

# Hormonal Contraceptive Microarray Patch: A Business Case Analysis

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## Abbreviations

COGS	cost of goods sold
EMA	European Medicines Agency
EU	European Union
FDA	US Food and Drug Administration
FP	family planning
HICs	high-income countries
HIV	human immunodeficiency virus
IRR	internal rate of return
LMICs	low- and middle-income countries
MAP	microarray patch
NPV	net present value
ROI	return on investment
SPC	social purpose corporation
UNFPA	United Nations Population Fund
USAID	US Agency for International Development

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## Executive summary

Despite the expanded access to modern contraceptive methods over the past decades, a significant number of women in low- and middle-income countries (LMICs) continue to report an unmet need for family planning. Research indicates that many women who do not want to become pregnant are not using contraception because currently available methods do not meet their needs. For some of these women, the cost of a provider-dependent method or one that requires return visits to a health facility can be a burden. The daily regimen for oral contraceptive pills can be difficult to comply with, affecting adherence and effectiveness. Also, discreetness of the method—in terms of both provision and use—can be important, especially if women do not want their partners to know they are using contraception.

Microarray patches (MAPs), also known as microneedle patches, for the delivery of sustained-release hormonal contraception has emerged as a potential novel technology to address some of the unmet contraception needs in LMICs and expand method choice for all women. Several contraceptive MAP designs are in early-stage development. These technologies are intended to be worn for a short period of time (less than 30 minutes) to deliver a depot of drug, which would then release continuously and provide contraceptive protection for one to six months. The high unmet need in LMICs suggests a potential market for contraceptive MAPs and an opportunity to expand the contraceptive method mix. There may also be demand for a contraceptive MAP in high-income countries (HICs) given its convenience and ease of use and the potential to meet the needs of some users.

This business case is a first-stage activity by the PATH Center of Excellence for Microarray Patch (MAP) Technology, to define and quantify the potential market opportunity for a progestin-only contraceptive MAP for commercialization in both LMIC and HIC markets based on a range of introduction assumptions. The findings from the analysis can be used to inform development on this early-stage product, including making decisions for future investment, identifying potential partnerships, and clarifying viable commercialization pathways.

To develop the business case, we:

- Generated a set of scenarios and assumptions on intent to use and on potential uptake of a contraceptive MAP.
- Estimated the potential market size in both LMICs and HICs.
- Assessed the potential revenues and costs of a contraceptive MAP for the estimated market size, producing return on investment estimates.
- Conducted scenario analyses to explore the impact of uncertainty on the estimates generated.
- Identified the potential risks and obstacles to commercialization.
- Considered innovative opportunities and strategies for improving the contraceptive MAP business case.

Our analysis found that the global market demand for a contraceptive MAP in the base scenario would reach an estimated 20 million units by 2040, with the majority of the demand generated from LMICs. The revenues were estimated to reach approximately US\$175 million by 2040, driven primarily by US sales due to the assumption of relatively higher product prices in HICs compared to LMIC markets. When assuming demand only from LMICs, we estimated that the global annual market for a contraceptive MAP



would reach about \$40 million in revenues (for demand of 19 million units) by 2040, and the net present value for contraceptive MAPs would be negative \$27 million and would not justify commercial investment. Assuming US demand for a contraceptive MAP and a relatively high price per unit in that market, these results suggest an interesting business opportunity for HIC markets and the potential for the license holder / marketing agency to subsidize LMIC markets. However, this only works if there is a global marketing agreement that encompasses both LMIC and HIC markets to support cost-sharing across regional markets, and this type of cross-subsidization strategy has yet to work in the contraceptive space. The successful introduction of the MAP in LMICs only would require substantial donor and developer alignment and commitment.

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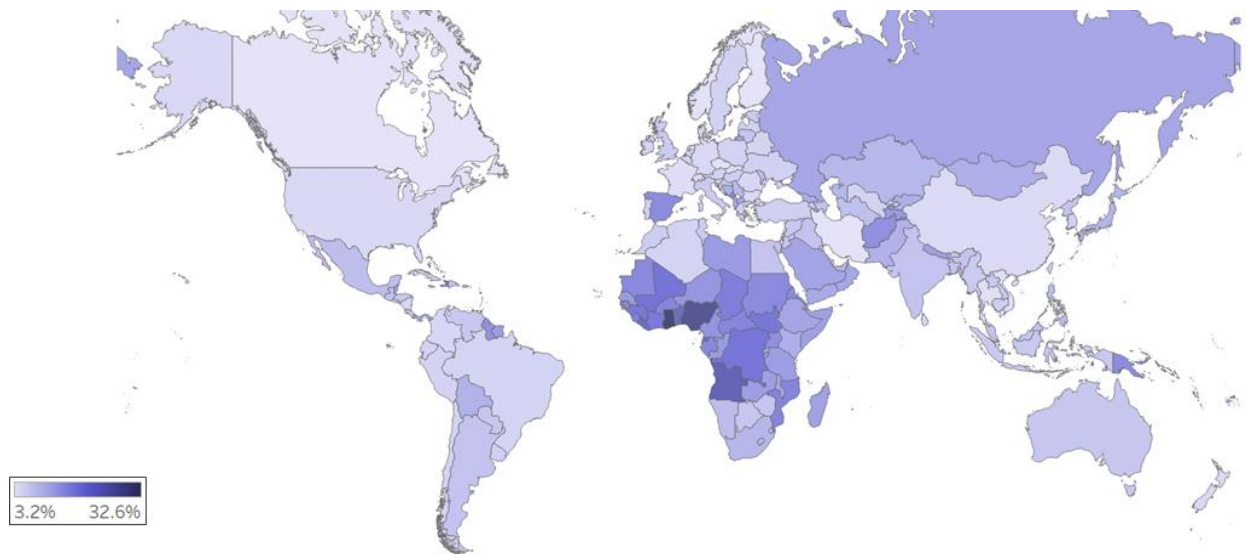
## Background

### Global unmet need for contraceptives

Ensuring access to and choice of effective contraceptive methods is a human right and is essential for achieving Goals 3 and 5 of the Sustainable Development Goals.<sup>1</sup> Contraceptive use prevents unplanned and mistimed pregnancies, especially for adolescent girls, and longer birth spacing has been shown to correlate with decreased infant mortality rates.<sup>2</sup> Contraception also offers a range of potential non-health benefits, including additional years in school and empowerment for women, as well as sustainable population growth and economic development for countries.<sup>3,4</sup>

Despite expanded access to modern contraceptive methods over the past decades, a significant number of women in low- and middle-income countries (LMICs) continue to have an unmet need for family planning (i.e., they want to avoid pregnancy but are not using a modern contraceptive method). In 2019, 218 million women of reproductive age in low-resource countries had an unmet need for contraception, which is a substantial contributor to unintended pregnancy, and about half of pregnancies in LMICs—111 million annually—were unintended.<sup>5</sup> Despite expected future increases in access to and use of modern methods, it is projected that unmet need will grow in absolute numbers and that more than half of the women with an unmet need for family planning in 2030 will live in LMICs.<sup>2</sup> (see Figure 1).

**Figure 1.** Estimated global unmet need for contraceptives in 2030.



Source: United Nations Department of Economic and Social Affairs, Population Division website. Estimates and projections of family planning indicators 2020 page. February 2020. [https://www.un.org/en/development/desa/population/theme/family-planning/cp\\_model.asp](https://www.un.org/en/development/desa/population/theme/family-planning/cp_model.asp).

