Improving Access Through the Inflation Reduction Act (IRA):

How Can Manufacturers Support Patients During IRA Implementation?

Magnolia market access

a medical knowledge group company

Magnolia Market Access: Meet Your Presenters

Amanda Forys

Managing Partner,
Magnolia Market Access

- Leader of Magnolia Market Access
- 18 years of industry and consulting experience in pharmaceuticals and devices
- Assists clients at the intersection of health policy, pricing, coverage, reimbursement, payer strategy, and real-world evidence
- Quantitative and qualitative background in pharmaceutical and device market access and commercialization strategy
- Extensive experience in specialty drug and rare disease space
- Master of Science in public health from the University of North Carolina at Chapel Hill, Bachelor of Science in biopsychology and cognitive sciences, and Bachelor of Musical Arts in voice performance from the University of Michigan

Amanda O'Hora

SVP,
Reimbursement & Market Access

- 25 years of industry and consulting experience designing and implementing reimbursement and market access strategies
- Expertise in commercialization plans that include coding/billing, payer coverage, and payment and reimbursement mechanisms in the US market
- Assists clients with conceptualizing patient support service offerings
- Knowledge and understanding in specialty pharmaceuticals, rare disease, cell and gene therapies, and medical devices
- Bachelor of Arts in history from Florida State University

Magnolia market access
a medical knowledge group company

Magnolia Market Access: Who We Are

Magnolia market access
a medical knowledge group company

Providing tailored strategies and insights to meet the market access, HEOR, and healthcare policy needs of pharmaceutical & biotech companies, device manufacturers, and trade associations.

Our team has **decades** of **experience** helping clients **develop market access strategies rooted in HEOR.**

Built on a bedrock of **policy, economics, and medical expertise**

Deep expertise in **federally and commercially sponsored programs,** including **Medicare Advantage**

Industry-leading integrated knowledge: data and analytics, market access research, and strategic consulting

We consider how the **dynamic health care environment** affects therapies through the **entire product life cycle**

Magnolia market access
a medical knowledge group company

Objectives

This webinar will help you and your organization understand:

Education

The IRA and its effects on patients

Outreach

Payer responsibilities and potential gaps in IRA

Enrollment

Actions that manufacturers are taking to prepare, address, and track patient access and IRA effects

Magnolia market access

a medical knowledge group company

Agenda

1 IRA Overview and Effects on Patients

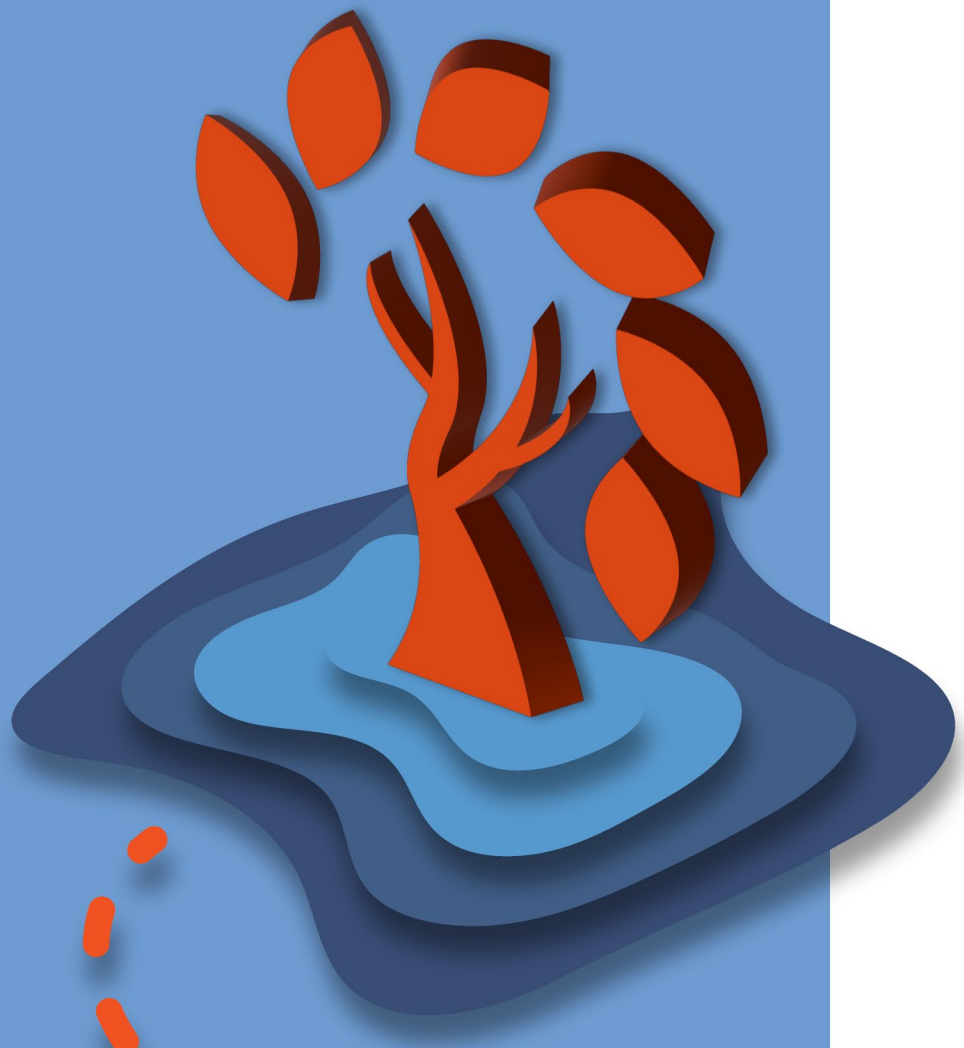
2 Payer Reactions and Requirements to Support Patients With the IRA

3 Manufacturer Support Opportunities to Prepare Patients for IRA Implementation

4 Webinar Wrap-Up

Magnolia market access

a medical knowledge group company



IRA Overview and Effects on Patients

Magnolia market access

a medical knowledge group company

Patient Effects: Major IRA Provisions Affecting Patients

Beginning January 1, 2025:

IRA Provision	Significance for Patients
Part D Redesign	The "coverage gap" phase of the Part D benefit will be eliminated, and maximum out-of-pocket costs will be **capped at $2,000 annually**
Medicare Prescription Payment Plan (M3P) Program	Patients will have the ability to **spread** (or "smooth") their out-of-pocket prescription drug costs over the course of the calendar year

Insight

The benefits of these changes for patients come with financial, operational, and administrative considerations for payers, providers, and manufacturers; however, **proactive planning, and training** can minimize barriers.

Magnolia market access
a medical knowledge group company

Overview: Four Components of the Medicare Part D Redesign

1

Benefit Redesign

Eliminate 5% beneficiary coinsurance above catastrophic coverage threshold

Cap out-of-pocket costs at $2,000 in 2025

2

Manufacturer Discount

Subject manufacturers to mandatory discounts on brand drugs in the initial coverage and catastrophic coverage phases

3

Out-Of-Pocket (OOP) Cap

Add hard cap on out-of-pocket spending of $2,000 in 2025, indexed in future years to the rate of increase in per capita Part D costs

