What is the preferred approach to US drug pricing reforms - international reference pricing or value-based pricing?

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Declaration of Interest

I am an employee of Aetion, Inc. and own stock options at Aetion Inc.

Opinions are my own and not of my employer or any other entity

Free-market policies in the US promote innovation but hinder access

60%
of Americans take a prescription drug

30%
of American adults report not taking their medicines in 2021 due to cost

75%
of worldwide drug company profits are derived from US consumer spending

~80%
of American regardless of political affiliation believe that pharmaceutical profits are driving the price of prescription drugs

50%+
across party lines believe there isn't as much drug pricing regulation as there should be

60%
of people believe that prescription drug innovations has improved the lives of the US population over the past ten years

Available at: https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
https://www.brookings.edu/research/the-global-burden-of-medical-innovation/
https://www.healthaffairs.org/do/10.1377/forefront.20201123.804451/
https://www.brookings.edu/research/the-global-burden-of-medical-innovation/

Need to balance affordability & access with innovation

Drug access, affordability, payment, and pricing policies*

Increasing ease of entrance of generic drugs and biosimilars

Rebate or tax penalties for price-hikes that outpace inflation

Medicare negotiating drug prices

International reference pricing

Domestic reference pricing

Value-based pricing

Medicare redesign

Out-of-pocket spending caps

Drug importation from Canada

Formulary restrictions

Prior authorization

Add-on payment caps

Cost-effectiveness analysis

Coverage with evidence development

Outcomes-based contract

Indication-based pricing

*Illustrative

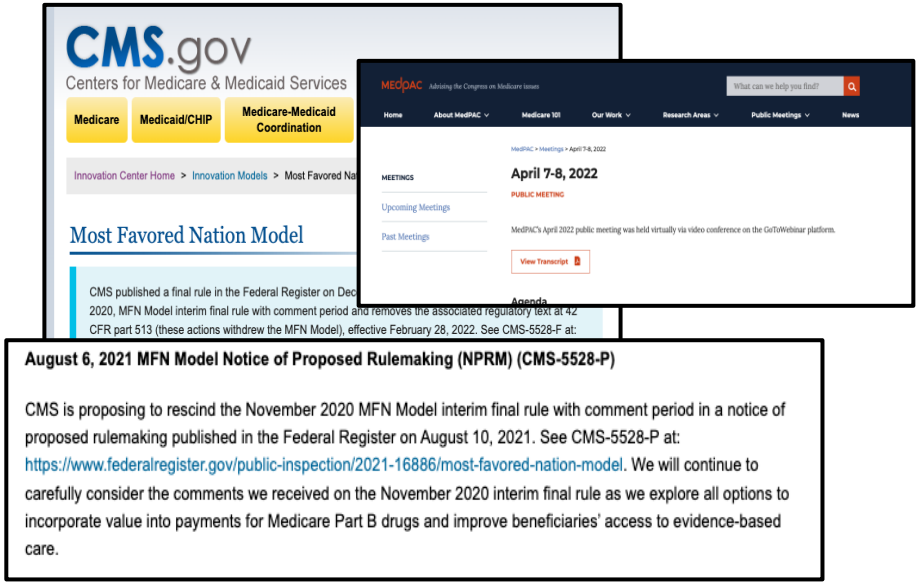
International Reference Pricing (IRP) vs. Value-based Pricing (VBP)

IRP

- Informs pricing negotiations by calculating a reference price from one or more countries
- Used in at least 70 countries to contain drug costs

Value Based Pricing (VBP)

- Result of an assessment, usually an economic evaluation, that attempts to align the price of a drug to its clinical value
  - Cost-utility analysis (CUA) is one type of economic evaluation, that explicitly takes into account the relative costs and outcomes of a therapy adjusted by health status preferences to inform decision-making
- Used in several high-income countries to determine if a therapy will be reimbursed, and is a gateway to market access



Available at: https://innovation.cms.gov/innovation-models/most-favored-nation-model#:~:text=The%20MFN%20Model%20was%20a,affecting%20quality%20of%20care%20for
https://www.medpac.gov/meeting/april-7-8-2022/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802694/
https://www.cdc.gov/dhdsp/docs/program_evaluation_tip_sheet_economic_evaluation.pdf

Expert panelists

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Disclosures

I have no actual or potential conflicts of interest in relation to this program/presentation.

