The Evolving Influence of the Inflation Reduction Act and Value Assessment in US Payer Decision-Making

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Introduction

Within the US, new policies and evolving value assessments have a growing influence on the decision making of US payers. For example, ongoing implementation of the Inflation Reduction Act (IRA) further complicates the US reimbursement landscape with new Medicare pricing regulations and redesign. Full impacts of Part D redesign will remain unknown for several years, but it is clear that Part D plans will more tightly control formularies as over $40B in costs are shifted to them. Rebate dynamics may also disrupt Part D formularies and patient access, with spillovers to commercial markets. Further, the Drug Price Negotiation Program (DPNP), allowing Centers for Medicare & Medicaid Services (CMS) to set prices for certain Part D and Part B drugs, increases pressure on the value of treatments in both Medicare and commercial markets. In addition, the independent Institute for Clinical and Economic Review (ICER) continues to advance value assessment methods for US markets, while providing payers with another source for evaluating products, particularly from an economic value perspective. While the influence and impact of these policies and value assessments is yet to be fully understood, initial research can help to uncover preliminary perspectives.

Objective

In light of these continuing changes, this study aimed to obtain perspectives regarding the influence of federal price-setting policies and external value assessment on diverse US payer organizations.

Methods

In May 2024, we recruited experienced stakeholders from US payer organizations via our Petauri Payer Network, inviting them to participate in an online quantitative and qualitative survey. Inclusion criteria for the survey included: Currently based in US, current or former US payer, at least 5 years of experience as payer or actuary, and a current or former voting member or participant on their organizations' Pharmacy and Therapeutics (P&T) committee. Within the survey, we explored 12 key themes, consisting of 53 questions. We conducted descriptive statistics and contextual analyses. Participants were provided with an honorarium for participation in the 30-minute survey based on fair market value.

Figure 1: Perceived level of impact of IRA on biopharmaceutical innovation

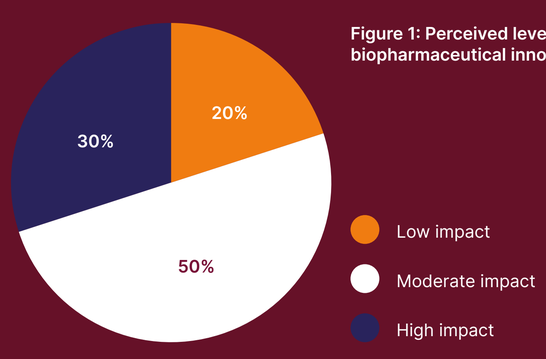


Figure 2: Anticipated Impact of DPNP process and MFPs on payer formulary decisions

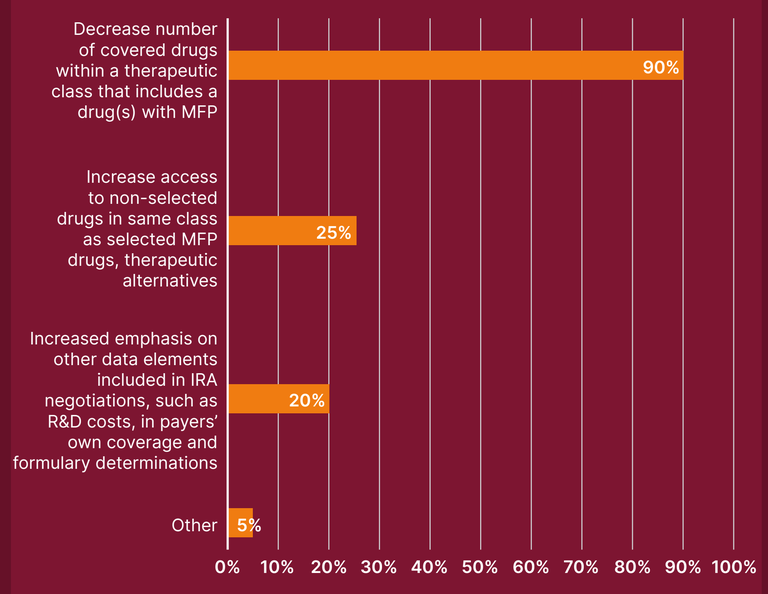


Figure 3: Perception of opportunities for other assessment and methods-oriented groups in the US (e.g., ICER, IVI/CIVR) to improve DPNP methods

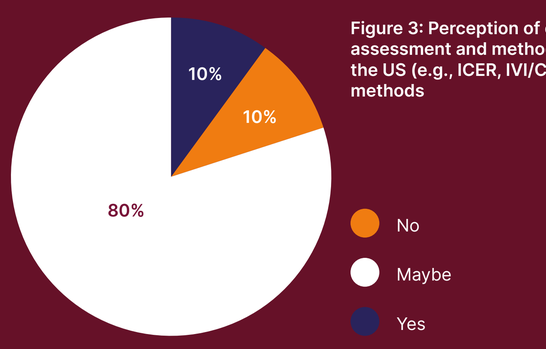
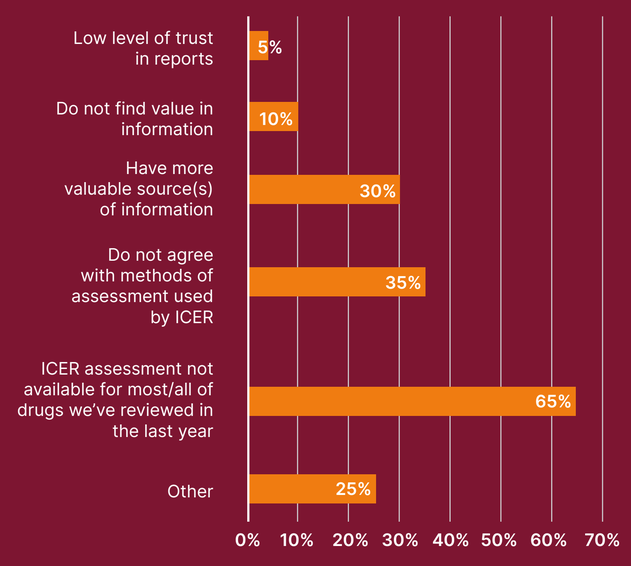