4

Premium Cap

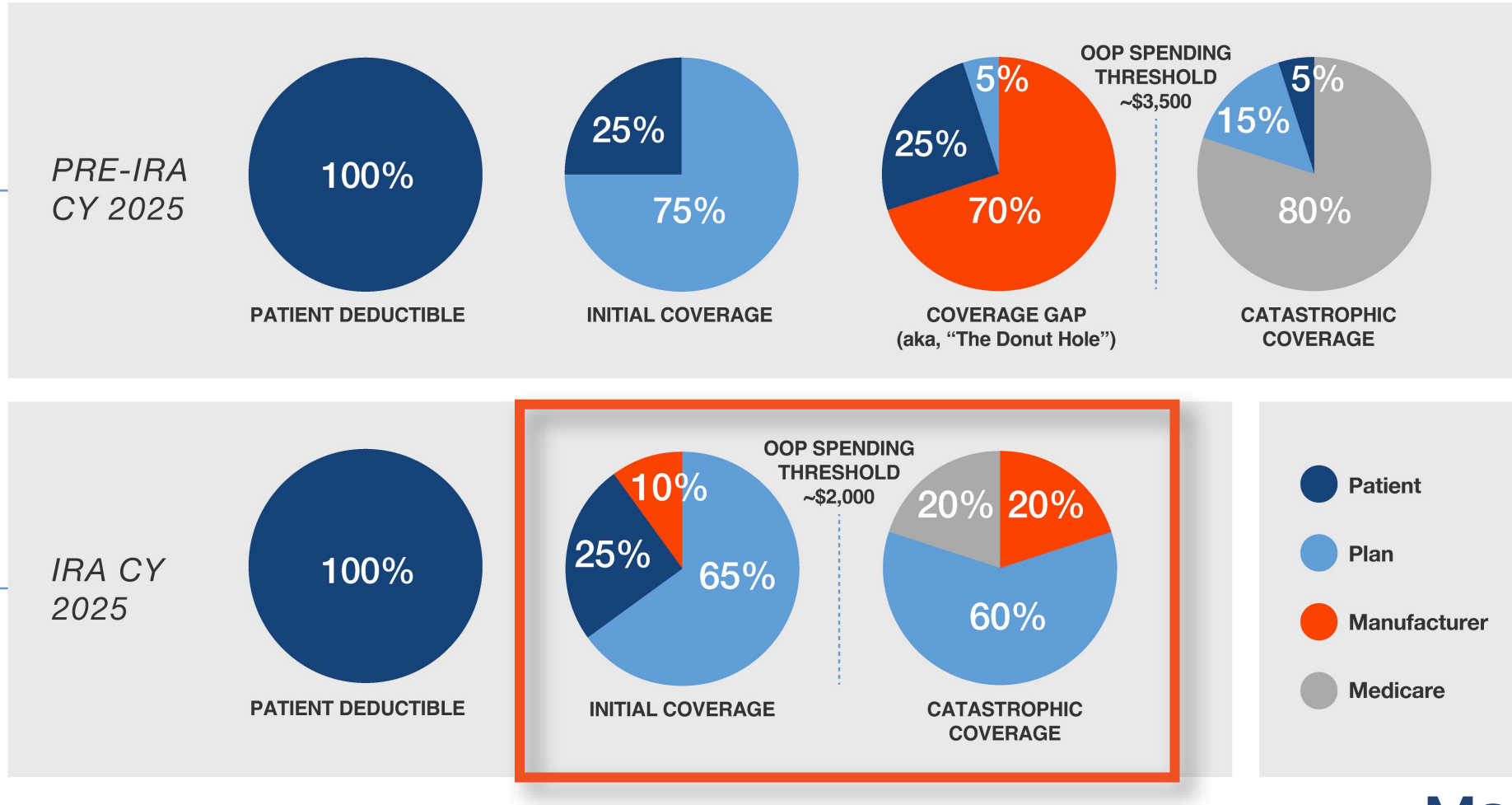
Limit base premium annual increase to 6% from 2024 to 2029

Lower beneficiary cost share of standard drug coverage in 2023

MEDICARE PART D REDESIGN

Changing Liabilities: Significant Shift of Financial Responsibility to Payers and Manufacturers

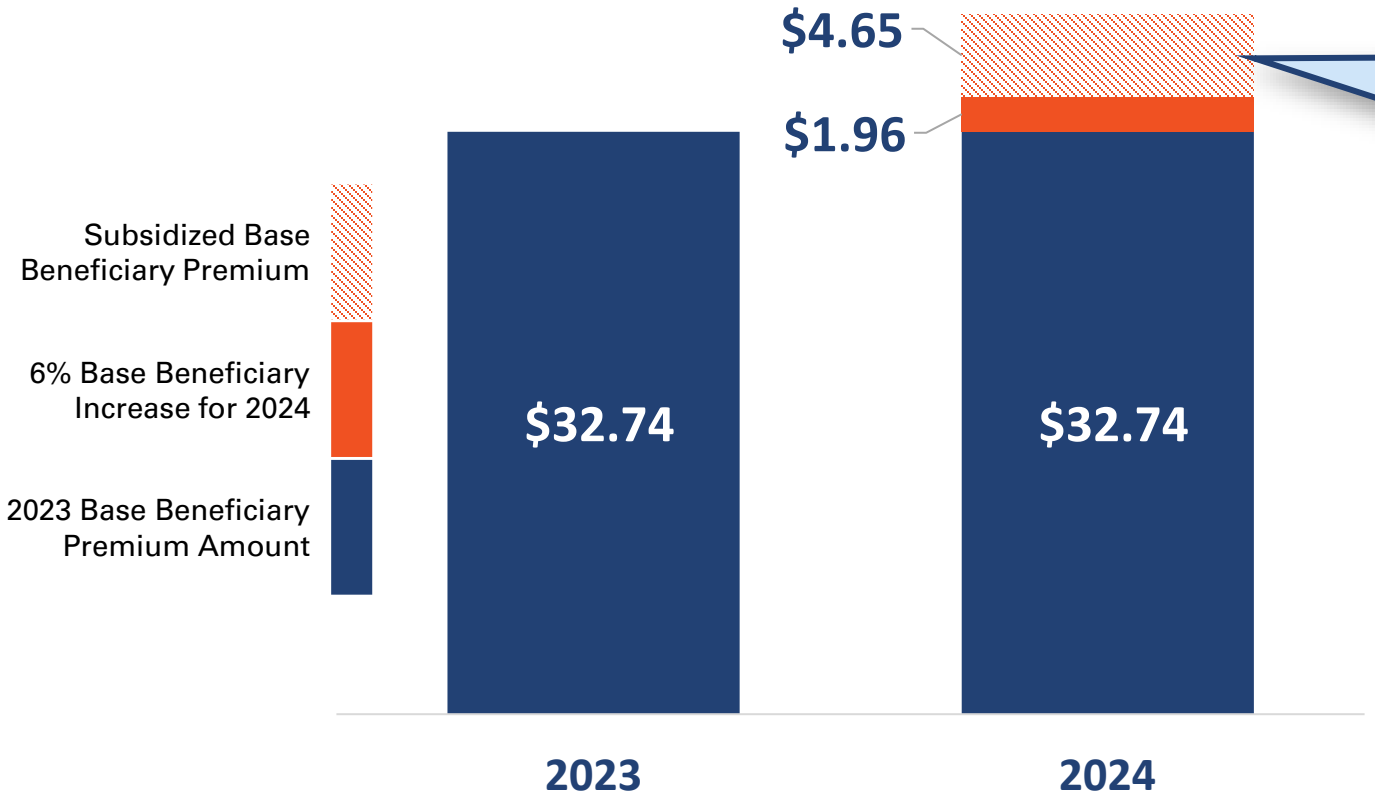
Part D Benefit Plan Redesign



Magnolia market access
a medical knowledge group company

Premium Stabilization: Plan Subsidies Based On the Base Beneficiary Premium (BBP)