## The case for a hormonal contraceptive microarray patch

Research indicates that many women who do not want to become pregnant are not using contraception because currently available methods do not meet their needs. There are wide-ranging reasons for not using or for discontinuing contraception, including side effects, family or community opposition to contraception, and access obstacles.<sup>6</sup> For some women, the cost of a provider-dependent method or one that requires return visits to a clinic can be a burden. Regimens that require daily action, such as oral contraceptive pills, can also be difficult to comply with, affecting adherence and effectiveness. Also, discreetness of the method—in terms of both provision and use—can be important, especially if women do not want their partners to know they are using contraception.

Expanding the choice of methods would allow people to address their varying needs based on personal and cultural preferences and circumstances. Broadened method availability leads to increased overall use; an analysis of demographic data from multiple countries showed that the addition of a new method is correlated with an increase of 4 to 8% in contraceptive prevalence rate.<sup>7</sup>

Microarray patches (MAPs), also referred to as microneedle patches, contain microprojections loaded with the active drug. When pressed firmly onto the skin, the microprojections painlessly pierce the outermost layer of the skin to release the drug into the body. MAP technology is now in development for various health indications, including immunization and sustained-release drug delivery.<sup>a</sup> Several designs for progestin-only contraceptive MAPs are currently in early-stage development, with the aim of allowing for self-administration, and could provide protection for one-to-six-months duration. It is anticipated that this novel drug delivery system could have advantages over some existing contraceptive methods.

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### **Potential advantages of MAP platform:**

- *Needle-free drug delivery—no sharps waste generated, no pain.*
  - *Reduced burden on health systems—potential for self-administration.*
  - *Ease of use—could improve acceptability and adherence.*
  - *Product stability (heat stable and freeze resistant).*
  - *Non-sharps waste disposal.*
  - *Typically perceived as less painful than an injection, improving acceptability.*
  - *May enable alternative delivery scenarios, such as self-administration.*
- 

Unlike the currently available transdermal contraceptive patch that must be worn continuously for days for drug delivery, the contraceptive MAP is intended to be worn for a short period (ranging from 10 seconds to 30 minutes) to deliver the drug, and then the patch backing is removed. Self-administration could reduce the burden on clinics, providers, and clients. It could also promote women's autonomy and support self-care.<sup>8</sup> As a sustained-release product, the MAP may also improve acceptance and adherence by simplifying the administration regimen. The MAP is anticipated to have a safety profile similar to that reported for other progestin-only hormonal contraceptives.

The widespread use of progestin-only injectable contraceptives—which provide two to three months of protection—in LMICs suggests a potential market for MAP

application and provides an opportunity to expand the method mix to address the high unmet need. Meanwhile, women in high-income countries (HICs) may also be interested in the MAP's convenience and ease of use. The contraceptive transdermal patch—which relies on passive diffusion of hormones and requires continuous wear and weekly replacement—has been available in high-income markets since

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<sup>a</sup> A novel multipurpose prevention technology MAP that combines hormonal contraception with additional drugs (e.g., a long-acting antiretroviral for HIV pre-exposure prophylaxis, etc.) has also been proposed as a novel family planning option for women. This business case focuses exclusively on the contraceptive-only MAP, since product is further along in development and considered a stepping-stone toward a multipurpose prevention technology.

the early 2000s, demonstrating that some women are comfortable/familiar with the concept of a contraceptive patch and find self-administration acceptable.

Based on the currently proposed product attributes, a MAP may provide increased adherence and patient acceptability compared to some currently available hormonal contraceptive products, including oral pills, injectables, and transdermal patches. While contraceptive MAPs are still in preclinical development, target product attributes suggest that a contraceptive MAP could be a global product suitable for use in both LMIC and HIC markets.

## Objective of hormonal contraceptive MAP business case

The objective of this analysis, done by the PATH Center of Excellence for Microarray Patch (MAP) Technology and Linksbridge SPC, is to evaluate the potential business case of a hormonal contraceptive MAP. Through the business case analysis, we estimate the potential market opportunity for investment in hormone-based contraceptive MAPs for both LMIC and HIC use, with the intent to inform the commercial viability of advancing hormonal contraceptive MAP development. Forming an early understanding of the possible market size and return on investment (ROI) will inform decisions on the support and resources needed for product advancement. It is important to note that the analysis presented here is based on assumptions and insights about the contraceptive MAP category in general and is not reflective of a specific product or any of the multiple development efforts underway.

## Contraceptive MAP product-development status and challenges

A snapshot of the contraceptive MAP product-development activities is summarized in Table 1. Seven research organizations are actively engaged in preclinical development of sustained-release hormonal contraceptive MAP products, which are funded by the Bill & Melinda Gates Foundation, National Key Research and Development Plan of China, and the US Agency for International Development (USAID).

**Table 1.** Contraceptive microarray patch (MAP) product-development status.

MAP developer	Partners	Status	Funders
Cardiff University	Population Council, InnoCore Pharmaceuticals, Maddison Product Design, MicroSystems UK, University of Bradford	Preclinical	Bill & Melinda Gates Foundation
Chinese Academy of Sciences		Preclinical	National Key Research and Development Plan of China
Georgia Institute of Technology	FHI 360, Micron Biomedical	Preclinical	USAID, Gates Foundation
India Institute of Technology Bombay		Preclinical	Gates Foundation
Massachusetts Institute of Technology, Brigham and Women's Hospital		Preclinical	Gates Foundation
Tufts University		Preclinical	Gates Foundation
Queen's University Belfast	PATH, Population Council	Preclinical	USAID

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## Approach

### Developing a business case

Currently, uncertain demand prospects and the unclear revenue potential of commercializing products for LMICs are challenges to assessing the business opportunity. In addition, commercial interest in advancing novel contraceptive technologies to market—even in HICs—has waned in recent decades due to the existence of many effective, low-cost products on the market, the high cost of research and development, and liability concerns due to the need for long-term use by healthy people.<sup>9</sup> To better understand the market potential for contraceptive MAPs, PATH developed a business case to help articulate the commercial viability and potential ROI for manufacturers.

To conduct the business case analysis, we developed a model to estimate the potential contraceptive MAP market size and expected cash flows (in both LMICs and HICs) and consulted with technical experts in the novel contraceptive development field to inform, review, and validate the rationale of our inputs and assumptions (see Appendix for details).

Subsequently, we:

- Assessed the potential revenues and costs of a contraceptive MAP for the estimated market size, producing ROI estimates.
- Identified the potential risks and obstacles to commercialization.
- Considered innovative opportunities and strategies for improving the contraceptive MAP business case.

This analysis reflects the early stage of contraceptive MAP development and makes several assumptions based on the current understanding of the desired product attributes and preclinical evidence that have been generated to date. The business case will serve as a living document that will benefit from stakeholder input, which will evolve over time as new data are generated and target attributes are defined. One key assumption of this analysis is the successful development and launch of the MAP in both LMICs and HICs.

Beyond articulating the commercial viability of contraceptive MAPs, this business case report also explores potential opportunities and risks associated with novel contraceptive commercialization. This analysis is intended to be a resource on commercial viability and market potential for a wide range of key stakeholders engaged in contraceptive MAP development including MAP developers, family planning experts, industry, donors, and procurement agencies.