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Disclosure Statement

I am an employee of Global Pricing Innovations (GPI), a company that provides analytics insights and consulting services to pharmaceutical companies.

Opinions are my own and not of my employer or any other entity.

Value-Based Pricing (VBP) vs International Reference Pricing (IRP) in the US

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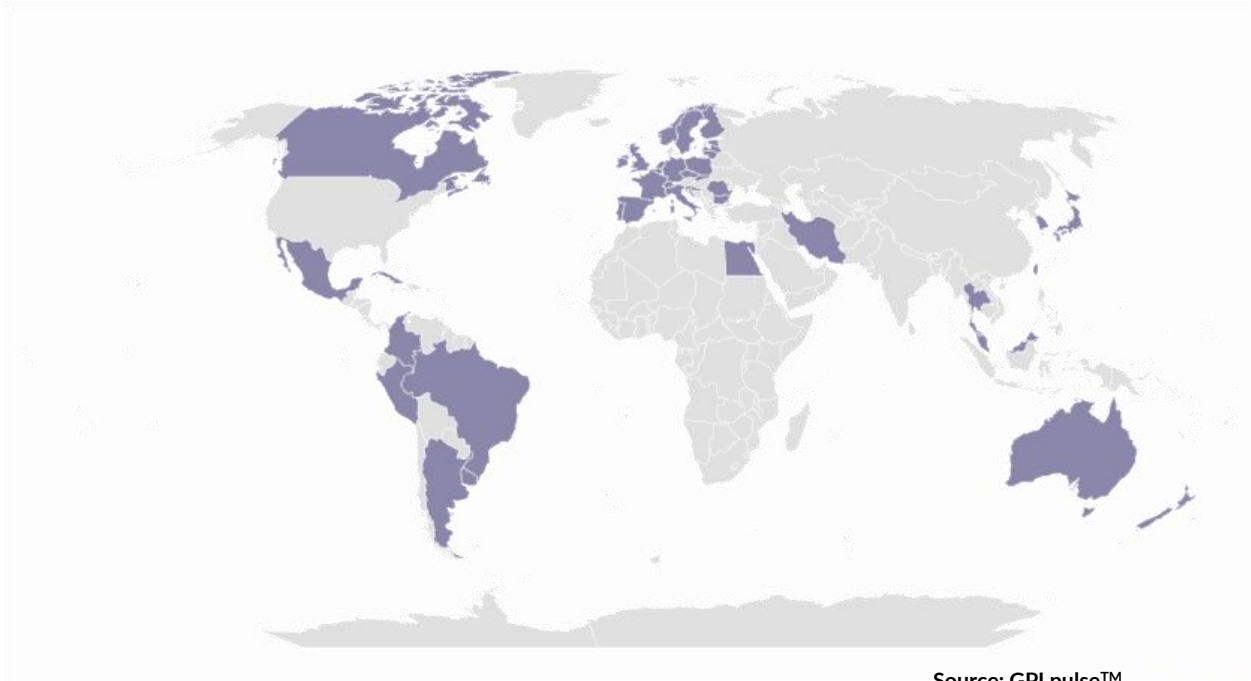
16 May 2022