Base Beneficiary Premium Change



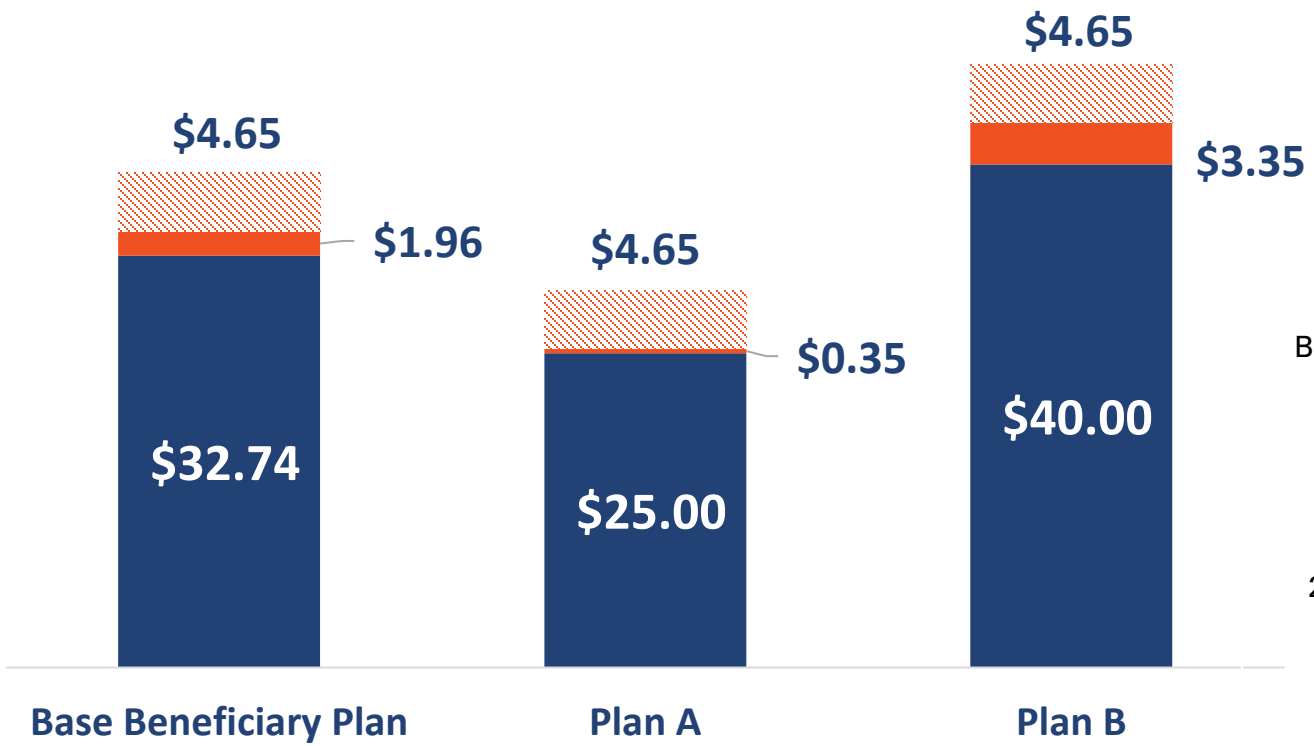
The $4.65 base beneficiary premium subsidy is based on the national average monthly bid amount (NAMBA) and **does not shift for payers with higher bids**

Plans may increase their PA and UM to avoid having to increase their beneficiary premiums beyond the premium subsidy– **without added stopgaps it may be difficult for them to compete**

Magnolia market access
a medical knowledge group company

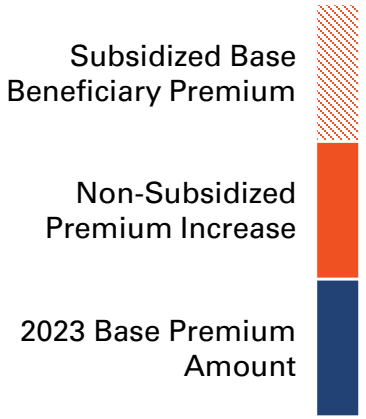
Premium Stabilization: Do Patients Really See a 6% Cap?

Premium Subsidies by Plan



Premium Increase Percentage by Plan

	Total Premium Increase Percentage	Non-Subsidized Premium Increase Percentage
Plan A	20%	1.4%
Plan B	20%	8.4%



Despite receiving the same subsidy amount and having the same premium increase **– the premium increase for patients will differ between Plan A and Plan B**

Magnolia market access
a medical knowledge group company

Overview: Medicare Prescription Payment Plan (M3P) Program to Spread Patient Cost-Share Over the Plan Year[1]

First Month Maximum Cap

$$\frac{\text{Annual OOP Threshold – Incurred Costs of the Enrollee}}{\text{Number of Months Remaining in the Plan Year}}$$

Subsequent Month Maximum Cap

$$\frac{\text{Sum of Remaining OOP Costs not yet Billed to Enrollee + Additional OOP Costs Incurred by Enrollee}}{\text{Number of Months Remaining in the Plan Year}}$$

Based on these formulas, some beneficiaries, such as those who opt in to M3P earlier in the plan year or have higher single-prescription costs, may find more benefit from the M3P Program. However, all Part D beneficiaries have the option to enroll.

1. CMS. Technical Memorandum on the Calculation of the Maximum Cap on Cost-Sharing Payments Under Prescription Drug Plans. Published July 17, 2023. https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf

Specialty Brand Product Example: Changes to Patient Out-of-Pocket Costs With the M3P[1]

Example Assumptions:

- Individual opts in to M3P in January
- Drug cost of $6000/month
- Enrolled in a standard benefit plan
- Defined standard deductible of $590

While the patient will pay more frequently throughout the year, the patient can **save $1,833** with the M3P in the first month and reduce the healthcare cost burden at the beginning of the year.

Month	Monthly Drug Cost	No M3P: Patient OOP Cost	With M3P: Patient OOP Cost	Difference
January	$6,000	$2,000	$167	+$1,833
February	$6,000	$0	$167	-$167
March	$6,000	$0	$167	-$167
April	$6,000	$0	$167	-$167
May	$6,000	$0	$167	-$167
June	$6,000	$0	$167	-$167
July	$6,000	$0	$167	-$167
August	$6,000	$0	$167	-$167
September	$6,000	$0	$167	-$167
October	$6,000	$0	$167	-$167
November	$6,000	$0	$167	-$167
December	$6,000	$0	$167	-$167
Total	**$72,000**	**$2,000**	**$2,000**	**$0**

1. CMS. Technical Memorandum on the Calculation of the Maximum Cap on Cost-Sharing Payments Under Prescription Drug Plans. Published July 17, 2023. https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf

Magnolia market access
a medical knowledge group company

Non-Specialty Brand Product Example: Changes to Patient Out-of-Pocket Costs With the M3P[1]

Example Assumptions:

- Individual opts in to M3P in January
- Drug cost of $500/month
- Started an additional $500/month drug in July
- Enrolled in a standard benefit plan
- Defined standard deductible of $590

The patient will experience **moderate savings** in the beginning of the year but will have to **make up payments** in the final months of the year as smoothed payments become due. Depending on their financial situation, patients could prefer **either option**.

Month	Monthly Drug Cost	No M3P: Patient OOP Cost	With M3P: Patient OOP Cost	Difference
January	$500	$500	$125	+$375
February	$500	$193	$52	+$141
March	$500	$125	$64	+$61
April	$500	$125	$78	+$47
May	$500	$125	$94	+$31
June	$500	$125	$111	+$14
July	$1,000	$250	$153	+$97
August	$1,000	$250	$203	+$47
September	$1,000	$250	$266	-$16
October	$1,000	$57	$285	-$228
November	$1,000	$0	$285	-$285
December	$1,000	$0	$284	-$284
Total	**$9,000**	**$2,000**	**$2,000**	**$0**

1. CMS. Technical Memorandum on the Calculation of the Maximum Cap on Cost-Sharing Payments Under Prescription Drug Plans. Published July 17, 2023. https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf

Magnolia market access
a medical knowledge group company

M3P PROGRAM

Non-Specialty Brand Product Example (cont.): Behind the Payment Amount[1]

After January:
OOP Cost = (Remaining Cost + New Costs) / months remaining in the year