### Estimating the contraceptive MAP market size

#### Attributes and assumptions

Since the product attributes of the contraceptive MAP product have not yet been finalized, we adopted a set of in-development product attributes for this analysis to drive our demand inputs and thinking (Table 2). To estimate market demand, we also consulted with experts in the contraceptive space to generate key assumptions about the contraceptive MAP launch strategy, market scope, and uptake. Since there are no quantitative data yet on user preference for the MAP relative to existing methods, and

there is limited literature on determining novel product uptake, we created low, base, and high scenarios to capture and account for the uncertainty (Table 3).

**Table 2.** Contraceptive microarray patch (MAP) product attribute assumptions.

Attribute	Assumption
<b>Intended use</b>	Safe and effective contraception for at least six months*
<b>Target population</b>	Reproductive-age (between 15 and 49 years old), non-pregnant, non-sterilized women who would like to space their pregnancies for at least one year
<b>Dosage schedule</b>	One administration every six months
<b>Ease of use</b>	Conducive to self-administration with minimal training
<b>Active pharmaceutical ingredient</b>	Progestin-only
<b>Side effect profile</b>	Same side effects as currently available progestin-based contraceptive products

\*Although MAPs are also being developed with the aim of providing contraceptive protection for less than 6 months, for the purpose of this analysis, we focused on a 6-month contraceptive MAP since this could fill a gap in existing contraceptive method mix.

## Initial launch

For the purpose of this model, we assumed that a contraceptive MAP product would need to achieve regulatory approvals in both the European Union (EU) and the United States. However, depending on the location of the MAP developer and commercialization partner, as well as the intended introduction strategy, approval from one regulatory body may be prioritized over the other. Contraceptive product developers identified EU regulatory approval as a key step for introduction in African countries. Experts also emphasized the importance of the US market for revenue generation. For product introduction, we assumed the earliest launch date of 2030 based on expert input. Although this timeline is aggressive, it was a reasonable assumption for the purpose of this model since there are many factors that could impact the product-development timeline for contraceptive MAPs at this early stage.

## Country scope

Three introduction scenarios were modeled for this business case. The country scope of the analysis includes EU countries, the United States, and countries that have procured or will procure Sayana® Press.<sup>b</sup> The analysis assumes that the MAP would be added to both the USAID and the United Nations Population Fund procurement catalogs to facilitate procurement and introduction. The introduction scenarios are summarized in Table 3.

<sup>b</sup> As reported by procurement data submitted to the Reproductive Health Interchange. Sayana Press is a registered trademark of Pfizer Inc.

**Table 3.** Introduction scenarios for business cases.

Scenario	Country scope	Source/rationale
<b>Low</b>	Sayana Press countries*	Assumes that countries that have introduced Sayana Press are more likely to adopt the MAP product; includes all countries that have received or planned Sayana Press shipments between 2014 and 2020.
<b>Base</b>	Sayana Press countries + EU + United States	In addition to Sayana Press countries (Scenario 1), assumes introduction in EU and United States.
<b>High</b>	Global	Provides unconstrained global demand; includes all countries captured in United Nations Procurement Division's World Population Prospects 2019.

*Abbreviations:* EU, European Union; MAP, microarray patch.

\* *Source:* Date from Reproductive Health Supplies Coalition website. Reproductive Health Supplies Visualizer page.

<https://www.rhsupplies.org/activities-resources/tools/reproductive-health-supplies-visualizer-rh-viz/>. Accessed February 1, 2021.

Launched in 2014, Sayana Press is a subcutaneous form of the depot medroxyprogesterone acetate injectable that can be self-administered by women and provides three months of protection. Countries' decision-making processes for introducing new contraceptives are complex, involving factors like unmet need, country interest, donor priority, current method mix, regulatory environment, etc. To simplify the analysis, we used the introduction history of Sayana Press as a proxy for contraceptive MAP introduction due to their similar product profiles. An important caveat, however, is that Sayana Press's launch received significant donor support, which a MAP may not receive.<sup>10</sup>

To simplify the assessment, we prioritized country introduction of the MAP based on unmet need only (from largest to smallest) for countries that have introduced Sayana Press, or plan to, which is summarized in Supplemental Figure 1 (in Appendix). We assumed that five additional countries would launch the product annually during the analysis period (2030–2040).

## Adoption and uptake

Key model input assumptions are summarized in Table 4. To estimate the proportion of women who may want to use the MAP, we used country prevalence data of injectable users and pill users as proxies. We theorize that the MAP would likely appeal to users of the injectable and the oral contraceptive pill, whose product profiles are more similar to the MAP's than options like male or female condoms or long-acting methods (e.g., IUDs and implants). Individuals with an unmet need for contraception (i.e., new users) are also included as potential MAP users in the analysis.

**Table 4.** Summary of key model input assumptions.

Category	Parameters			Rationale/assumption
	All scenarios			
<b>Target population</b>	Forecast of population of women of reproductive age between 15 and 49 years old from 2030 to 2040*			
<b>Intent to use contraceptives</b>	Forecast of women that intend to use contraception from 2030 to 2040, including women who are currently on any contraceptive method (modern or traditional) or have indicated an unmet need for contraception†			% women who are using any contraceptive method + % unmet need
	<b>Low</b>	<b>Base</b>	<b>High</b>	
<b>Intent to use microarray patch (MAP)</b>	All injectable user prevalence + 10% of pill user prevalence‡	All injectable user prevalence + 15% of pill user prevalence*	All injectable user prevalence + 20% of pill user prevalence*	Injectable and pill users would be the most likely adopters of the MAP
<b>Uptake</b>	<b>2030–2032:</b> 1% <b>2033–2035:</b> 2% <b>2036–2040:</b> 3%	<b>2030–2032:</b> 2% <b>2033–2035:</b> 3% <b>2036–2040:</b> 4%	<b>2030–2032:</b> 3% <b>2033–2035:</b> 4% <b>2036–2040:</b> 5%	% of women who may take up the MAP or switch from their current contraceptive method to MAP
<b>Dose schedule</b>	2 doses per year	2 doses per year	2 doses per year	6-month duration of protection
<b>Annual discontinuation rate</b>	75%	50%	25%	Annual discontinuation rate based on previous Sayana Press study§

\* Source: Data from United Nations World Population Prospects (WPP) 2019 website. WPP home page.

<https://population.un.org/wpp/>. Accessed February 1, 2021.

† Source: Data from United Nations Population Division (2019).<sup>1</sup>

‡ Source: Data from United Nations Department of Economic and Social Affairs, Population Division website. World contraceptive use 2020 page. January 2020.

<https://www.un.org/en/development/desa/population/publications/dataset/contraception/wcu2020.asp>.

§ Source: Data from Burke HM, Chen M, Buluzi M, et al. Effect of self-administration versus provider-administered injection of subcutaneous depot medroxyprogesterone acetate on continuation rates in Malawi: a randomised controlled trial. *Lancet Global Health*. 2018;6(5):e568–e578. [https://doi.org/10.1016/s2214-109x\(18\)30061-5](https://doi.org/10.1016/s2214-109x(18)30061-5).