HTA assessments among most commonly-used drug pricing controls globally

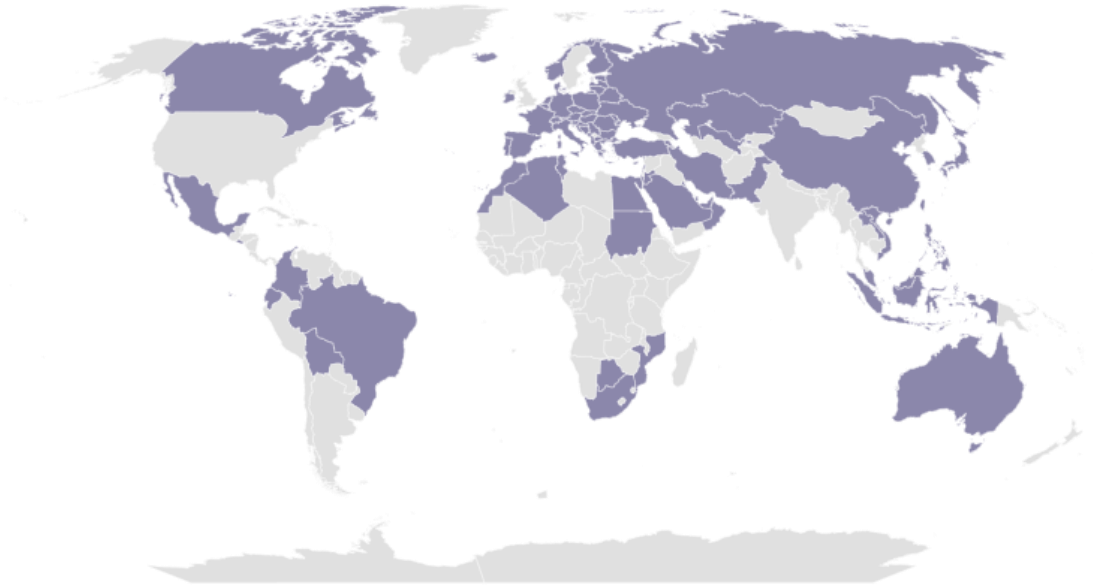
Health Technology Assessments (HTA)



Source: GPI pulse™

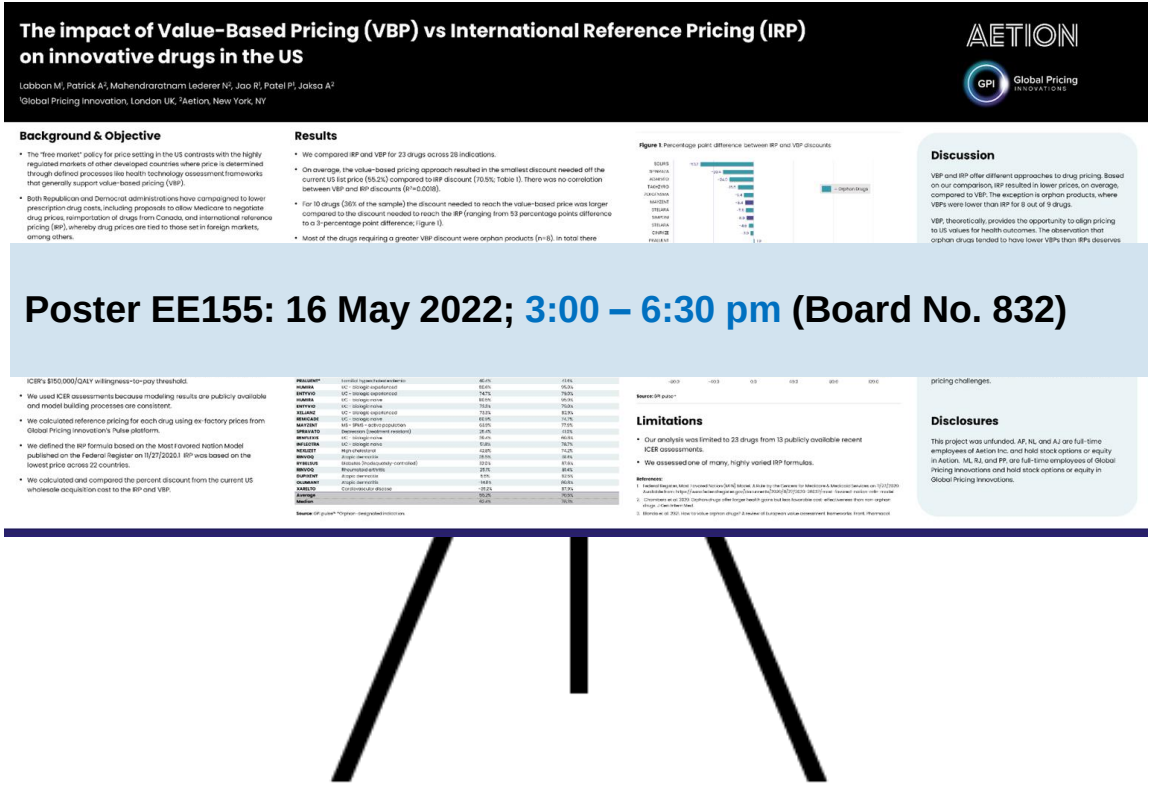
IRP mechanisms among most commonly-used drug pricing controls globally