		Annual OOP Threshold	$2,000					
A	B	C	D	E	F	G	H	I
			=D1+C2 (recursive)	2025 Part D Benefit Design	=F1+E2 (recursive)	=G1+I2 (recursive)	=F-G	= (H1+E2)/A2
Months Left	Month	Monthly Drug Cost	Total Incurred Drug Cost	Patient Cost w/out M3P	Accumulated Cost w/out M3P	Accumulated Cost w/ M3P	Not yet paid by patient	Patient Cost w/ M3P
12	January	$500.00	$500.00	$500.00	$500.00	$125.00	$375.00	$125.00
11	February	$500.00	$1,000.00	$193.00	$693.00	$176.64	$516.36	$51.64
10	March	$500.00	$1,500.00	$125.00	$818.00	$240.77	$577.23	$64.14
9	April	$500.00	$2,000.00	$125.00	$943.00	$318.80	$624.20	$78.03
8	May	$500.00	$2,500.00	$125.00	$1,068.00	$412.45	$655.55	$93.65
7	June	$500.00	$3,000.00	$125.00	$1,193.00	$523.96	$669.04	$111.51
6	July	$1,000.00	$4,000.00	$250.00	$1,443.00	$677.13	$765.87	$153.17
5	August	$1,000.00	$5,000.00	$250.00	$1,693.00	$880.30	$812.70	$203.17
4	September	$1,000.00	$6,000.00	$250.00	$1,943.00	$1,145.98	$797.02	$265.67
3	October	$1,000.00	$7,000.00	$57.00	$2,000.00	$1,430.65	$569.35	$284.67
2	November	$1,000.00	$8,000.00	$-	$2,000.00	$1,715.33	$284.67	$284.67
1	December	$1,000.00	$9,000.00	$-	$2,000.00	$2,000.00	$-	$284.67
			Total	$2,000.00			Total	$2,000.00

1. CMS. Technical Memorandum on the Calculation of the Maximum Cap on Cost-Sharing Payments Under Prescription Drug Plans. Published July 17, 2023. https://www.cms.gov/files/document/monthly-cap-cost-sharing-technical-memo-july-2023.pdf

Magnolia market access
a medical knowledge group company

Timeline: Implementation of the M3P from Mid-2023 to Launch in Early 2025[1]

July 17, 2023
Summary and Sample Calculations technical memo was published

August 21, 2023
M3P Draft Part One Guidance was published

September 20, 2023
Deadline for comments on M3P Draft Part One Guidance

February 15, 2024
M3P Draft Part Two Guidance was published

February 29, 2024
M3P Final Part One Guidance was published

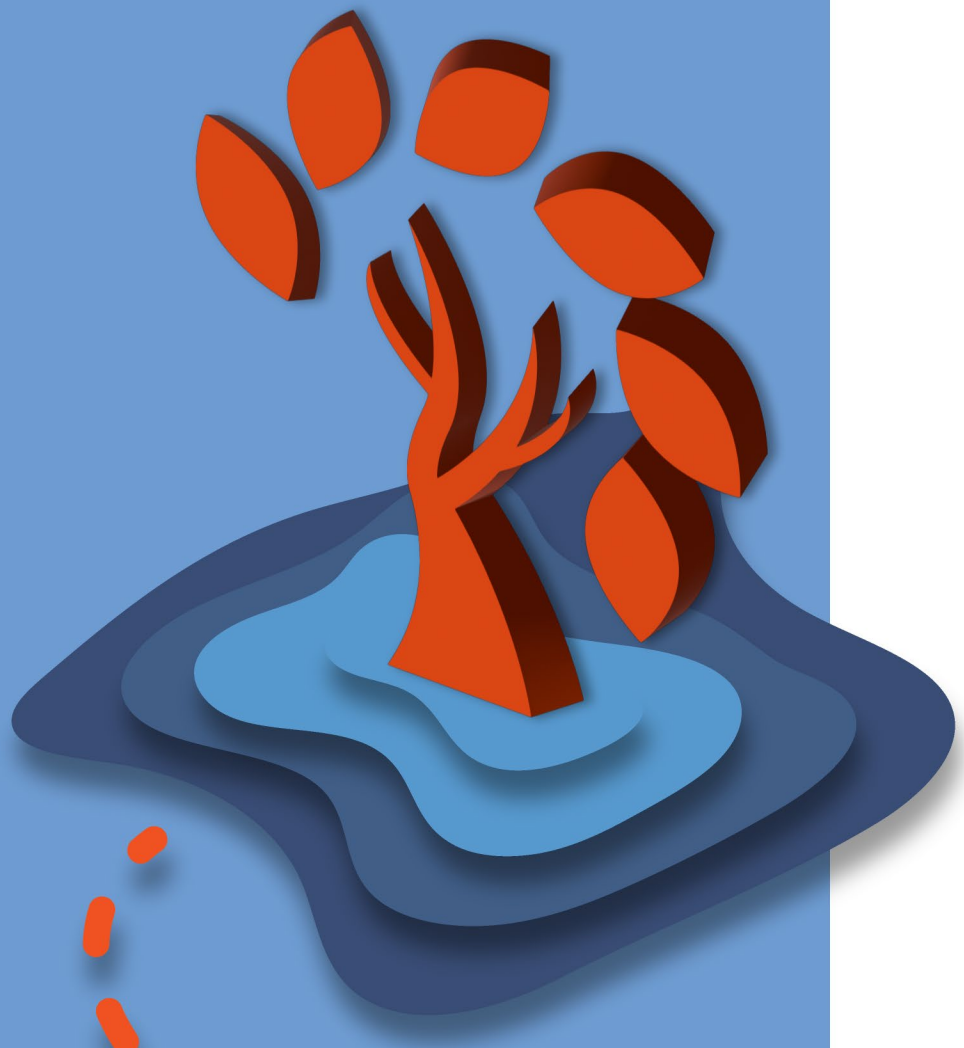
March 16, 2024
Deadline for comments on M3P Draft Part Two Guidance

Summer 2024
Expected finalization of M3P Part Two Guidance

October 15, 2024
Part D enrollees can opt in to the M3P during Medicare Open Enrollment

January 1, 2025
M3P will launch

1. CMS. Medicare Prescription Payment Plan Implementation Timeline. https://www.cms.gov/files/document/medicare-prescription-payment-plan-timeline.pdf. Accessed June 19, 2024.

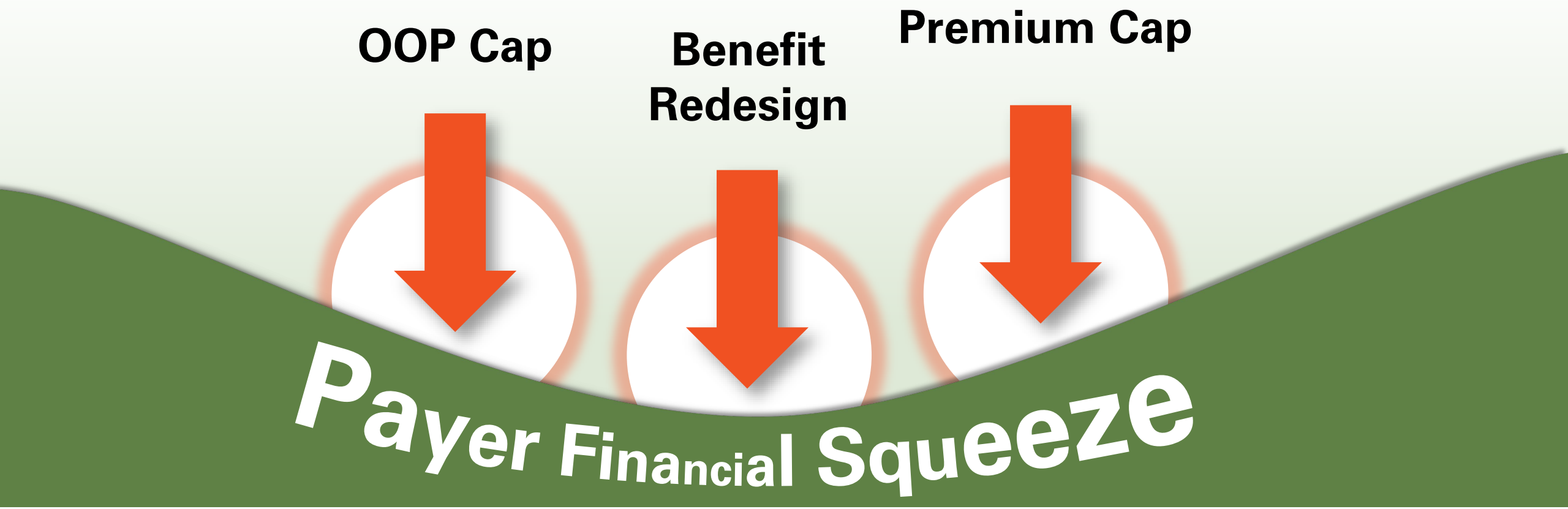


Payer Reactions and Requirements to Support Patients With the IRA

Magnolia market access

a medical knowledge group company

Financial Strain: Payer Struggles With Balancing Competitive Plan Offerings and Absorbing Costs Associated With Part D Redesign