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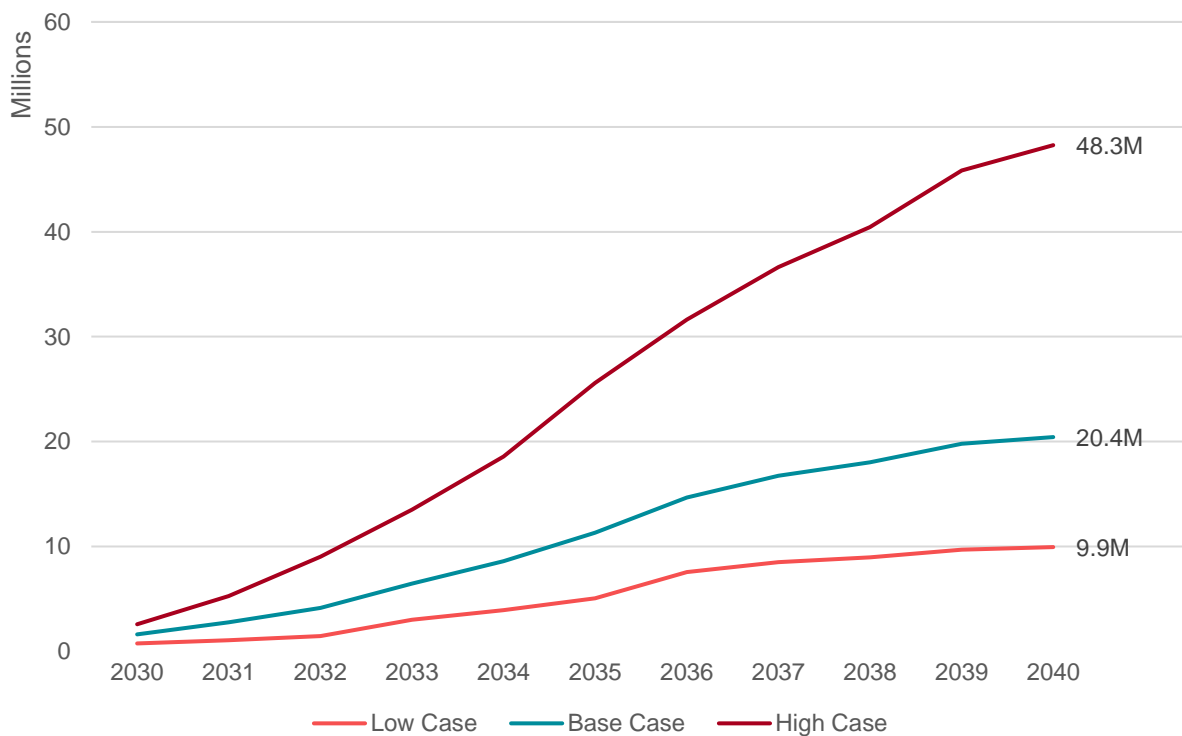
## Results

### Contraceptive MAP market size estimates

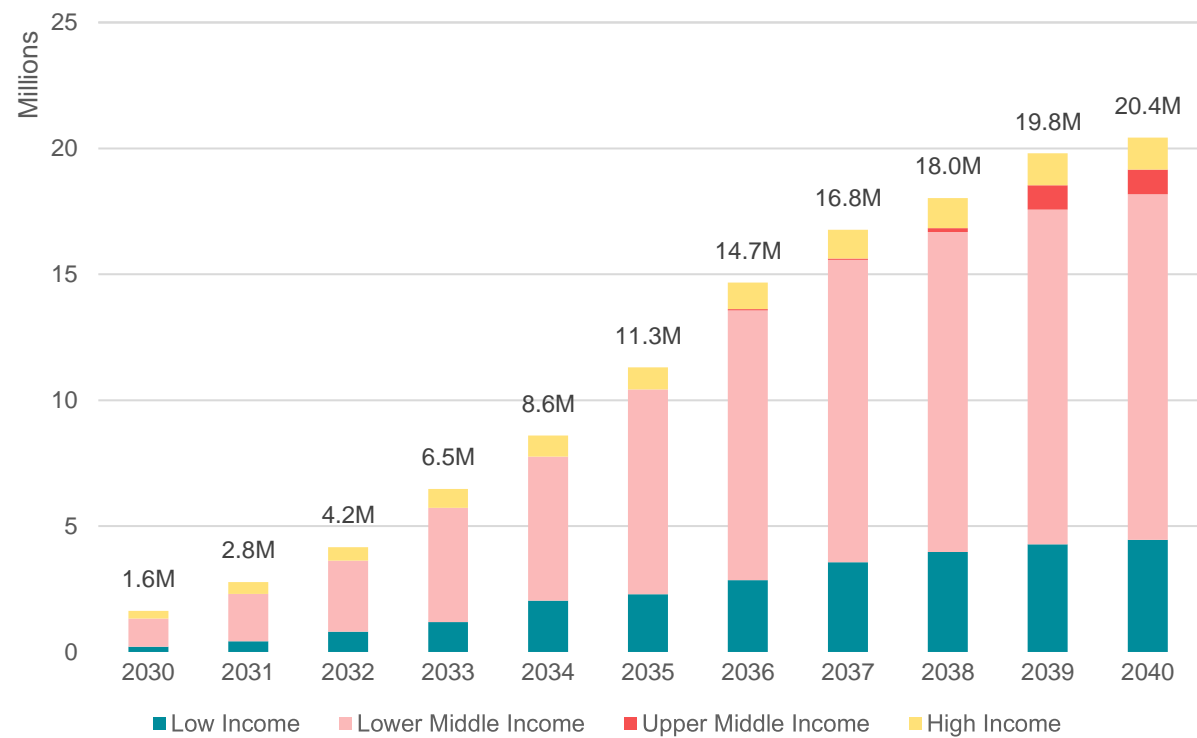
Applying the demand model assumptions outlined above, we derived the following global contraceptive MAP demand estimates across 2030–2040 for the low, base, and high cases (Figure 2). Detailed views of each demand estimate by World Bank country income classification<sup>11</sup> (low income, lower-middle income, upper-middle income, high income) are presented in Figure 3 (base), Figure 4 (low), and Figure 5 (high). We did not apply annual supply constraints to our analysis.

As expected per the country scope, low-income countries and lower-middle-income countries would demand the bulk of the doses in all three cases. Meanwhile, HICs—which include the EU countries and the United States only—would demand a small portion of the total doses.

