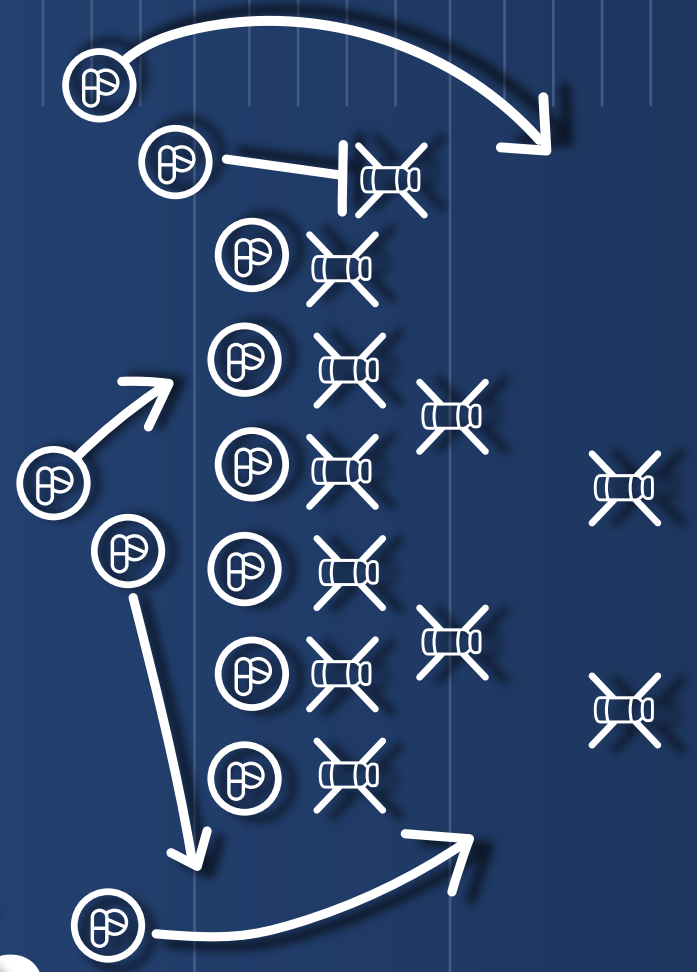


INFLATION REDUCTION ACT
PAYER INSIGHTS REPORT

Chartbook: Summary of Key Findings

VERSION 4.0, SUMMER 2024

Magnolia market access

a medical knowledge group company

Background and Methodology

Background

Passed in August 2022, the IRA is the largest and most consequential piece of legislation affecting the healthcare and pharmaceutical industries since the passage of the ACA back in 2009.

This research is the fourth in a series that MMA has conducted and provides insights into how payers will design their formularies, set their premiums, and negotiate contracts with manufacturers as the individual provisions of the IRA are enacted.

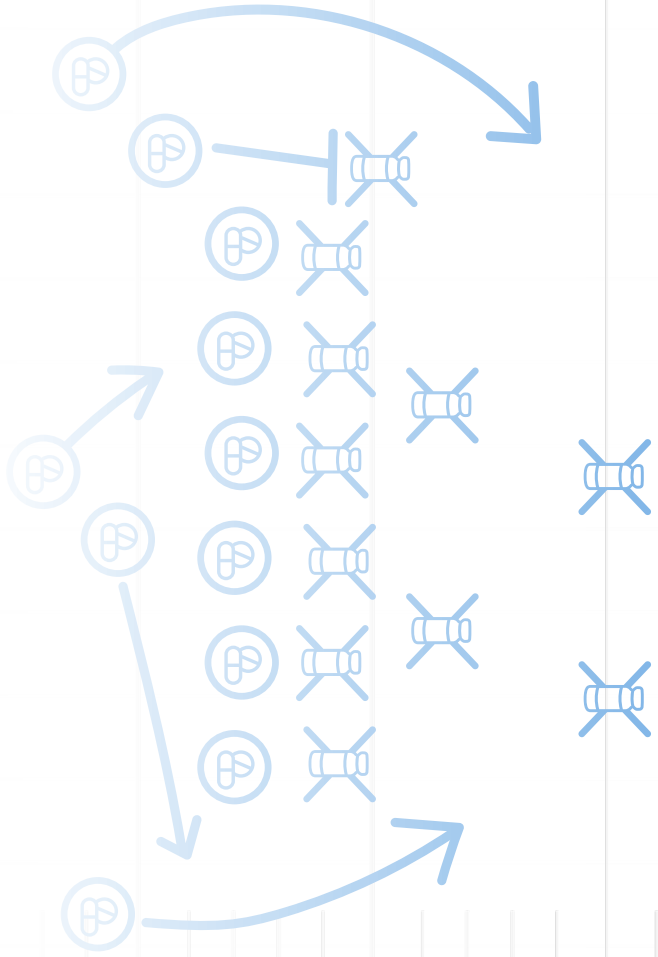
Previous IRA research surveys were conducted in the Fall of 2022, Spring of 2023, and Fall of 2023.

Survey Methodology

- Double-blinded web-based survey (45 minutes)
- Respondents: N = 23 medical and pharmacy directors from payers and PBMs (13 national/10 regional)
- Respondents represent >300 million covered lives

Interview Methodology

- Double-blinded interviews (60 minutes)
- Respondents: N = 9 medical and pharmacy directors from national/regional payers, PBMs, and IDNs (~ 200 million covered lives) and N = 2 consulting actuaries