International Reference Pricing (IRP)



Source: GPI pulse™

Objective: Compare the impact of IRP vs VBP on US drug prices



The impact of Value-Based Pricing (VBP) vs International Reference Pricing (IRP) on innovative drugs in the US

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Background & Objective

- The "free market" policy for price setting in the US contrasts with the highly regulated markets of other developed countries where price is determined through defined processes like health technology assessment frameworks that generally support value-based pricing (VBP).
- Both Republican and Democrat administrations have campaigned to lower prescription drug costs, including proposals to allow Medicare to negotiate drug prices, reimportation of drugs from Canada, and international reference pricing (IRP), whereby drug prices are tied to those set in foreign markets, among others.

Results

- We compared IRP and VBP for 23 drugs across 28 indications.
- On average, the value-based pricing approach resulted in the smallest discount needed off the current US list price (55.2%) compared to IRP discount (70.5%; Table 1). There was no correlation between VBP and IRP discounts (R^2=0.008).
- For 10 drugs (36% of the sample) the discount needed to reach the value-based price was larger compared to the discount needed to reach the IRP (ranging from 53 percentage points difference to a 3-percentage point difference; Figure 1).
- Most of the drugs requiring a greater VBP discount were orphan products (n=8). In total there

Figure 1. Percentage point difference between IRP and VBP discounts

Discussion

VBP and IRP offer different approaches to drug pricing. Based on our comparison, IRP resulted in lower prices, on average, compared to VBP. The exception is orphan products, where VBPs were lower than IRP for 8 out of 9 drugs.

VBP, theoretically, provides the opportunity to align pricing to US values for health outcomes. The observation that orphan drugs tended to have lower VBPs than IRPs deserves

Poster EE155: 16 May 2022; 3:00 – 6:30 pm (Board No. 832)

ICER's $150,000/QALY willingness-to-pay threshold.

- We used ICER assessments because modeling results are publicly available and model building processes are consistent.
- We calculated reference pricing for each drug using ex-factory prices from Global Pricing Innovation's Pulse platform.
- We defined the IRP formula based on the Most Favored Nation Model published on the Federal Register on 11/27/2020.[1] IRP was based on the lowest price across 22 countries.
- We calculated and compared the percent discount from the current US wholesale acquisition cost to the IRP and VBP.

PRALUENT®	Familial hypercholesterolemia	46.4%	-11.6%
HUMIRA	MC - biologic-experienced	66.6%	55.3%
ENTYVIO	MC - biologic-experienced	74.7%	79.3%
HUMIRA	MC - biologic-naive	66.5%	66.7%
ENTYVIO	MC - biologic-naive	75.0%	79.0%
XELJANZ	MC - biologic-experienced	73.0%	82.9%
REMICADE	MC - biologic-naive	66.9%	74.7%
SKYRIZI	MS - IPMS - active population	0.0%	77.5%
SPRAVATO	Depression (treatment resistant)	28.4%	-13.5%
BENLYSTA	HC - biologic-naive	35.4%	46.5%
INFLECTRA	MC - biologic-naive	51.8%	78.7%
REPATHA	High cholesterol	42.8%	74.2%
NEXLETOL	High cholesterol	42.8%	74.2%
RYBELSUS	Diabetes (inadequately-controlled)	33.0%	87.6%
ORENCIA	Rheumatoid arthritis	29.7%	81.4%
DUPIXENT	Atopic dermatitis	9.9%	92.9%
DUPIXENT	Atopic dermatitis	19.8%	86.1%
XARELTO	Cardiovascular disease	-28.2%	87.3%
Average		36.2%	70.5%
Median		42.4%	76.9%