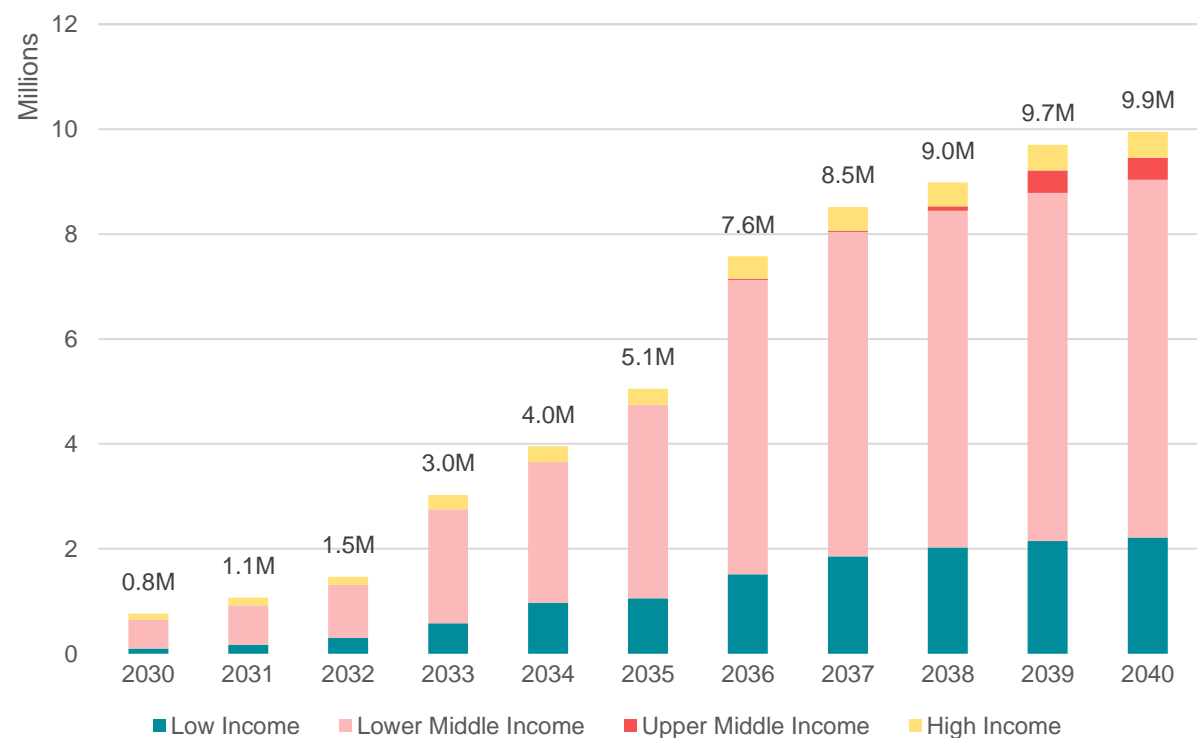
**Figure 2.** Summary of global market demand in contraceptive microarray patch units, by case.



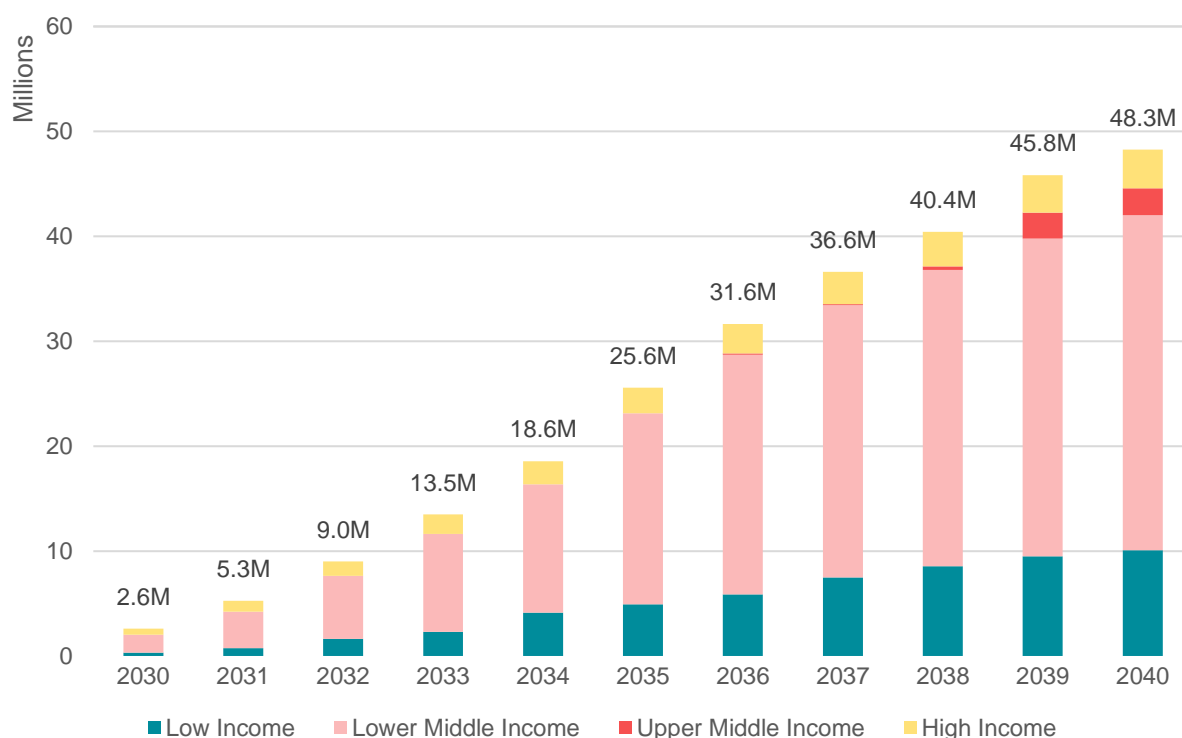
**Figure 3.** Global market demand in contraceptive microarray patch units, base case.



**Figure 4.** Global market demand in contraceptive microarray patch units, low case.



**Figure 5.** Global market demand in contraceptive microarray patch units, high case.



## Estimating the financial returns of a contraceptive MAP

### Pricing

We generated a set of contraceptive MAP price tiers summarized in Table 5 for different country groups based on doubling the price of the currently available three-month progestin-based injectables on the market. This analysis assumes that a single contraceptive MAP product would come to market (i.e., no competitors) and that the price would remain unchanged throughout the analysis period.

**Table 5.** Contraceptive MAP price tiers.

Price Tier	Unit price assumption for a contraceptive MAP (USD)	Rationale
UNFPA/USAID	\$2	Assume same annual price as Sayana Press of \$1 per unit at launch*
Upper-middle income	\$8	Estimate based on approximate three-month Depo-Provera® unit price in Thailand (~\$4) <sup>†</sup>
High income	\$8	Estimate based on approximate Depo-Provera unit price in Taiwan (~\$4)

Price Tier	Unit price assumption for a contraceptive MAP (USD)	Rationale
Super-high income <sup>‡</sup>	\$18	Internal estimate based on UK Sayana Press unit price (£6.9)
United States	\$300	Internal estimate based on approximate Depo-Provera US unit price (~\$150) For the purpose of this model, we did not estimate price differential for public sector in the United States)

Abbreviations: MAP, microarray patch; UNFPA, United Nations Population Fund; USAID, US Agency for International Development.

\* Source: Data from Pfizer's Sayana® Press becomes first injectable contraceptive in the United Kingdom available for administration by self-injection [press release]. New York, NY: Pfizer; September 23, 2015.

<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-s-sayana-press-becomes-first-injectable-contraceptive-in-the-united-kingdom-available-for-administration-by-self-injection>.

<sup>†</sup> Depo-Provera is a registered trademark of Pfizer Inc.

<sup>‡</sup> Austria, Belgium, Denmark, France, Germany, Italy, Luxembourg, Netherlands, Norway, Sweden, Switzerland, and the United Kingdom.

## Development and production costs

Contraceptive MAP-specific cost of goods sold (COGS) analyses have not been conducted yet because product formulation is still underway, and manufacturing plans are in very early stages. For this analysis, we used PATH's previous COGS analysis results for the inactivated poliovirus vaccine (IPV) MAP as a proxy.<sup>c</sup> Based on the financial disclosures of other novel contraceptives on the market, we estimate non-risk-adjusted development costs in a HIC of around US\$10 million per year, including machine and clean room capital expenditure. Based on expert input, we assumed a duration of five years from Phase 3 initiation (2025) to commercial launch (2030). We also assumed existing infrastructure could be used for production and excluded the costs of building a new facility, which would likely require a much larger up-front investment. To simplify the analysis, we excluded potential milestone-based licensing fees commonly paid out to the innovator.

