)	41% (29%, 59%)	
2018 (n = 32)	16 (50%)		+47%* (164%)	1% (+50%*, 39%)	
2019 (n = 10)	6 (60%)		+64%* (202%)	18% (+34%*, 56%)	
2020 (n = 16)	11 (69%)		10% (104%)	53% (+5%*, 74%)	
Evaluated for first approved indication					
First approved indication (n = 78)	56 (72%)	.62	+7%* (134%)	37% (+9%*, 61%)	<.001
Not first approved indication (n = 24)	16 (67%)		+23%* (148%)	29% (+21%*, 57%)	
Drugs to treat rare disease					
Rare disease (n = 22)	18 (82%)	.19	+17%* (195%)	47% (12%, 67%)	<.001
Not rare disease (n = 80)	54 (68%)		+9%* (117%)	31% (+19%+, 57%)	
Therapeutic area					
Other (n = 18)	11 (61%)	.04	+11%* (107%)	42% (+66%*, 59%)	.70
Inherited disorders (n = 15)	13 (87%)		5% (192%)	62% (33%, 69%)	
Autoimmune (n = 50)	37 (74%)		8% (91%)	31% (+1%*, 51%)	
Oncology (n = 13)	9 (69%)		+19%* (158%)	36% (+19%*, 57%)	
Cardiometabolic (n = 6)	2 (33%)		+189%* (226%)	+162%* (+368%*, 11%)	
Market competition					
Less competitive (n = 32)	24 (75%)	.51	+16%* (171%)	43% (+1%*, 66%)	<.001
More competitive (n = 70)	48 (69%)		+8%* (119%)	33% (+18%*, 56%)	
Timing of ICER draft evidence report relative to drug approval					
Drug approved after draft report posted (n = 18)	12 (67%)	.73	+19%* (104%)	16% (+77%*, 56%)	<.001
Drug approved before draft report posted (n = 84)	60 (71%)		+9%* (143%)	37% (+8%*, 60%)	

ICER indicates Institute for Clinical and Economic Review; IQR, interquartile range; QALY, quality-adjusted life-year; SD, standard deviation; VBP, value-based price.
*The plus sign (+) indicates an increase on net price to reach the ICER-estimated VBP.

(72%) for first approved indications exceeding ICER-estimated VBP at $150 000 per QALY versus 16 of 24 drugs (67%) with prior approvals ($P = .62$). Drugs evaluated for the first approved indication had a higher median reduction in net price needed to reach the ICER-estimated VBP at $150 000 per QALY (37% reduction vs 29% reduction, respectively; $P < .001$).

Rare Diseases

A numerically greater proportion of drugs for rare diseases (n = 22) had net prices exceeding the ICER-estimated VBP at $150 000 per QALY compared with nonrare diseases (n = 80; 82% vs 68%; $P = .19$). The median reduction in net price needed to reach the ICER-estimated VBP at $150 000 per QALY was higher for drugs to treat rare diseases versus nonrare diseases (47% reduction vs 31% reduction, respectively; $P < .001$).

Market Competition

A numerically lower proportion of drugs in competitive markets (n = 70) had net prices which exceeded ICER-estimated VBPs at $150 000 per QALY than those in less competitive markets (n = 32; 69% vs 75%; $P = .51$), but median reduction in net price needed to reach the ICER-estimated VBP at $150 000 per QALY were higher for less competitive markets (43% reduction vs 33% reduction; $P < .001$).

Timing of Publication of Draft ICER Report Relative to Drug Approval

The majority of drugs evaluated by ICER with an ICER-estimated VBP were approved before the publication of the draft ICER report (n = 84; 82%). Of the 18 drugs with Food and Drug Administration approval dates after the date of publication of the draft ICER report, 12 (67%) had net prices which exceeded the ICER-estimated VBP at $150 000 per QALY, with a median reduction in net price of 16% to reach this threshold. The median reduction in net price needed to reach the ICER-estimated VBP at the $150 000 per QALY threshold was notably lower in the subgroup of drugs approved after publication of the ICER report (16%) versus for drugs approved before the draft report (37%; $P < .001$).

Discussion

Multiple surveys of payers have shown that ICER has growing impact on payer decision making regarding access,[15,16] and some demonstrable examples of impact on drug pricing exist.[6,9] In this

Table 3. Comparison of ICER-estimated VBPs at $150 000 per QALY for targeted immune modulators in autoimmune diseases.

	Annual estimated net price	ICER-estimated annual VBP		
		Psoriasis (2018)	RA (2017)	UC (2020)
Adalimumab	$45 187	$39 800	$26 270	$6 941
Certolizumab pegol	$57 365	$39 700	$24 111	N/E
Etanercept	$42 766	$35 400	$29 104	N/E
Golimumab	RA: $28 826; UC: $35 912	N/E	$23 707	$7 649
Infliximab	$36 652	$35 000	$15 728	$10 872
Tofacitinib	$28 021	N/E	$25 010	$15 292
Ustekinumab	Psoriasis: $26 882; UC: $53 764	$37 800	N/E	$12 922

ICER indicates Institute for Clinical and Economic Review; N/E, not evaluated; RA, rheumatoid arthritis; QALY, quality-adjusted life-year; UC, ulcerative colitis; VBP, value-based price.