Magnolia market access
a medical knowledge group company

Payer Responsibilities: CMS Guidance to Payers About the M3P[1,2]

- Identification of "likely-to-benefit" participants
- Participation
- Program outreach and education
- Payment issues
- Billing
- Reimbursement
- Data submission requirements
- Program calculations

1. CMS. Medicare Prescription Payment Plan Final Part One Guidance. Published February 29, 2024. https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf
2. CMS. Medicare Prescription Payment Plan Draft Part Two Guidance. Published February 15, 2024. https://www.cms.gov/files/document/medicare-prescription-payment-plan-draft-part-two-guidance.pdf

What is Missing?: CMS Guidance Leaves Ambiguity in Payer Responsibilities[1,2]

Outreach

- Is the $600 single prescription likely-to-benefit (LTB) notification threshold established by CMS sufficient to capture all/enough LTB beneficiaries?
- What beneficiaries are missed with that threshold?

Enrollment

- What enrollment benchmarks will payers have to meet?
- What role do payers play in program enrollment at the pharmacy counter?

Education

- Given the ambiguous requirements for educational resources, should CMS require that payers provide standard information to decrease enrollee confusion?

1. CMS. Medicare Prescription Payment Plan Final Part One Guidance. Published February 29, 2024. https://www.cms.gov/files/document/medicare-prescription-payment-plan-final-part-one-guidance.pdf
2. CMS. Medicare Prescription Payment Plan Draft Part Two Guidance. Published February 15, 2024. https://www.cms.gov/files/document/medicare-prescription-payment-plan-draft-part-two-guidance.pdf

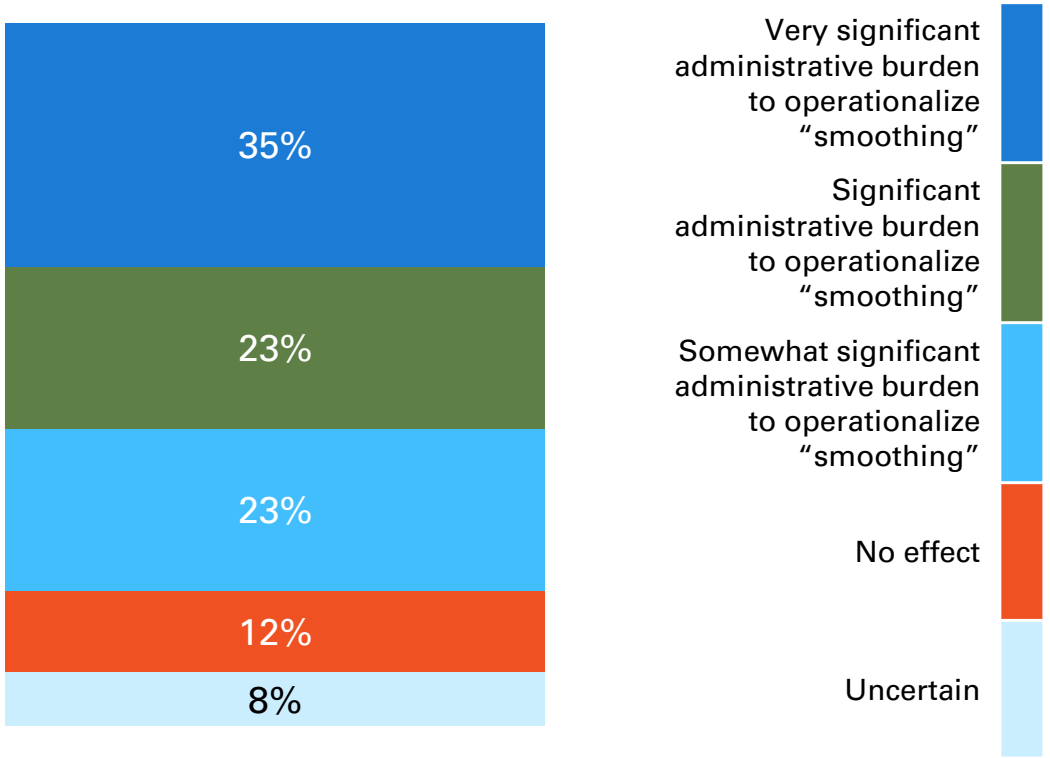
Payer Insights Survey: Payer Concerns and Lack of Understanding About Operationalizing the M3P

"We've never done anything like this. It is so massive. This is the biggest provision I think we are all going to screw up. Someone wants it at $12.22 a month, and another wants it at $19 a month, and someone else wants it at $5. I don't even know. We're working on it."

--*Pharmacy Director*

Administrative Burden Imposed on Part D Sponsors by M3P Program[1]

All Respondents



1. Magnolia Market Access IRA Payer Insights Survey 3.0.

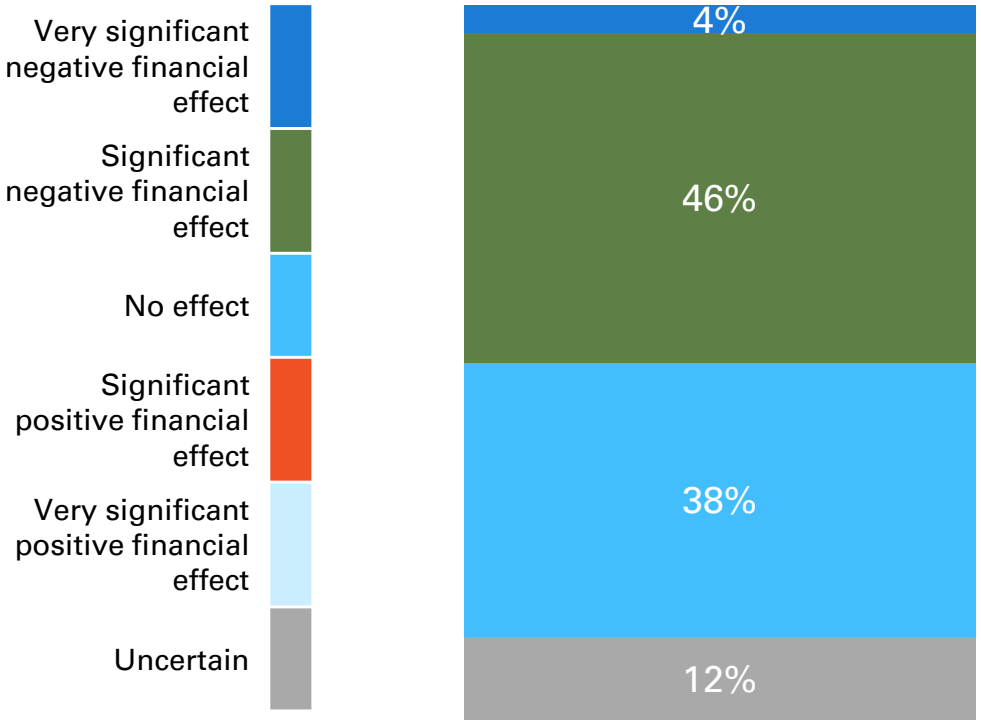
Magnolia market access
a medical knowledge group company

M3P PROGRAM

Payer Insights Survey: Mixed Concerns of the Financial Burden of the M3P

Anticipated Financial Effects of M3P Program[1]

All Respondents



"I am not really sure of the financial impact unless it's medical debt; people don't pay their bills. It's more of a 'how do I actually operationalize this and stay in compliance with Medicare.'"
--Pharmacy Director

1. Magnolia Market Access IRA Payer Insights Survey 3.0.

Magnolia market access
a medical knowledge group company

Payer Responsibilities: What *Should* Payers Be Doing to Prepare Patients for the IRA?