## Contraceptive MAP ROI

We estimated the potential ROI to a commercial partner by weighing all the up-front and yearly development and production costs against the expected cash inflows from product sales. The model assumes that the commercial partnership would begin after Phase 2 trials have been completed. The estimates do not include any assumptions of potential external funding (i.e., to support technology transfer costs). To determine the net present value (NPV)<sup>d</sup> of the contraceptive MAP over the time of this analysis (2025–2040, including development), we applied a discount rate<sup>e</sup> of 20% to account for the time value of future annual cash flows—a typical rate for biotech companies with late-stage drug candidates. We also assessed the internal rate of return (IRR)<sup>f</sup> to illustrate the annualized rate of return that makes the NPV equal to zero.

<sup>c</sup> COGS for different MAP products may vary.

<sup>d</sup> Net present value (NPV) is the current value of a series of future projected cash flows. NPV is often used in capital budgeting and investment planning to analyze the profitability of projected investments or projects.

<sup>e</sup> A discount rate is the rate of return used to discount future cash flows back to their present value, which describes the rate of return needed to see a return on an investment.

<sup>f</sup> Internal rate of return (IRR) is the expected compound annual rate of return that will be earned on a project or investment. When calculating IRR, expected cash flows for a project or investment are given, and the NPV equals zero.

NPV is an analysis used by investors to make go/no-go screening decisions: only products that meet a certain level of return are considered for further investment. A positive NPV indicates that the projected earnings generated by an investment exceed the anticipated costs and that an investment is sound. However, the threshold for what constitutes sufficient NPV for prioritizing an investment may vary by manufacturer, depending on resources and strategic opportunities. The decision to go ahead with a project involves additional criteria, such as strategic benefits, which are not captured in the NPV analysis.

A summary of the contraceptive MAP financial returns is presented in Table 6. Assuming a 20% discount rate and delivery beginning in 2030, a commercial partner could expect an NPV between \$9 million and \$209 million for the contraceptive MAP between 2025 (at partnership entry, prior to Phase 3 clinical studies) and 2040. At a higher discount rate of 30%, the returns are still positive in the base and high cases, but the low-demand case yields negative returns. Detailed descriptions for each case are provided below (see Figures 6, 7, and 8).

Lastly, we also evaluated the contraceptive MAP cash flow by year and market (base case), excluding high-income markets (Figure 9).

**Table 6.** Summary of contraceptive MAP financial returns.

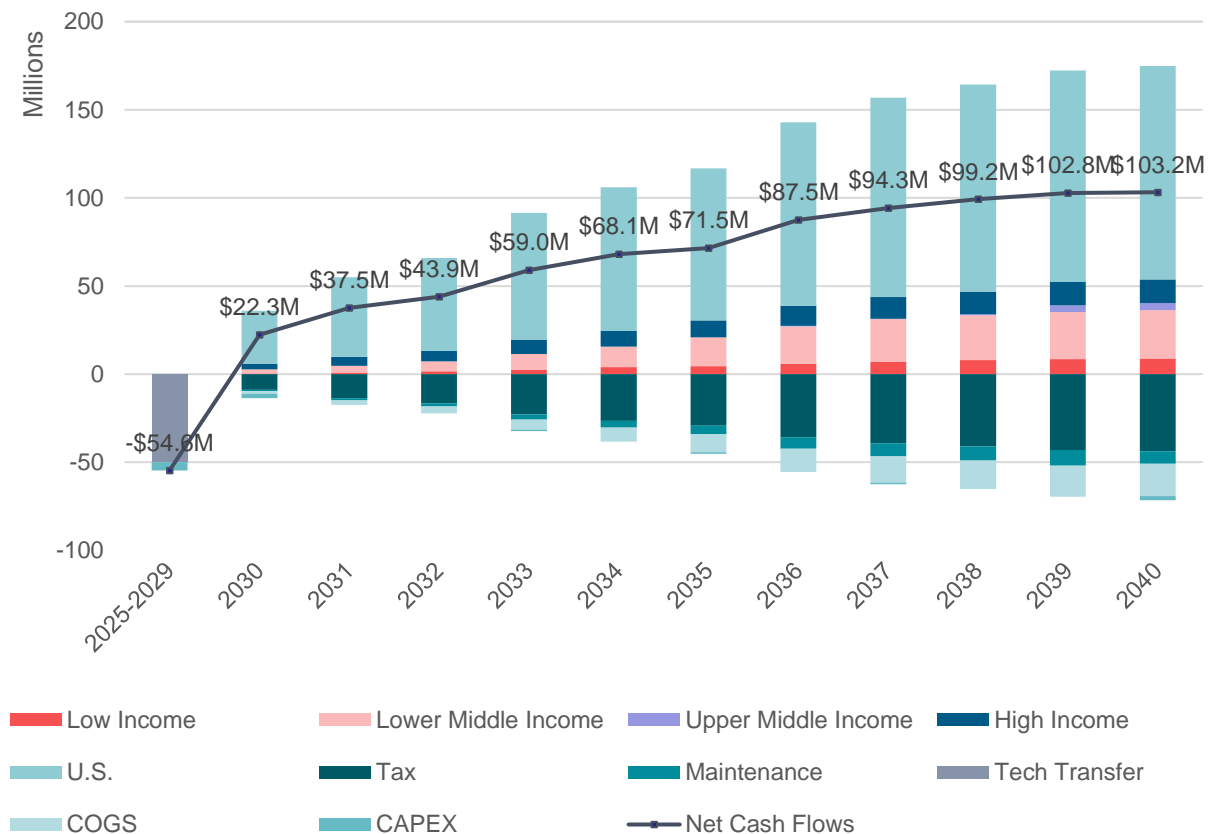
	Low-case return	Base-case return	High-case return
<b>20% NPV (in USD)</b>	\$9.1M	\$70.2M	\$208.6M
<b>30% NPV (in USD)</b>	(\$7.4M)	\$19.8M	\$78.6M
<b>IRR (per 2025 USD)</b>	24%	41%	59%
<b>Total units delivered (2030–2040)</b>	60.1M	124.6M	277.3M

*Abbreviations:* IRR, internal rate of return; M, million; MAP, microarray patch; NPV, net present value.

## Base case

In the base scenario shown in Figure 6, we estimated that the global annual market for a contraceptive MAP would reach \$175 million in revenues (20 million units) in 2040. Despite a smaller demand, the US market would account for the majority of the revenues (due to the relatively high assumed price of the product), reaching \$121 million (403,800 units) in 2040. The remainder would stem from LMICs, which are expected to generate nearly \$36 million (18 million units) in 2040. At a 20% discount rate, a commercial partner would realize an NPV of \$70 million. The IRR of the investment is 41%.