retrospective review of ICER evaluations which presented VBPs, the majority of drug net prices were higher than ICER-estimated VBPs. Half of drugs needed at least a 36% reduction in net price to be considered cost-effective at the $150 000 per QALY threshold under the ICER framework and half had net prices more than twice the $100 000 per QALY VBP. Drugs with net prices that were less aligned with VBPs tended to be those with less market competition, those to treat rare diseases, those approved before the ICER evidence report, and those with the ICER-estimated VBP pertaining to the first approved indication. These findings lend optimism that in the right circumstances, the availability of ICER-estimated VBPs at the right time encourages the alignment of net price and incremental value. Those circumstances may currently be unfolding in nonrare diseases in more competitive markets when the drug is priced according to first approved indication and when the ICER-estimated price is available when the pricing decisions or negotiations takes place. However, we are unable to confirm that the ICER-estimated VBPs were referenced in these cases.

Drugs to treat rare diseases present unique challenges to provide incentives and compensation to drug manufacturers for the investigation and development of novel treatments for very small patient populations, with several recent notable examples of new technologies with extraordinary list prices but also substantial benefits. Similarly, innovations in oncology have yielded gains in life expectancy, but at significant incremental cost. Despite often high list prices for drugs intended for the treatment of rare diseases, the alignment of net price and ICER-estimated VBP for these classes was not substantially different than the overall sample, with oncology drugs often in closer alignment to ICER-estimated VBPs than other therapeutic areas.

Our analysis found that net prices for drugs in more competitive markets were slightly more aligned to ICER-estimated VBP than drugs in markets with low levels of competition. This suggests that market forces and presence of competition may be driving drug prices for these indications into alignment with VBPs. However, the actual ICER VBPs may be less impactful on pricing pressure in this case than the existence of competition, generics, and biosimilars.

Although our results provide an informative snapshot of the current alignment between net prices and ICER-estimated VBPs, it is subject to a number of limitations. Our findings only pertain to the United States due to between-country differences in drug availability, country-specific base-case model assumptions and costs, drug costs, and willingness-to-pay thresholds. ICER does not systematically or comprehensively evaluate all new and existing drugs, but rather selects certain drugs or classes. We limited our analysis to pharmaceutical interventions for which ICER has estimated a VBP. We did not include nondrug interventions or those where a VBP was not estimated for other reasons, such as combination treatment with multiple drugs. The drugs selected by ICER for review may have been targeted because of anticipated high pricing, low clinical value, or unusually high clinical value. As such, our results are not representative of all drugs, but rather to the types of drugs that ICER selects for review. In addition, overall results are disproportionately influenced by a few class evaluations with several drugs (eg, rheumatoid arthritis, psoriasis, multiple sclerosis, and ulcerative colitis).

Some drugs can be used for more than one indication that ICER has evaluated and each different indication is associated with a different VBP, and thus some drugs contribute multiple observations in our dataset. This nonindependence of observations limits our ability to conduct rigorous statistical analysis of trends and between-group comparisons. Even if all duplicate drug entries were to be removed, some drugs were assessed as part of class evaluations (eg, multiple sclerosis), with VBPs calculated from a single economic model of a disease state, creating clusters of data which are not truly independent observations. However, this also provided an opportunity to explore how ICER-estimated VBPs have varied across indications for these same products, showing a high degree of variability. The complexity of negotiating pricing according to VBP is especially challenging for drugs which have multiple uses, where differences in clinical benefit across different indications can translate into substantially different ICER-estimated VBPs. Across 7 targeted immune modulators, ICER-estimated VBPs were highest for psoriasis ($35 000-$45 000) and lowest for ulcerative colitis ($6000-$15 000). For these drugs, perfect alignment with ICER-estimated VBPs would be impossible without indication-based pricing, a practice that is not currently widely used in the United States.

An inherent assumption in our analysis is that ICER-estimated VBPs truly reflect the benefit in relation to the price of these drugs. ICER-estimated VBPs are based on an established framework for cost-effectiveness modeling,[4] but they are inherently subject to data gaps and assumptions which are required to construct these models. For the purposes of the present study, we took the results of ICER economic evaluations at face value. A detailed review of the accuracy and appropriateness of the ICER economic models which produced the VBPs was outside the scope of our analysis.

Finally, our analysis of drug prices relies on published list prices and estimated discounts from SSR Health. This may not represent the actual price paid for a drug due to confidential, contractually-negotiated discounts and rebates between individual payers, pharmacy benefit managers, and manufacturers.

We found that drug current net prices are poorly aligned with ICER-estimated VBPs. However, our analysis may underestimate the true impact of ICER-estimated VBPs if in the absence of ICER, the net price would be even higher than it is.

Conclusion

For the majority of drugs evaluated by ICER, a reduction in net price is needed to justify the incremental clinical value. Our study identified several significant predictors of the alignment of net prices with ICER-estimated VBPs. Drugs evaluated for the first approved indication, those for rare diseases, drugs in less competitive markets, and drugs approved before the ICER report was available tended to be less aligned with ICER-estimated VBP and may present an opportunity to leverage ICER-estimated VBPs in these settings. As ICER has only released estimated VBPs in the past 5 years, the long-term impact of ICER evaluations on pricing and access continues to evolve.

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