IRA Payer Insights Survey 4.0

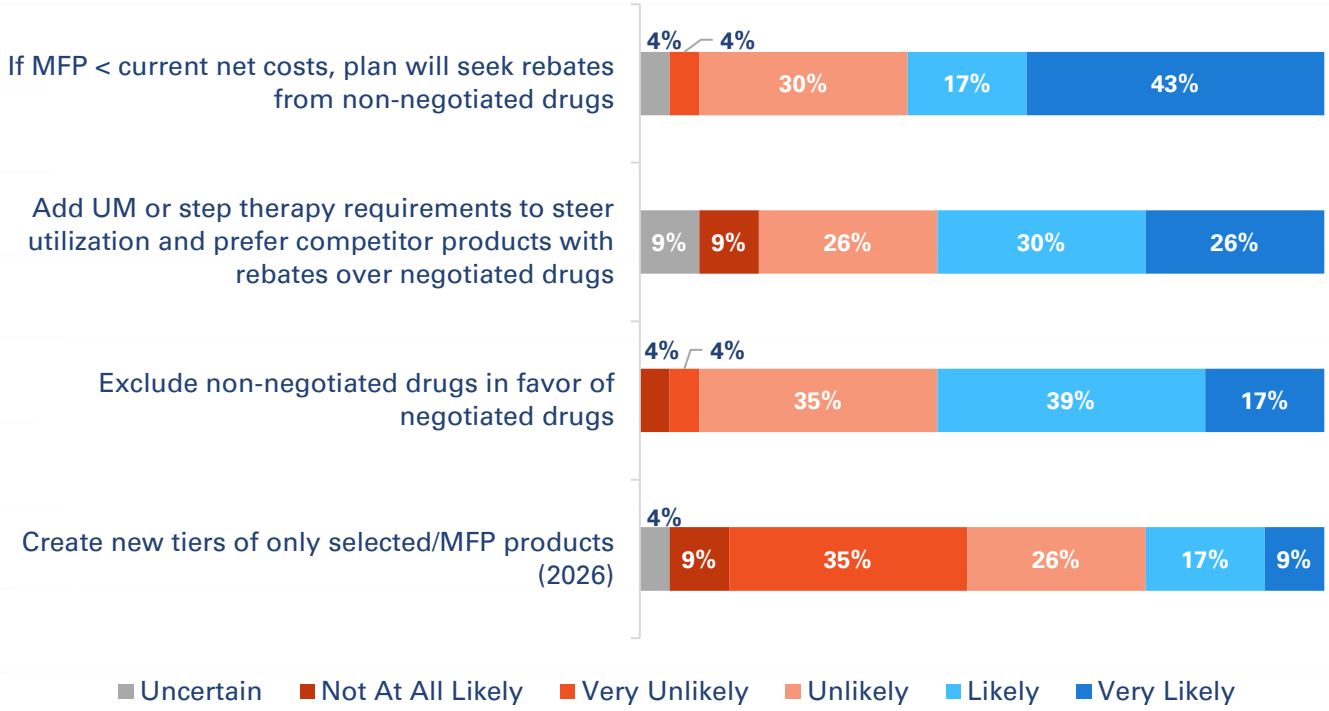
Drug Price Negotiation Program

Approximately 60% of Payers Plan to Add UM Requirements and Seek Additional Rebates in Response to Price Negotiations

In anticipation of price negotiations and MFPs in CY 2026, payers interviewed expect more restricted formularies and increased deployment of utilization management tools

CY 2026 Plan Year Actions in Anticipation of Price Negotiations

N = 23



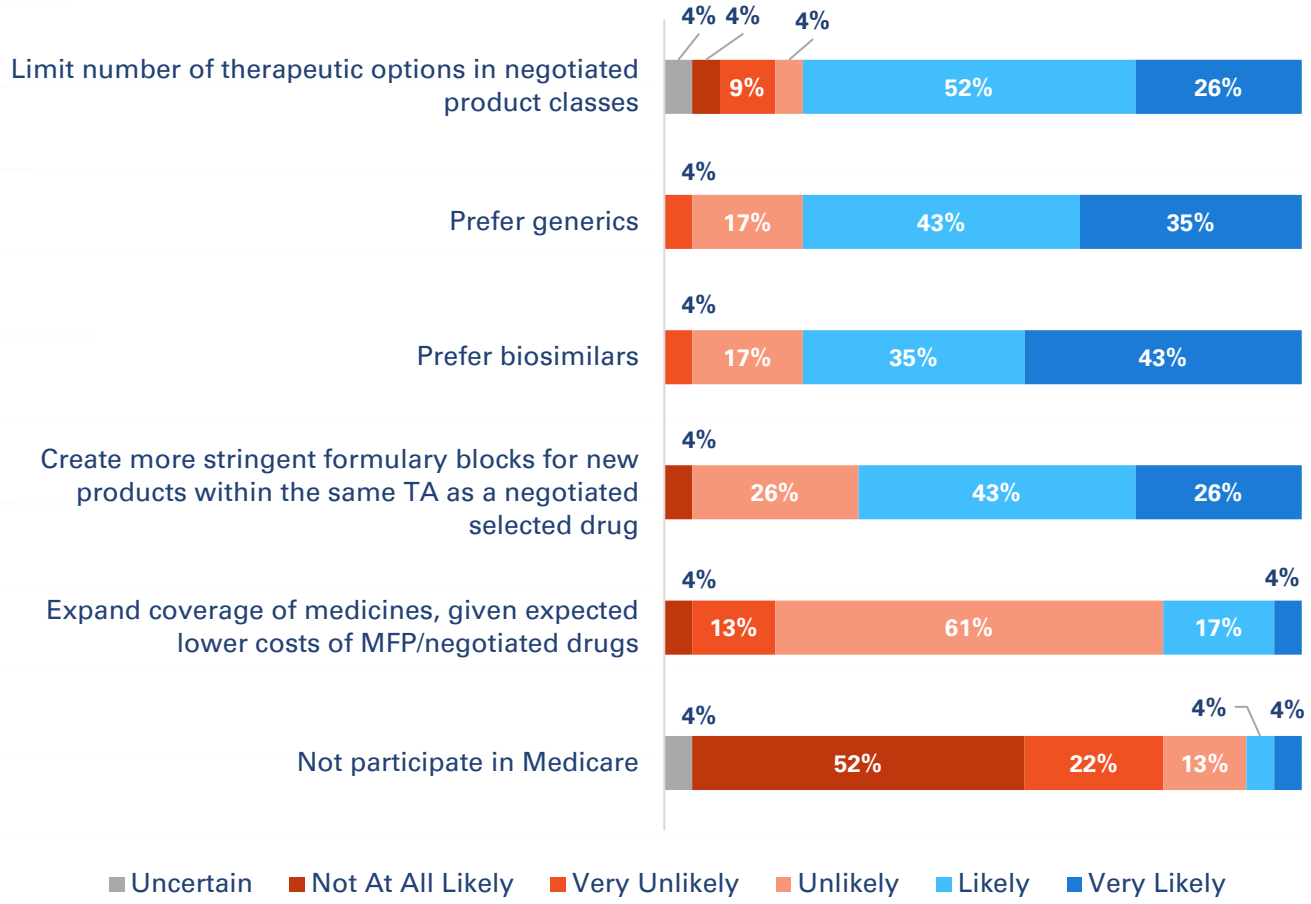
> "We're going to **keep covering the drugs that are negotiated by CMS**. I believe that's a requirement, but then we're going to look at how it compares on a net cost basis relative to other competitors. And if **a manufacturer is willing to beat the MFP and we don't get a supplemental rebate from the MFP drug**, then we will likely **advantage it via tiering and potentially step therapy**. Maybe have a PA on the MFP drug and no PA on the non-MFP drug."
>
> *- Payer 1, Pharmacy Director, National Health Plan*

Q. On August 29, 2023, CMS announced the 10 initial Part D drugs that are selected for negotiation under the Drug Price Negotiation Program (DPNP) for Price Applicability Year 2026. How likely do you expect your organization will take the following actions for the CY 2026 plan year, in anticipation of price negotiations and the resulting CMS-established Maximum Fair Prices (MFPs)?