Source: GPI pulse® *Orphan-designated indications

Limitations

- Our analysis was limited to 23 drugs from 13 publicly available recent ICER assessments.
- We assessed one of many, highly varied IRP formulas.

References:

1. Federal Register, Most Favored Nation [MFN] Model. A Rule by the Centers for Medicare & Medicaid Services on 11/27/2020. Available from: https://www.federalregister.gov/documents/2020/12/02/2020-26037/cms-innovation-center-model-
2. Chambers et al. 2020. Orphan drugs offer larger health gains but less favorable cost- effectiveness than non-orphan drugs. J Gen Intern Med.
3. Blondel et al. 2021. How to value orphan drugs? A review of European value assessment frameworks. Front. Pharmacol.

pricing challenges.

Disclosures

This project was unfunded. AP, NL, and AJ are full-time employees of Aetion Inc. and hold stock options or equity in Aetion. ML, RJ, and PP, are full-time employees of Global Pricing Innovations and hold stock options or equity in Global Pricing Innovations.

Methodology

We identified a sample of drugs reviewed by the Institute for Clinical and Economic Review (ICER) from 2019-2021.

Value-Based Pricing was estimated based on ICER's $150,000/QALY willingness-to-pay threshold

International Reference Pricing formula was defined based on the Most Favored Nation (MFN) Model.

The percent discount from the current US wholesale acquisition cost (WAC) to the IRP and VBP were calculated and compared for our sample (n=28).

Results: On average, IRP discount was greater than the VBP discount

55.2%

Discount for VBP

70.5%

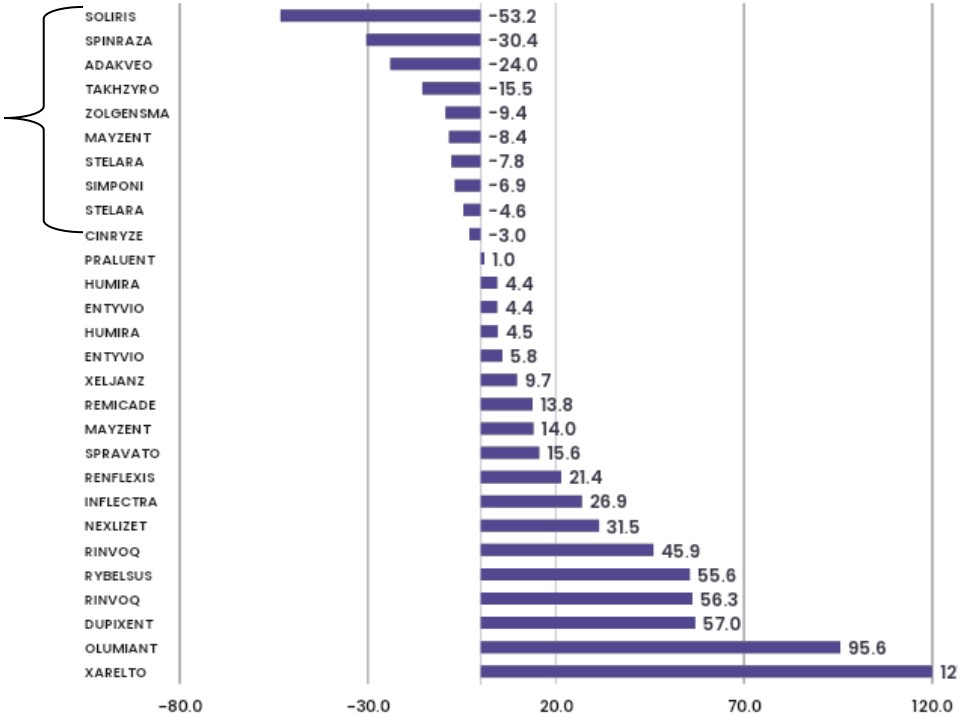
Discount for IRP

No correlation between IRP and VBP discounts (R^2=0.0018)