Education

Creating educational materials beyond what CMS has developed to ensure benefits of the IRA are clear, concise, and easy to understand for both patients, providers, and pharmacists

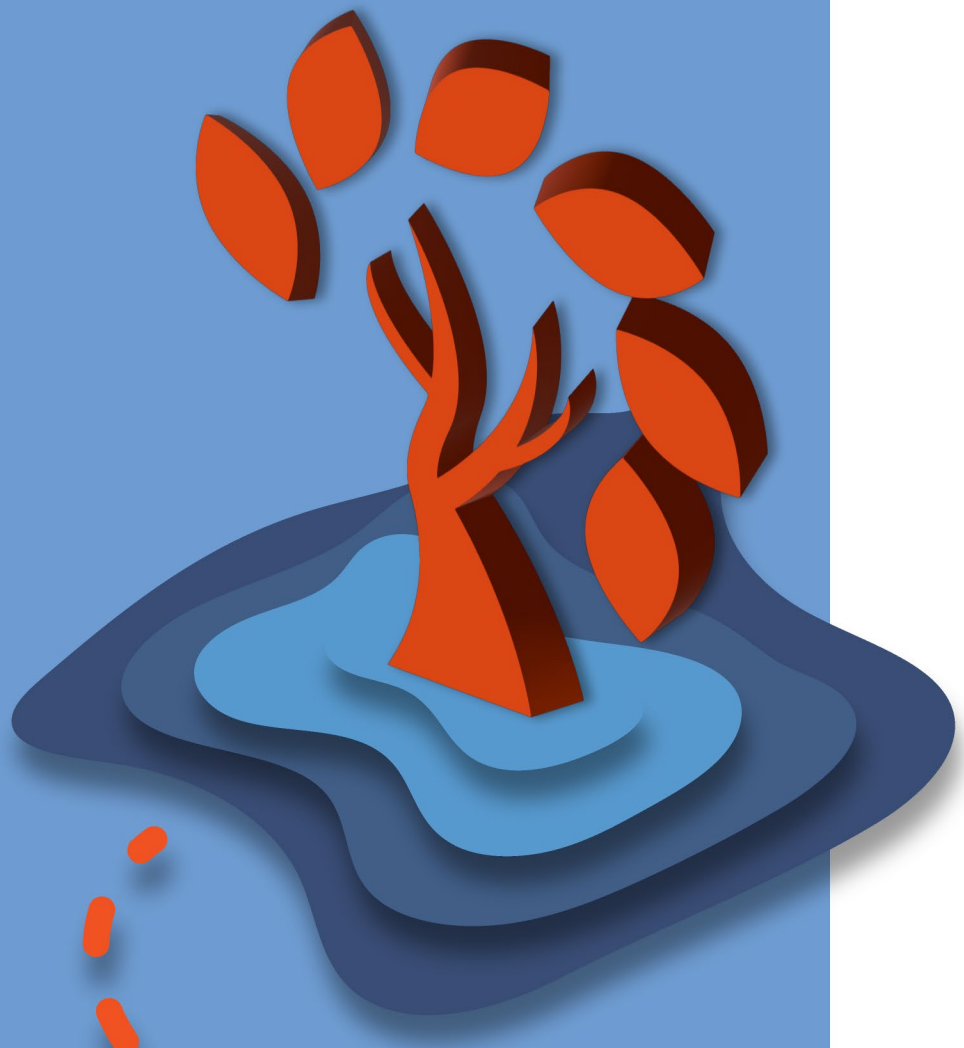
Outreach

Leveraging educational resources to ensure anyone who could benefit from the IRA knows about these provisions and is participating, as appropriate

Enrollment

Proactively prompting patients to enroll in the M3P program at the time of general plan enrollment and/or creating ways for patients to enroll at the pharmacy counter when they fill their first prescription for the year

Magnolia market access
a medical knowledge group company



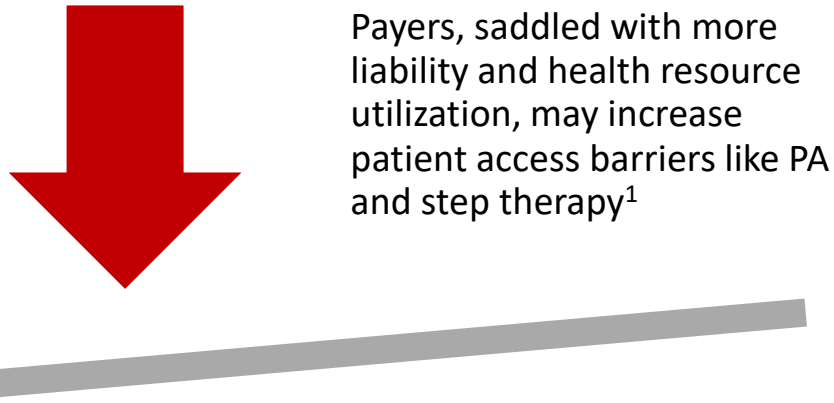
Manufacturer Support Opportunities to Prepare Patients for IRA Implementation

Magnolia market access

a medical knowledge group company

Patient Preparation: Responding to Approaches Payers May Take to Prepare Patients

The IRA is a 2-sided patient access coin…



Payers, saddled with more liability and health resource utilization, may increase patient access barriers like PA and step therapy[1]

Patients, with a $2000 out-of-pocket cap and prescription payment plans, will have more prescription affordability and predictability

Insight

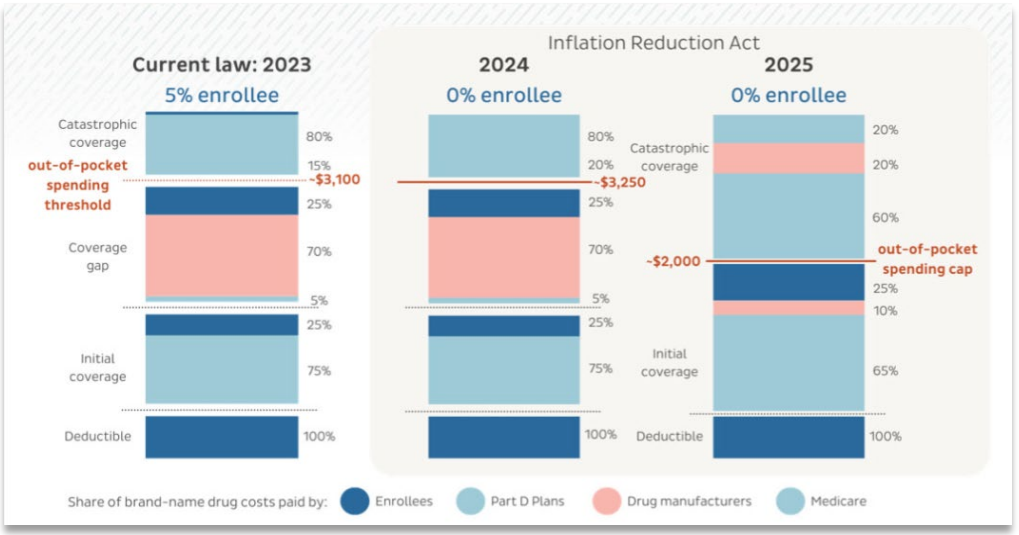
Manufacturers need a plan to:

1. Minimize IRA-induced patient access barriers caused by increased plan management and
2. Maximize opportunities caused by the Part D benefit redesign and M3P