78% of Payers Plan to Increase Use of Generics and Biosimilars, and Limit Therapeutic Options in Response to Price Negotiations

CY 2026 Plan Year Actions in Anticipation of Price Negotiations

N = 23



Note: "Formulary block" refers to payers not listing a new drug on formulary for a specific period of time following launch.

Q. On August 29, 2023, CMS announced the 10 initial Part D drugs that are selected for negotiation under the Drug Price Negotiation Program (DPNP) for Price Applicability Year 2026. How likely do you expect your organization will take the following actions for the CY 2026 plan year, in anticipation of price negotiations and the resulting CMS-established Maximum Fair Prices (MFPs)?

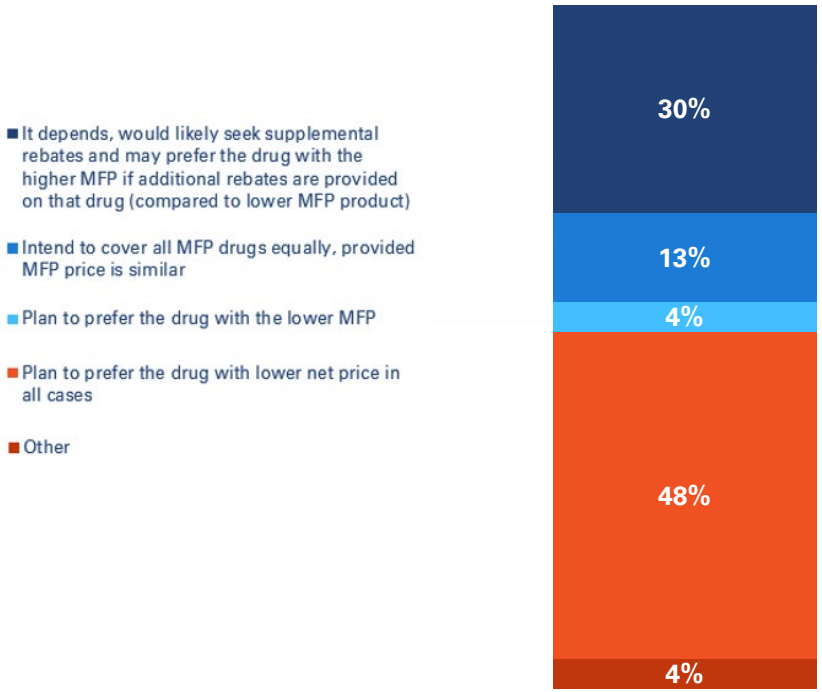
"There's going to be **more willingness to jump quickly to a generic or biosimilar** I think on our end and disrupt membership to do that, and **just to go with the lower net cost product**. Then from my understanding, once a product goes generic or as a biosimilar, then it's no longer eligible for MFP negotiation. But I think we're **still going to evaluate those as competitors and likely move to those quickly if the MFP goes away from the originator and go to the biosimilar generic in hopes of saving**."

- Payer 1, Pharmacy Director, National Health Plan

Approximately 50% of Payers Plan to Prefer the Lowest Net Price Product in Drug Classes With More Than One MFP Drug

Impact of MFP on Formulary Development

N = 23



MMA Insight

Manufacturers need to develop a strong HEOR strategy — a package of clinical, financial, and other relevant product-value based data — that works to raise the MFP of their negotiated products and, potentially, competitor negotiated products. This will be critical to establishing flexibility in product pricing and providing supplemental rebates instead of a higher, forced, MFP-based rebate.

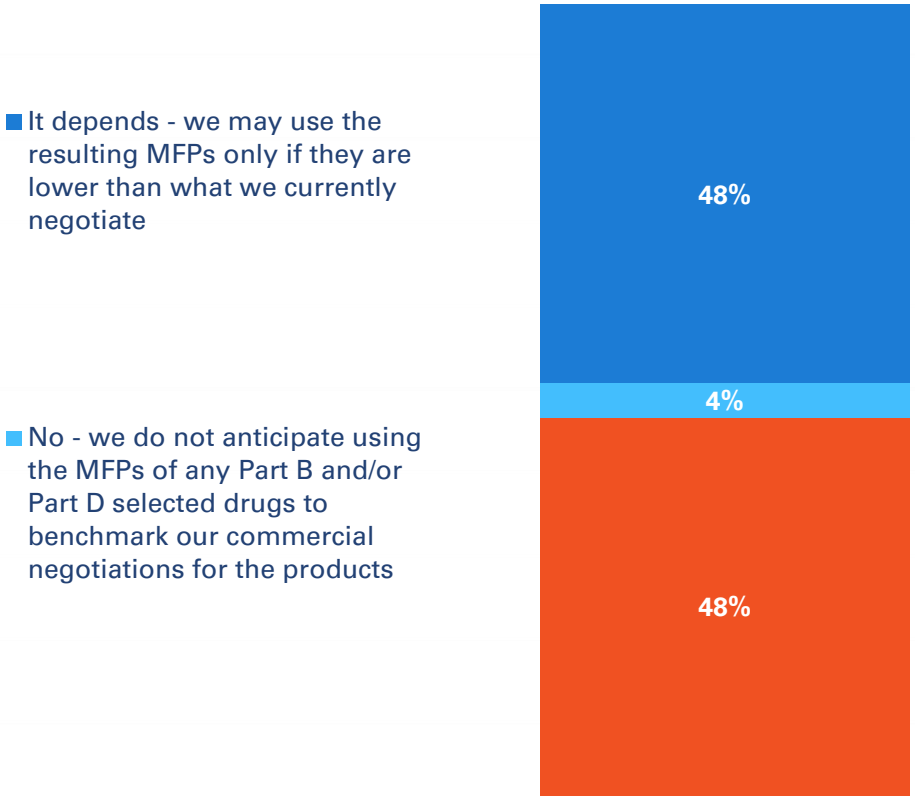
The release of any data around the initial MFPs for 2026 can guide manufacturers in post-approval research to receive higher MFPs.

Q. Several drug classes (e.g. diabetes, anticoagulants, autoimmune) have multiple drugs that have been selected for negotiation. When thinking about how you may cover one MFP drug versus another MFP drug in the same class, how does your organization plan to approach the formulary development of these classes?