Results: Percentage point difference between IRP and VBP discounts vary widely

Around 36% of our sample would have required greater discounts under VBP vs IRP

Difference between IRP and VBP discounts vary widely across products



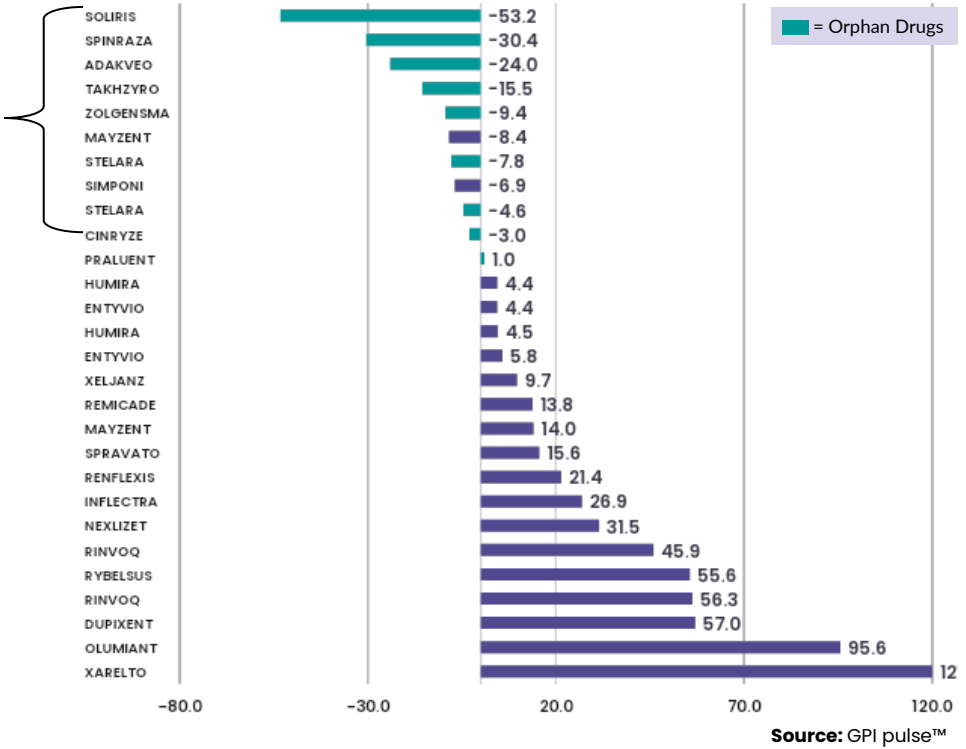
Source: GPI pulse™

Results: Orphan drugs required greater VBP discounts than IRP

Around 36% of our sample would have required greater discounts under VBP vs IRP

Difference between IRP and VBP discounts vary widely across products

Orphan drugs were predominantly found in the category with larger VBP discounts vs IRP



Source: GPI pulse™

Summary and next steps

Results Summary

- On average, IRP led to greater discounts (lower prices) than VBP for innovative drugs in the US
- There was no correlation between IRP and VBP discounts
- For select group of products (orphan drugs), VBP could require greater discounts (lower prices) than IRP

Next Steps

- Understand why orphan drugs required greater discounts under VBP
- Understand impact of IRP and VBP on net pricing
- Understand the impact any policy might have on access and innovation

Declaration of interest:
Randy Burkholder is an employee of PhRMA, which represents leading biopharmaceutical research companies in the U.S. and globally

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Discussion