1. Magnolia Market Access IRA Payer Insights Survey 3.0.

Magnolia market access
a medical knowledge group company

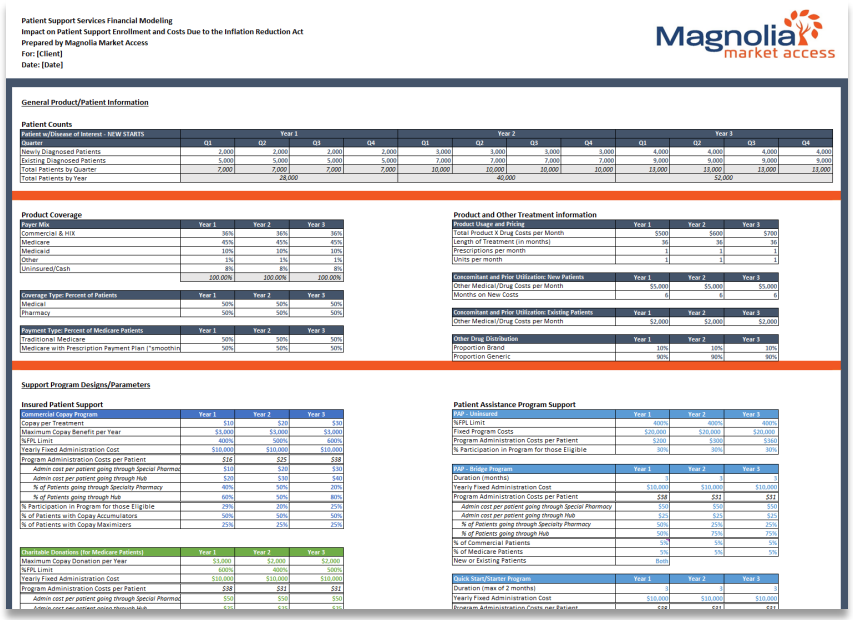
Minimizing Barriers: Expanding Patient Support Through Provider, Patient Advocacy, and Hub Education and Resources[1]



To support education efforts, patient advocacy groups have been sharing implementation timelines and fact sheets on benefits of the IRA provisions. Manufacturers may be able partner with patient advocacy group actions to develop patient resources.

Magnolia market access
a medical knowledge group company

Minimizing Barriers: Understanding the Financial Effects of IRA on Patient Assistance Program Enrollment and Offerings



Patient Support Services Financial Modeling
Impact on Patient Support Enrollment and Costs Due to the Inflation Reduction Act
Prepared by Magnolia Market Access
For: [Client]
Date: [Date]

Magnolia market access

General Product/Patient Information

Patient Counts

Patient w/Disease of Interest - NEW STARTS	Year 1				Year 2				Year 3			
Quarter	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Newly Diagnosed Patients	2,000	2,000	2,000	2,000	3,000	3,000	3,000	3,000	4,000	4,000	4,000	4,000
Existing Diagnosed Patients	5,000	5,000	5,000	5,000	7,000	7,000	7,000	7,000	9,000	9,000	9,000	9,000
Total Patients by Quarter	7,000	7,000	7,000	7,000	10,000	10,000	10,000	10,000	13,000	13,000	13,000	13,000
Total Patients by Year	28,000				40,000				52,000			

Product Coverage

Payer Mix	Year 1	Year 2	Year 3
Commercial & HIX	36%	36%	36%
Medicare	45%	45%	45%
Medicaid	10%	10%	10%
Other	1%	1%	1%
Uninsured/Cash	8%	8%	8%
	100.00%	100.00%	100.00%

Coverage Type: Percent of Patients	Year 1	Year 2	Year 3
Medical	50%	50%	50%
Pharmacy	50%	50%	50%

Payment Type: Percent of Medicare Patients	Year 1	Year 2	Year 3
Traditional Medicare	50%	50%	50%
Medicare with Prescription Payment Plan ("smoothin	50%	50%	50%

Product and Other Treatment Information

Product Usage and Pricing	Year 1	Year 2	Year 3
Total Product X Drug Costs per Month	$500	$600	$700
Length of Treatment (in months)	36	36	36
Prescriptions per month	1	1	1
Units per month	1	1	1

Concomitant and Prior Utilization: New Patients	Year 1	Year 2	Year 3
Other Medical/Drug Costs per Month	$5,000	$5,000	$5,000
Months on New Costs	6	6	6

Concomitant and Prior Utilization: Existing Patients	Year 1	Year 2	Year 3
Other Medical/Drug Costs per Month	$2,000	$2,000	$2,000

Other Drug Distribution	Year 1	Year 2	Year 3
Proportion Brand	10%	10%	10%
Proportion Generic	90%	90%	90%

Support Program Designs/Parameters

Insured Patient Support

Commercial Copay Program	Year 1	Year 2	Year 3
Copay per Treatment	$10	$20	$30
Maximum Copay Benefit per Year	$5,000	$5,000	$5,000
%FPL Limit	400%	500%	600%
Yearly Fixed Administration Cost	$10,000	$10,000	$10,000
Program Administration Costs per Patient	$16	$25	$38
Admin cost per patient going through Special Pharmac	$10	$20	$30
Admin cost per patient going through Hub	$20	$30	$40
% of Patients going through Specialty Pharmacy	40%	50%	20%
% of Patients going through Hub	60%	50%	80%
% Participation in Program for those Eligible	29%	20%	25%
% of Patients with Copay Accumulators	50%	50%	50%
% of Patients with Copay Maximizers	25%	25%	25%

Charitable Donations (for Medicare Patients)	Year 1	Year 2	Year 3
Maximum Copay Donation per Year	$3,000	$2,000	$2,000
%FPL Limit	600%	400%	500%
Yearly Fixed Administration Cost	$10,000	$10,000	$10,000
Program Administration Costs per Patient	$38	$31	$31
Admin cost per patient going through Special Pharmac	$50	$50	$50

Patient Assistance Program Support

Bridge Program	Year 1	Year 2	Year 3
%FPL Limit	400%	400%	400%
Fixed Program Costs	$20,000	$20,000	$20,000
Program Administration Costs per Patient	$200	$200	$200
% Participation in Program for those Eligible	30%	30%	30%

PAP - Bridge Program	Year 1	Year 2	Year 3
Duration (months)	3	3	3
Yearly Fixed Administration Cost	$10,000	$10,000	$10,000
Program Administration Costs per Patient	$38	$31	$31
Admin cost per patient going through Special Pharmacy	$50	$50	$50
Admin cost per patient going through Hub	$25	$25	$25
% of Patients going through Specialty Pharmacy	50%	25%	25%
% of Patients going through Hub	50%	75%	75%
% of Commercial Patients	5%	5%	5%
% of Medicare Patients	5%	5%	5%
New or Existing Patients	Both		

Quick Start/Starter Program	Year 1	Year 2	Year 3
Duration (max of 2 months)	3	3	3
Yearly Fixed Administration Cost	$10,000	$10,000	$10,000
Program Administration Costs per Patient	$38	$31	$31

PAP modeling can answer questions such as:

1. How will legislative changes (eg, IRA Medicare benefit design changes) affect patient cost-sharing and subsequent enrollment in PAPs?
2. What is the ideal timing to distribute program funding throughout the year?
3. How much should our company donate to charitable foundations to support Medicare patients who are not qualified for PAP support?