Most Payers (96%) Plan on Conditionally Using the MFPs to Baseline Prices in Their Commercial Business

Anticipated Impact of Negotiated Drug MFPs on Commercial Lines of Business

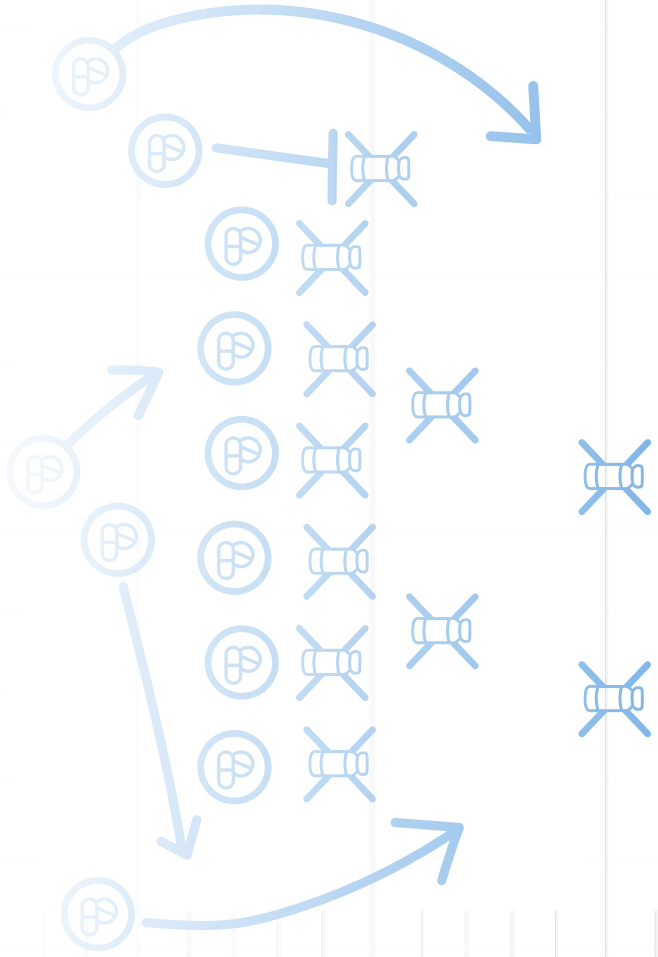
N = 23



"[That is] a good question that we don't have a good answer for. I think that **we are hopeful that there will be spillover and that we will be able to get competitive pricing on the commercial side, and even bigger discounts just to try to make up for some of the financial losses** that we're going to have as a result of the catastrophic stage and the $2,000 maximum out of pocket and other financial hits we're going to take on the Part D side."

- Payer 6, Medical Director, National Health Plan

Q. Do you anticipate the resulting MFPs of selected drugs will spill over into negotiations in your commercial line of business?



IRA Payer Insights Survey 4.0

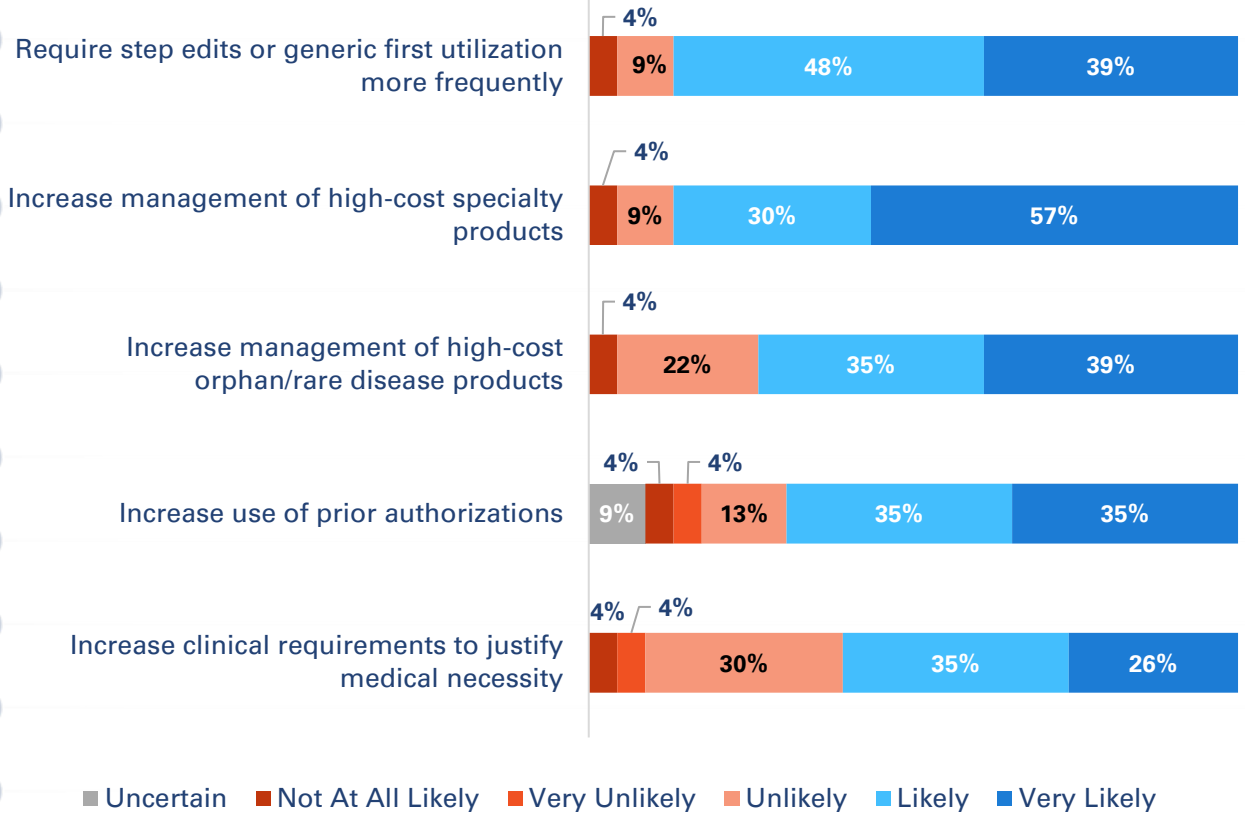
Part D Redesign

96% of Payers Are Increasing Utilization Management of High-Cost Products in Response to Part D Redesign

Most payers interviewed (89%) envision increased use of utilization management tools and pared-down formularies with respect to high-cost products