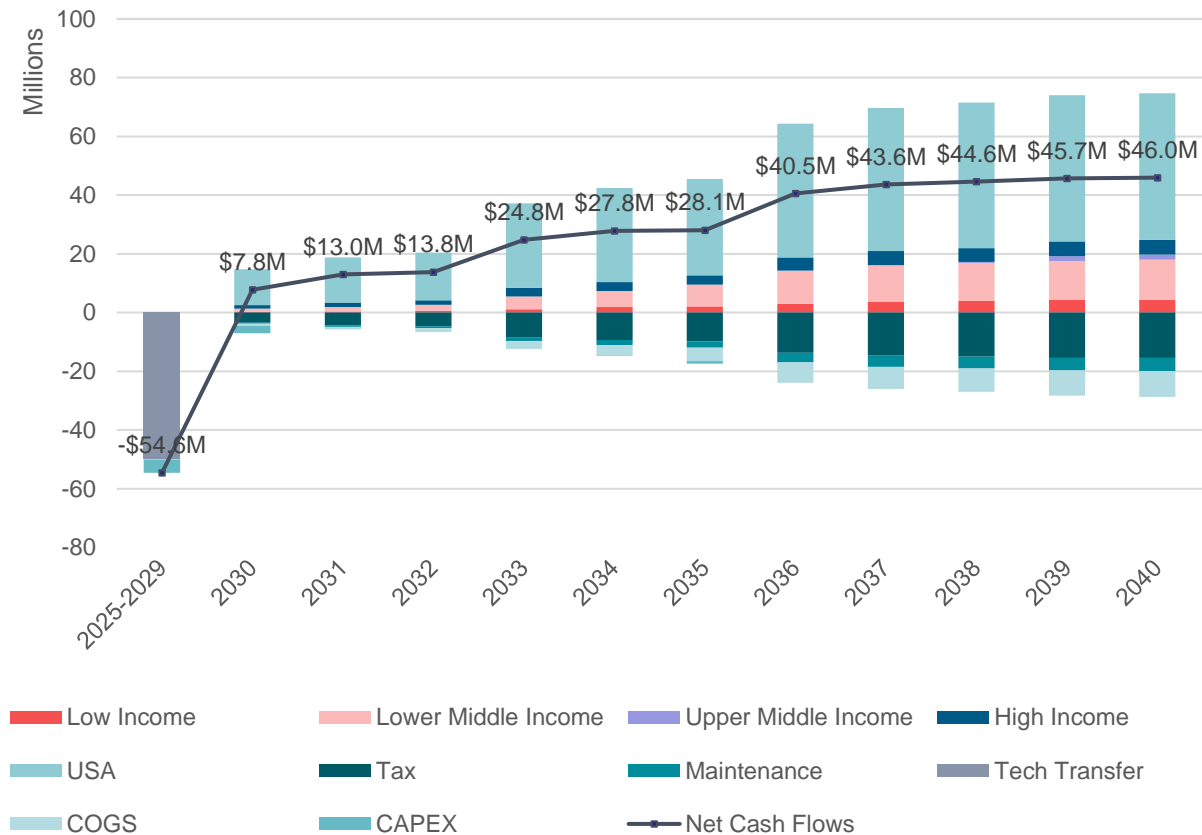
**Figure 6.** Contraceptive microarray patch cash flow by year and market, base case.



## Low case

In the low scenario shown in Figure 7, we estimated that the global annual market for a contraceptive MAP would reach \$75 million in revenues (10 million units) in 2040. The US market would generate the majority of the revenues, reaching \$50 million (166,449 units) in 2040. The remainder would come from LMICs, which would generate nearly \$18 million (9 million units) in 2040. At a 20% discount rate, a commercial partner could realize an NPV of \$9.1 million. The IRR of the investment is 24%.

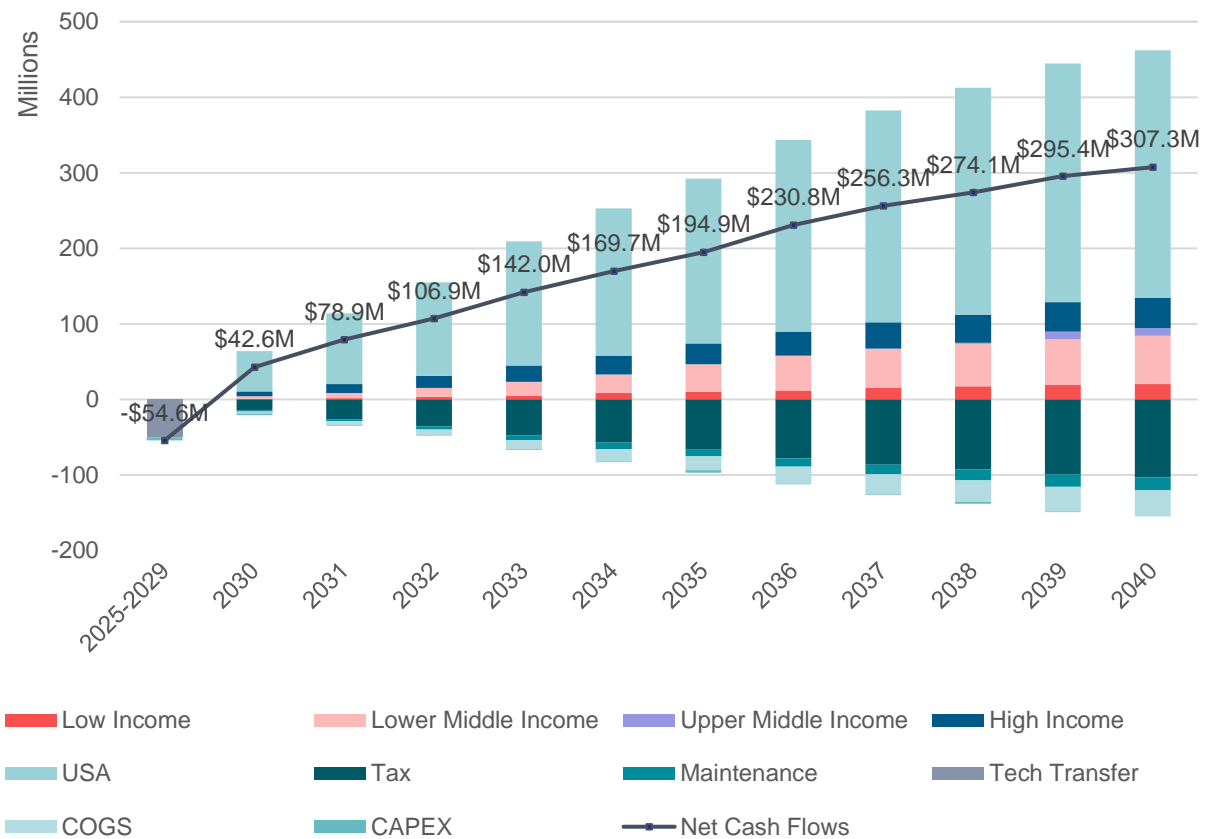
**Figure 7.** Contraceptive microarray patch cash flow by year and market, low case.



## High case

In the high scenario shown in Figure 8, we estimated that the global annual market for a contraceptive MAP would reach about \$462 million in revenues (48 million units) in 2040. The US market would generate the majority of the revenues, reaching \$327 million (1 million units) in 2040. The remainder would come from LMICs, expected to generate nearly \$84 million (42 million units) in 2040. At a 20% discount rate, a commercial partner would realize an NPV of \$208.6 million. The IRR of the investment is 59%.