Figure 4: Reason(s) for inconsistent use of ICER reports by payers



Results

The survey included 20 participants (4 medical directors, 11 pharmacy directors, 4 industry/trade relations professionals, and 1 actuary), who represented national and regional Managed Care Organizations (MCOs), Pharmacy Benefit Managers (PBMs), and Integrated Delivery Networks (IDNs). Overall, 80% of participants reported 15 or more years at payer organizations, with 75% of participants were currently in-role. Most (87%) of the pharmacy and medical directors were voting members in their organization's P&T committee, with the remaining 13% serving as non-voting P&T members.

Most participants (80%) felt that the US IRA will have a moderate to high negative impact on biopharmaceutical innovation (Figure 1). Of the payers expressing concerns about the expected impact of IRA on innovation, several noted common themes that: 1) manufacturers may not conduct research and development (R&D) for new indications for already-approved drugs likely to be affected by the DPNP; 2) overall investments in R&D may be redirected into other diseases and patient populations; and, 3) together the anticipated reduction in R&D will result in less competition and therefore higher costs for payers. Payers also noted that research into treatments for rare and orphan diseases are unlikely to be affected by the DPNP and may actually increase as R&D dollars are reallocated.

When asked how CMS's DPNP negotiations and Maximum Fair Prices (MFPs) will impact payer formulary decisions, 90% felt this would decrease the number of covered drugs within a therapeutic class that includes a drug with an MFPs (Figure 2). If these payer concerns were to become a reality, patient access to needed medicines may be drastically reduced. While 25% of respondents indicated that access to non-selected drugs in an MFPed class may increase, this likely reflects rebate dynamics and hints that rebate pressures may be what will drive the anticipated reduction in numbers of covered drugs within an MFPed drug class. Echoing concerns of spillovers into commercial markets, one respondent noted that the MFPs will be a strong anchor for drug negotiations of non-MFP products in Medicare and Commercial plans. Yet, reflecting the lack of enforcement mechanisms in the IRA, others noted that the impact of MFPs on access will depends on how rigorous CMS will be with its enforcement of coverage for MFPed drugs.

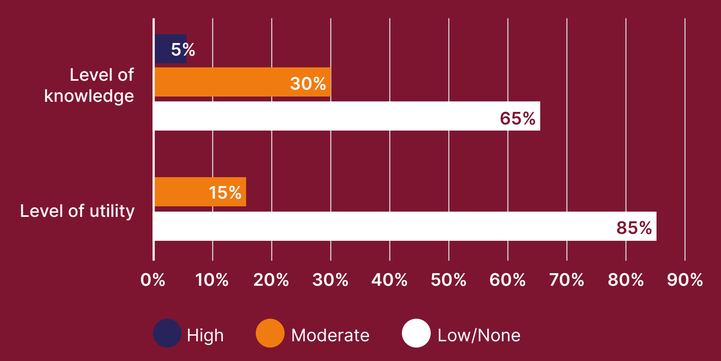
Shifting to the DPNP evaluation process, payers were also asked how the DPNP may influence their evidentiary needs and comparators used for price referencing. Results were mixed with 45% of payers saying that the DPNP negotiations will have no impact on their evidentiary needs, while another 45% were unsure of the potential impact.

Payers were unsure as to whether the DPNP evaluation process could improve by adopting other value assessment practices and methods. Only 10% of payers surveyed felt that there were opportunities for CMS to learn from other US assessment and methods groups (e.g., ICER, IVI), another 80% were uncertain.

Regarding the influence of ICER reports on their own assessments and formulary decisions, responses also continue to vary widely. 45% of payers reported they have a moderate influence, 25% high influence, and 30% no influence at all. The reasons for low influence were mainly due to ICER assessment not being available for most/all drugs reviewed (65%), lack of agreement with ICER assessment methods (35%), and more valuable sources of information available (30%) (Figure 4).

Considering ICER's 'shared savings' approach to cost-offsets in economic modeling, 65% of participants had a low level of knowledge, and 85% had no/low utilization of this controversial approach (Figure 5), demonstrating a need for further education on this topic.

Figure 5: Payer knowledge and utility of ICERs 'Shared Savings' approach



Conclusion

With a rapidly evolving healthcare policy and value assessment landscape in the US, it is critical to understand how these changing dynamics may impact access to biopharmaceutical innovations. US payers almost uniformly expect that the DPNP will result in meaningful reductions in patient access to medications in classes with a drug selected for the program. A majority of respondents also believe that the DPNP will cause a substantial reduction in R&D for drugs likely to be targeted by the DPNP. At the same time, US payers see mixed opportunities to improve the DPNP's evaluation methods. The influence of ICER still seems to be mixed between payers, with most citing at least a moderate level of influence of ICER reports on their formulary decision making processes. Payers and manufacturers alike must keep a strong pulse on these evolving policies and value assessment bodies in the US to understand potential impacts while continuing to support patient access.

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Abbreviations

CMS: Centers for Medicare & Medicaid Services
DPNP: Drug Price Negotiation Program
ICER: Institute for Clinical and Economic Review
IDN: Integrated Delivery Network
IRA: Inflation Reduction Act
IVI: Innovation and Value Initiative
MCO: Managed Care Organization
MFP: Maximum Fair Price
PBM: Pharmacy Benefit Manager