Payer Responses to the Part D Redesign

N = 23



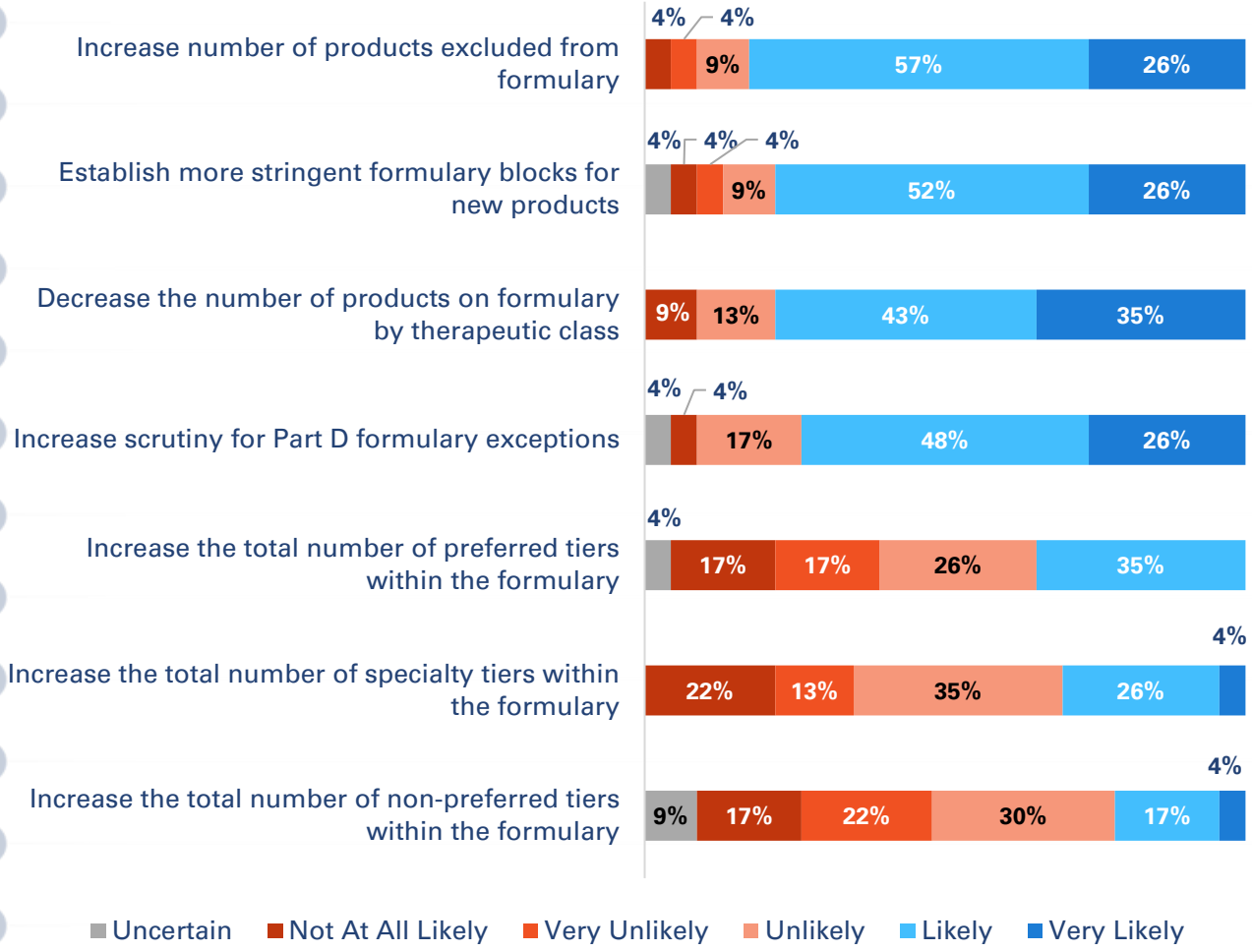
> "It's just going to be **more of prior authorizations, more exclusions, more step therapy**. I would say…**managing the medical benefit a lot more tightly is what we're looking at and a Part B step therapy…in categories that have historically been hands-off [like] oncology, rare disease.** So, things like for SOLIRIS and ULTOMIRIS, getting a little more hands-on and managing that…[with] more like step therapy. So, for example, we have a step therapy for an IV oncology class, right, and have a preferred agent there? So, I think you're going to see more of that in particular." - *Payer 1, Pharmacy Director, National Health Plan*

Q. With many of the IRA Part D redesign ("redesign") provisions taking effect beginning program year 2025, how likely is it that your organization will take the following actions with your Part D plans in the next 12 months?

In Response to Part D Redesign, Payers Expect to Tighten Formularies and Increase Clinical Criteria for Coverage

Payer Responses to the Part D Redesign

N = 23



Q. With many of the IRA Part D redesign ("redesign") provisions taking effect beginning program year 2025, how likely is it that your organization will take the following actions with your Part D plans in the next 12 months?

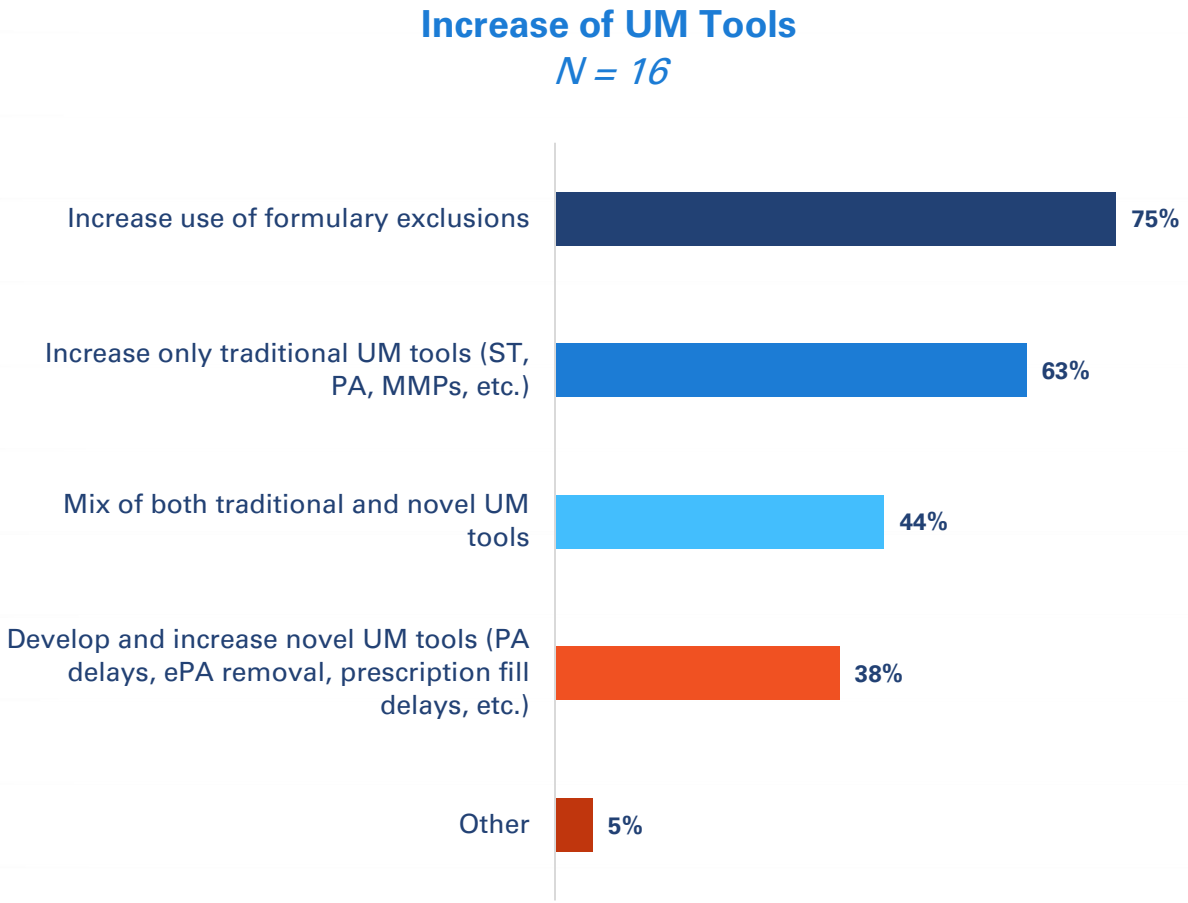
MMA Insight

Payers are evolving and going beyond the typical UM tactics. They plan to tighten formularies and increase clinical justification requirements for formulary exceptions, which places more burden on providers and patients to access treatment.