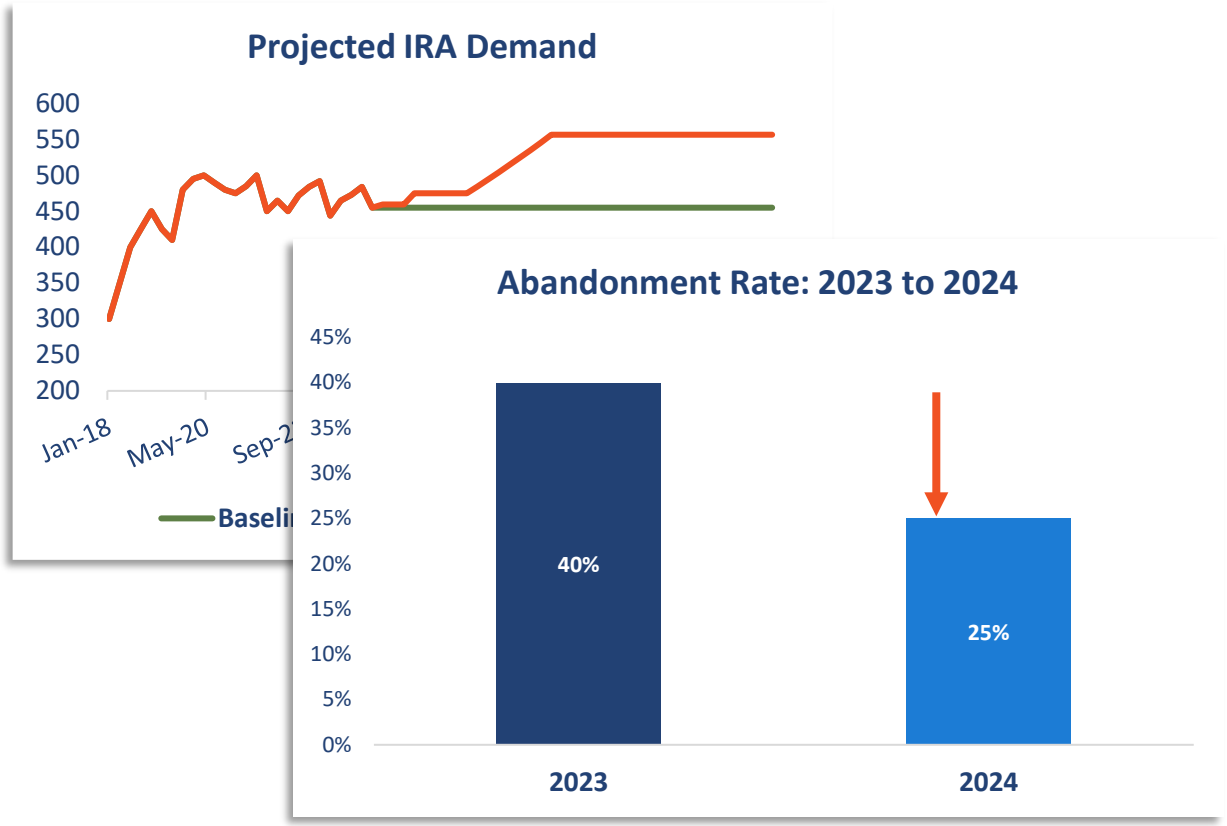
PAP Modeling Action Items

1. Re-evaluate PAP eligibility criteria
2. Develop buy-in on IRA educational and outreach investments

Magnolia market access
a medical knowledge group company

Maximizing Affordability Increases: Manufacturers Can Utilize IRA Forecasting to Complete Several Financial Action Items

IRA Abandonment & PAP Demand Modeling

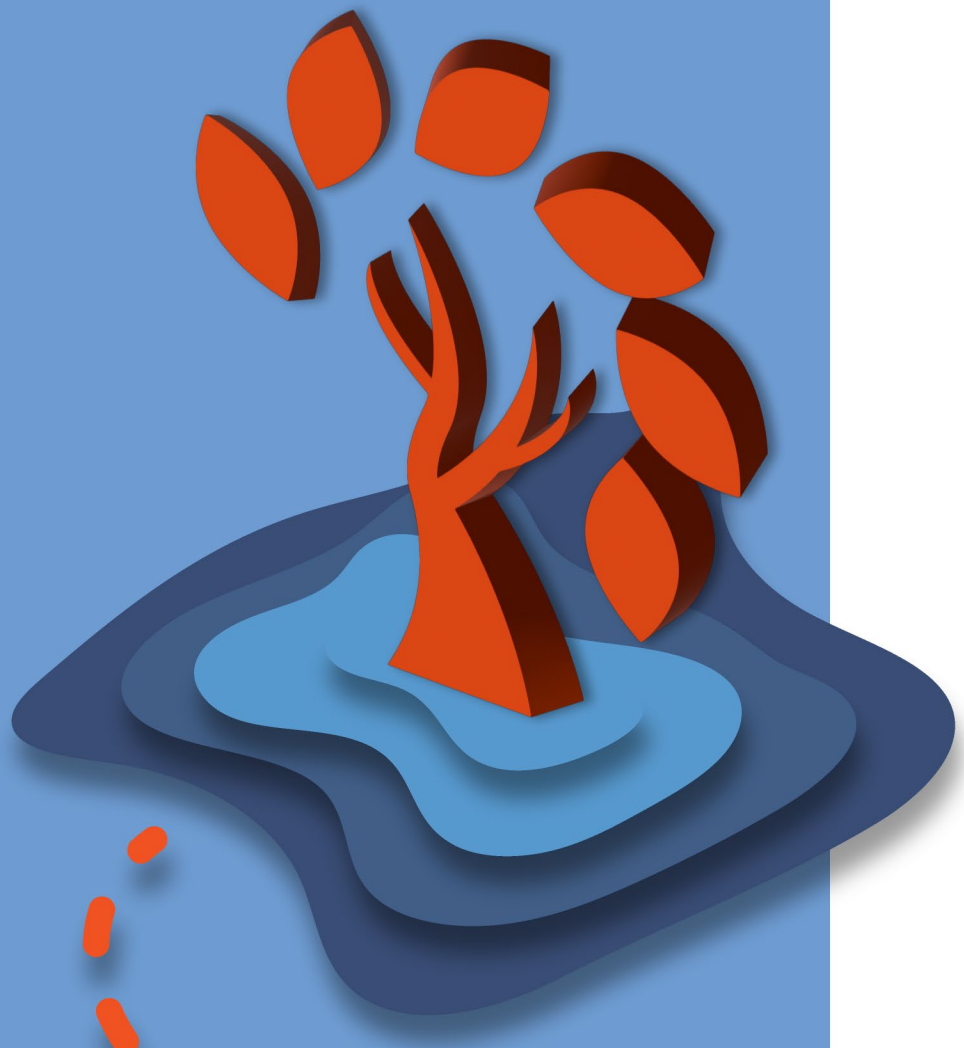


Financial Action Items

Manufacturers can utilize IRA demand and PAP forecasts to:

1. Adjust gross revenue forecasts
2. Assess PAP patient gross-to-net effects

Magnolia market access
a medical knowledge group company



Webinar Wrap-Up

Magnolia
market access
a medical knowledge group company

Webinar Wrap-Up: Key Takeaways and Action Items for Manufacturers

Patient Effects

The IRA—specifically the Part D redesign and M3P program next year—will have tremendous effects on the affordability and accessibility of needed medications

Payer Responsibilities

Operational and financial burden on payers, coupled with vague guidance from CMS, means payers may not adequately address patient needs

Filling the Gaps

Manufacturers can develop materials and conduct strategic planning to maximize patient access and business growth opportunities offered by IRA provisions

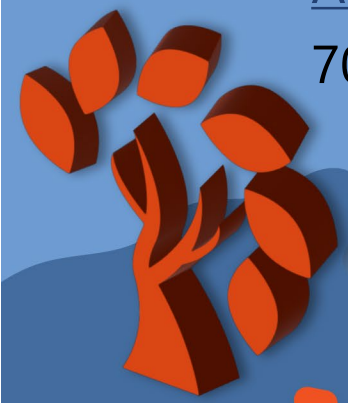
Magnolia market access

a medical knowledge group company

Thank You!

Amanda Forys
Managing Partner, Magnolia Market Access
Aforys@magnoliamarketaccess.com
571.251.8452

Amanda O'Hora
SVP, Market Access & Reimbursement
Aohora@magnoliamarketaccess.com
704.905.1094



Magnolia market access
a medical knowledge group company