"[An] **increase in the number of exclusions** and **decrease the number of drugs on formulary**… that will be the lever that everyone's going to be pulling."

- Payer 8, Pharmacy Director, National PBM

Some Payers (38%) Plan on Developing and Increasing the Use of Novel UM Tools Within Their Formularies



MMA Insight

While payers are planning on doing much of the same through requiring more step edits and prior authorizations, they are going **to increase utilization management** by being more detailed in their prior authorization approaches through delays and exclusions.

Manufacturers need to prepare their hub resources to help patients navigate these novel approaches to achieve timely product access. If problematic access trends are identified, manufacturers should consider engaging CMS and/or patient groups to assist in increasing access through the removal of these UM tools.

Q. You mentioned your organization plans to increase the use of UM tools in response to the IRA. How does your organization plan to increase the use of UM tools for their plans? What other tools does your organization plan to implement to manage beneficiary utilization in your Part D plans considering the IRA?

In Response to the Part D Redesign, Payers Plan to Target a Variety of High-Spend Drug Classes for Increased Formulary Management

Over **65%** of plans expect to target **diabetes drugs** for increased formulary management in 2025

Other drug classes highlighted by payers for increased management include:

- Oncology
- Immunology
- Cardiology
- Rare Disease and Orphan Drugs

MMA Insight

While these spaces are known payer cost targets, the addition of rare diseases and orphan products may present new access and affordability challenges for rare disease patients.

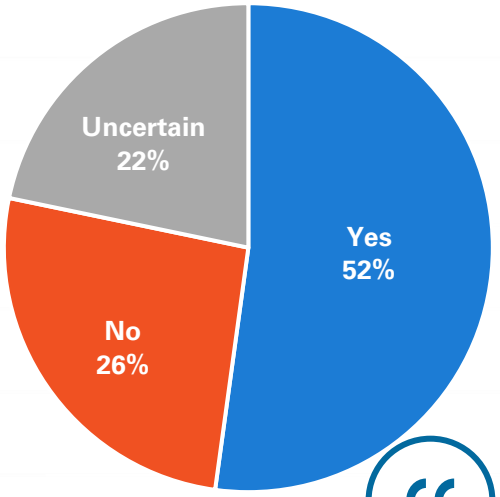
Manufacturers should consider evaluating patient support program eligibility criteria and offerings to identify new opportunities to ensure access during UM delays. Manufacturers should also consider working with patient groups to encourage CMS to enforce access requirements for the six protected classes.

Q. Considering the Part D redesign, what are the top three drug classes that your organization is targeting for increased formulary management in program year 2025?

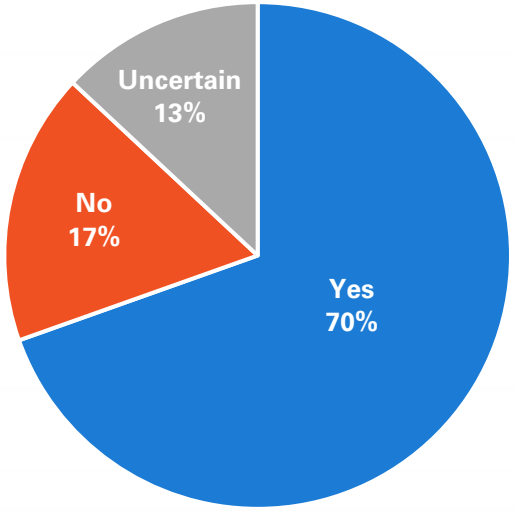
Payers Plan to Manage Protected and Non-Protected Classes More Aggressively in Response to the Part D Redesign

Increased Management Due to the Part D Redesign

Protected Classes
N = 23



Non-Protected Classes
N = 23



"**With protected drug classes, I really have very limited options**. I can step edit new starts and prior auth brands, and we'll do that if we can do it, we do it today. **Could we do it more so? Maybe.** Maybe there's a couple of classes where we might look at pushing the envelope…[such as] **more step therapy through generic options**."
- *Payer 8, Pharmacy Director, National PBM*

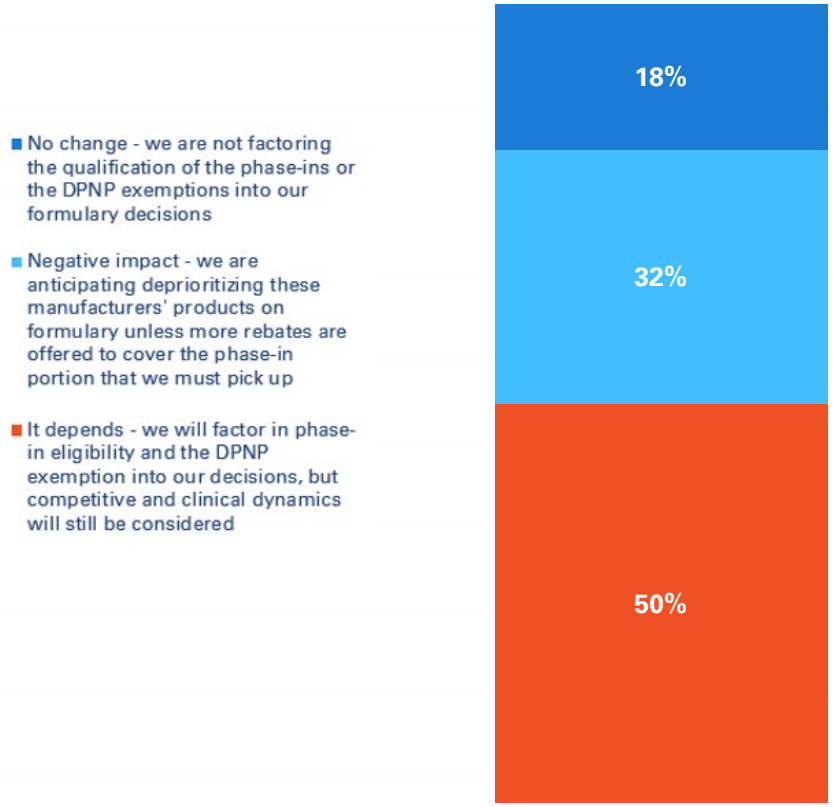
"**Even in protected classes, we have utilization strategy controls**…There's clinical pathways or preferencing for some agents over others. And so even if it's protected, there's utilization controls contracting that is driving not just choice, but then even where product stands in terms or being preferred or not preferred."
- *Payer 3, Medical Director, Regional IDN*

Q. Do you anticipate your organization to manage Part D protected classes more aggressively than before in response to the redesign? Do you anticipate your organization to manage Part D non-protected classes more aggressively than before in response to the redesign?

>80% of Payers Indicated Phase-In Eligibility to Be a Factor in Formulary Decision-Making

Impact of DPNP Phase-In Option for Qualifying Small Manufacturers

N = 22

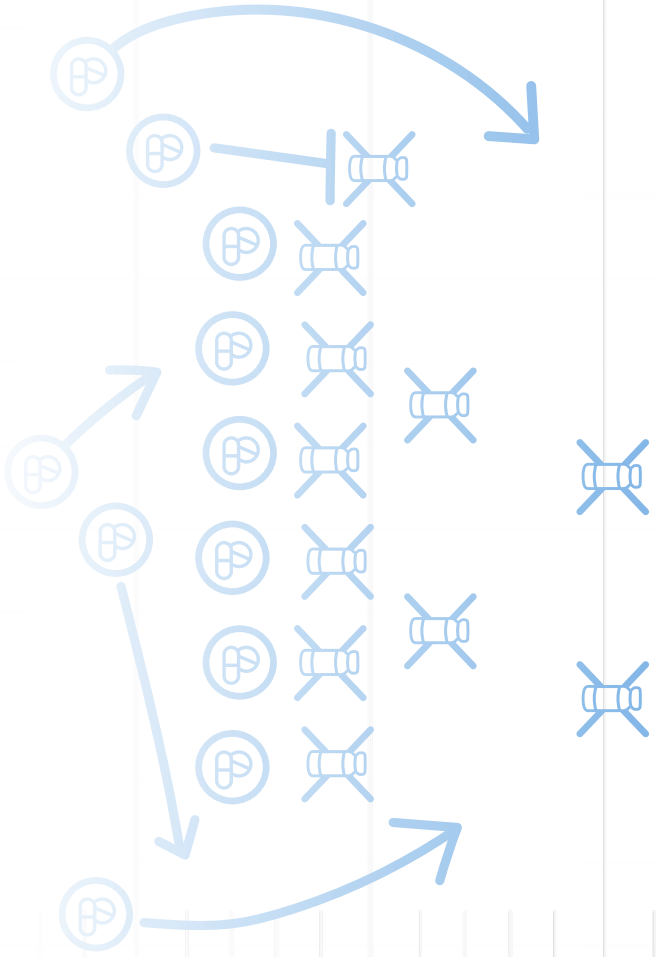


MMA Insight

While qualifying for the phase-ins could be beneficial, manufacturers that qualify need to be prepared for rebate requests from payers.

Manufacturers can prepare for payer phase-in rebate requests by conducting market research and gross-to-net scenario planning to understand which of their competitors qualify for these phase-ins and how a payer might approach the market. This will help manufacturers assess whether payer rebate requests need to be addressed.

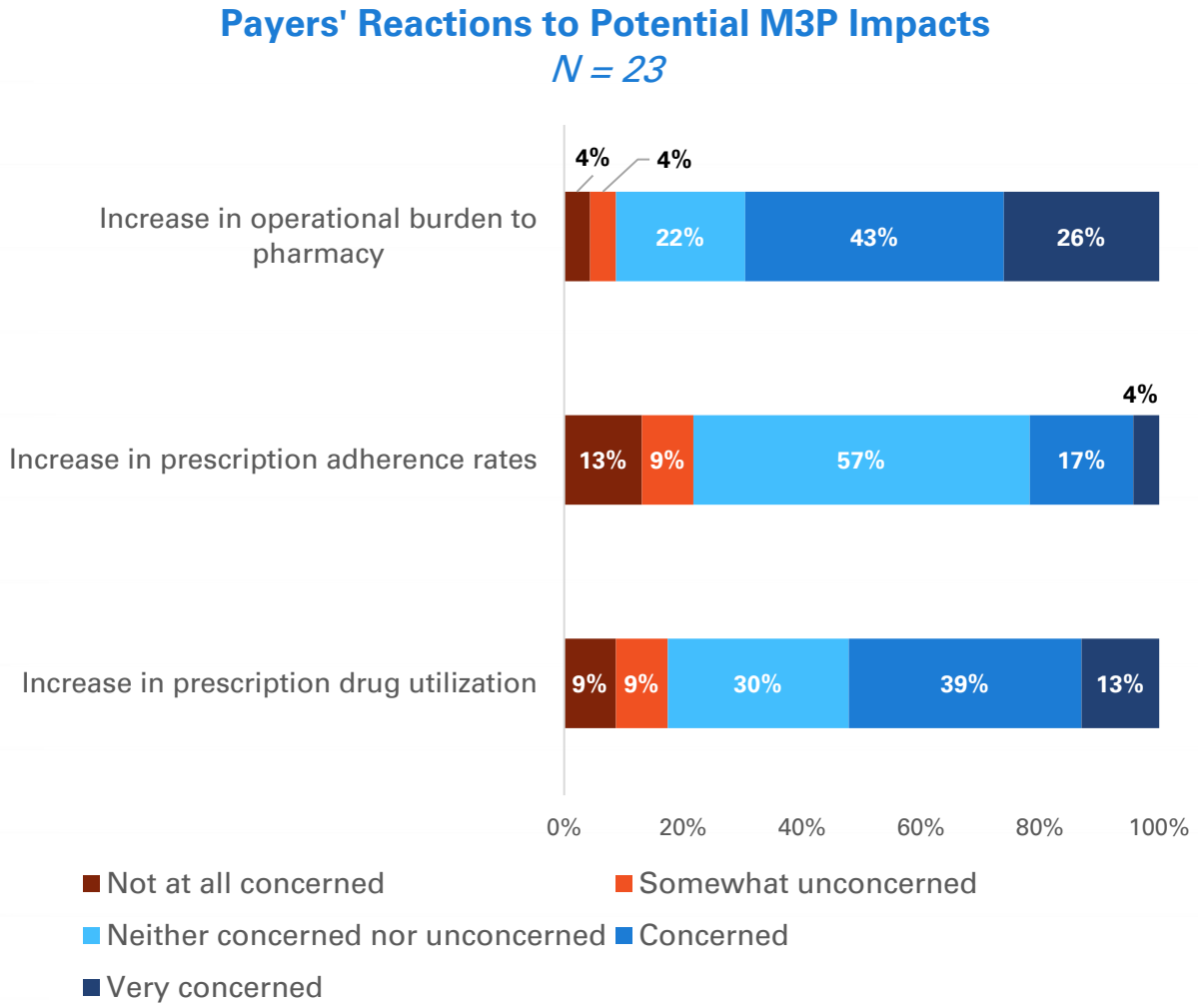
Q. Manufacturers are able to qualify for a specified manufacturer Part D discount program phase-in and a specified small manufacturer DPNP exemption/Part D discount program phase-in. Payers will be responsible for the leftover amount that manufacturers do not pay in the discount program due to the phase-in. How does your organization anticipate contracting with manufacturers who qualify as a specified manufacturer or specified small manufacturer?



IRA Payer Insights Survey 4.0

M3P Program

Payers Believe M3P Will Improve Adherence and Utilization Increase Operational Burden to Pharmacies



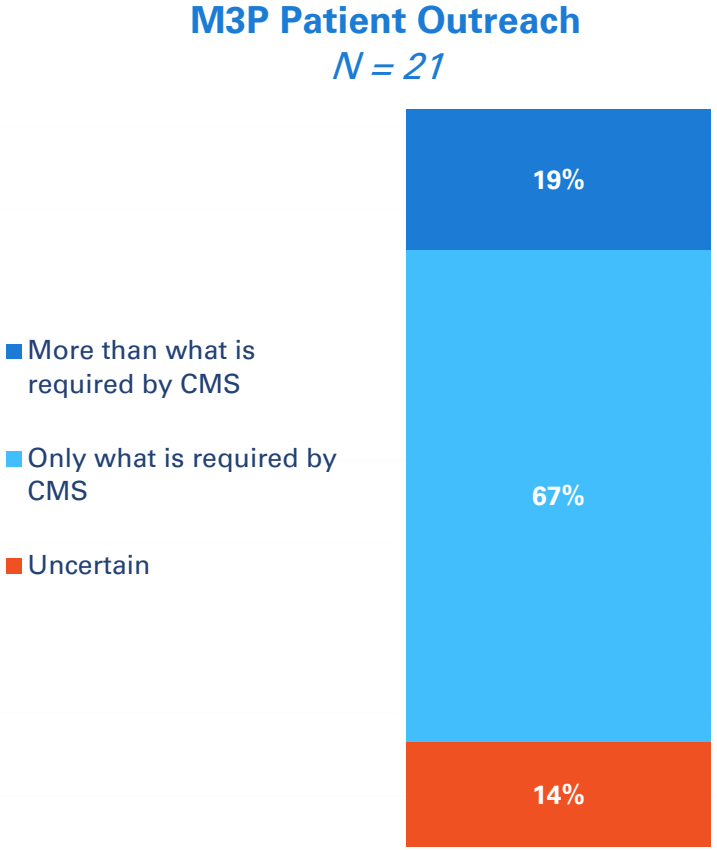
MMA Insight

While payers are concerned about the operational burden M3P creates for pharmacies, they recognize its value in improving patient adherence and utilization.

Manufacturers should develop educational materials and training programs for pharmacies, providers, and patients to raise awareness of the program.

Q. How concerned, if at all, is your organization with the potential impacts listed below due to implementation of the M3P program?

Many Payers (67%) Intend to Only Meet CMS' Basic Requirements for Beneficiary Outreach



MMA Insight

CMS' definition of patients likely to benefit could reduce enrollment in them M3P. Manufacturers should utilize hub data to initiate education and enrollment.

"I think there'll **be enough promotion** … coming from advocacy, pharmacies, others that will **help offset the minimum we're doing here**."

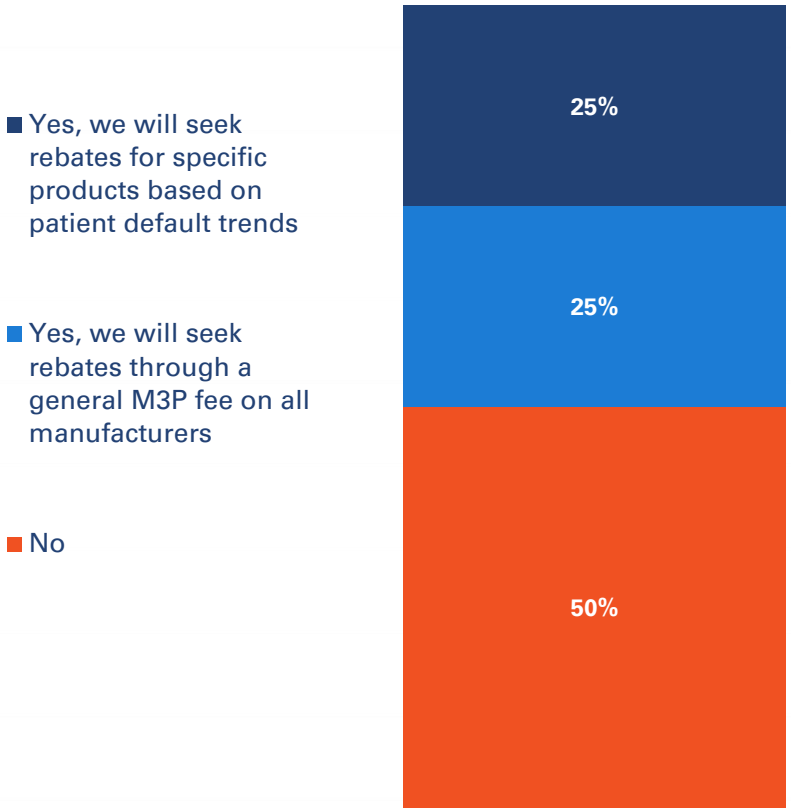
- Payer 8, Pharmacy Director, National PBM

Q. How does your organization intend to approach educational materials regarding participation in the M3P program?

Payers are Split on Seeking Financial Reimbursement From Manufacturers for M3P Payment Defaults

Late Payment Reimbursement Through Manufacturer Rebates

N = 20



MMA Insight

Looking forward to 2026 and 2027, manufacturers should monitor how payers are reacting to late payments and develop strategies for those payers that may seek additional rebates. Non-branded provider and patient education will be an important opportunity to increase patient understanding and timely payment. Health equity issues are likely to play a role in patient default rates, and state and local assistance funds should be identified and shared in patient education materials.

Q. How flexible will your organization be in its approach to ending patients' participation in the M3P program if they are late for payments?

If you have questions, or would like to purchase a copy of the full survey, please contact us at:

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