**Figure 8.** Contraceptive microarray patch cash flow by year and market, high case.

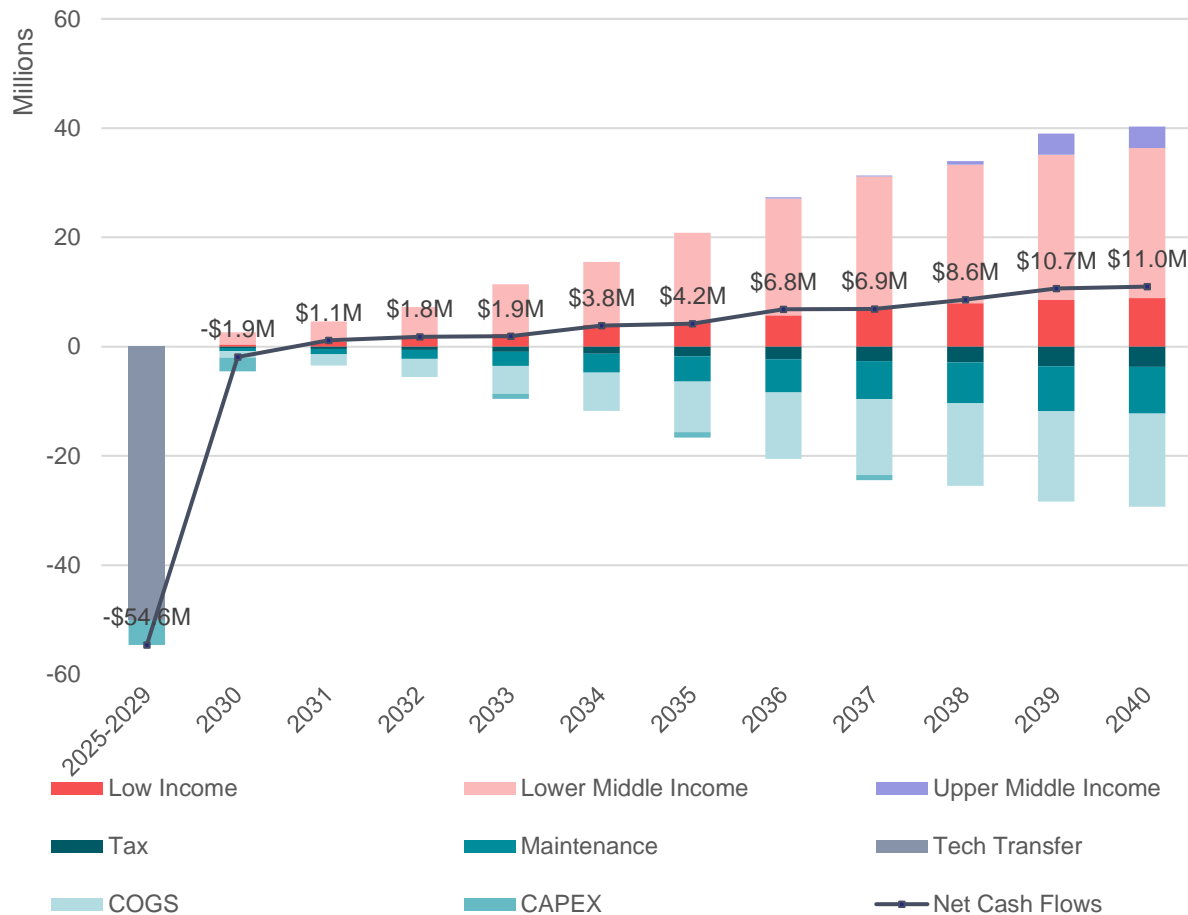




### Base case (excluding HICs)

In the scenario shown in Figure 9, we estimated that, without the HIC market, the global annual market for a contraceptive MAP would reach about \$40 million in revenues (19 million units) in 2040. Without the HIC market, the potential ROI for the contraceptive MAP is drastically different. At a 20% discount rate, the NPV for contraceptive MAPs without contribution from HICs would be negative \$26.7 million and would not justify commercial investment.

**Figure 9.** Contraceptive microarray patch cash flow by year and market, excluding high-income markets.



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## Challenges and opportunities in contraceptive MAP development and commercialization

Based on the results of the ROI analysis, several areas were identified as critical to the successful development and commercial viability of contraceptive MAPs.

### **Identifying a commercial partner with proven experience and commitment to women's health**

In parallel to early development activities for contraceptive MAP candidates, MAP developers should prepare for negotiations with potential manufacturers and commercialization partners. Identification of such partners to leverage resources and expertise will be critical to advancing contraceptive MAP candidates through clinical development, regulatory approval, manufacturing scale-up, and eventual program introduction, given the limitations of donor funding. In order to initiate these stakeholder conversations, it is important to understand what commercial partners will want to know before engaging with contraceptive MAPs, including proof-of-concept data, the value proposition, and the business case.

Understanding the landscape of contraceptive product manufacturers is also critical to understanding how MAPs could fit into the market. Multinational pharmaceutical companies have exited the contraceptive space in recent years,<sup>9</sup> making novel contraceptive technologies a unique opportunity for smaller and medium-sized biotechnology firms seeking to enter the market. However, it is crucial to partner with a company with the right experience and expertise to take the MAP through late-stage trials, regulatory approval, licensure, and marketing. Interviewed experts indicated that the right partner might be a company with an existing hormonal contraceptive portfolio or potentially a firm specializing in women's health technologies that is looking to add hormonal contraception to its suite of products.

### **Making LMIC market access a priority from the beginning**

Our business case shows that revenue from HICs could help subsidize MAP access in LMICs, which by themselves would not generate sufficient returns to justify investment. This approach could create a dual market and support sustainable introduction. However, this cross-subsidization scenario has been discussed for decades but has not been demonstrated in the contraceptive market. This type of agreement is challenging to structure because it relies on revenue generated in HICs being available for expanding market access in LMICs, when often the commercialization partners in these regions may be different entities, each of which have a separate relationship with the manufacturer of record or license holder. For a dual-market strategy to be successful, it is critical to have alignment and commitment to this vision from the outset. The product attributes should be driven by the needs of women and health care system requirements in low-resource settings, while also being suitable for users in HICs, to facilitate introduction and access to a contraceptive MAP in LMICs.

### **Generating a regulatory strategy**

Regulatory approval in the United States (Food and Drug Administration, or FDA) and/or the EU (European Medicines Agency, or EMA) is critical for a product launch in LMICs. Since regulatory requirements vary by country, generating a regulatory plan early on is crucial to developing an efficient process for market access. While receiving FDA approval has been identified as critical for revenue

potential in the United States, interviewees noted that EMA approval may be more straightforward—and important—when considering regulatory approval and introduction in African countries. Stakeholders also emphasized that World Health Organization prequalification is not required by procurement agencies for contraceptive products that have attained approval from a globally recognized stringent regulatory authority (i.e., FDA or EMA), which could shorten the timeline to market introduction in LMICs. In any event, targeting the appropriate pathway and engaging with authorities early helps mitigate regulatory risks and ensures that the regulatory strategy aligns with the market introduction strategy.<sup>9</sup> In addition to the safety and efficacy data required by regulatory authorities for licensure of any new contraceptive drug product, as a combination product (drug/device) intended for self-administration, a contraceptive MAP will require submission of device-related information, as well as data demonstrating the safety and reliability of self-administration by target user groups. Regulatory authorities are gaining experience with MAP technologies. The first MAP product New Drug Application (for zolmitriptan delivery for migraine treatment) was submitted by Zosano in 2019, and several other products are in various stages of clinical development, and it may be possible to draw learnings from their regulatory processes. PATH's MAP Center of Excellence has convened a Regulatory Working Group, which is in the process of generating a white paper on Critical Quality Attributes for the MAP technology platform—particularly those that will require test methods unique to the MAP technology, such as skin penetration and dose delivery—which will also be informative for the contraceptive MAP regulatory strategy.<sup>12</sup>

## **Sustaining and expanding donor interest and garnering financial commitment**

While the market opportunity for contraceptive MAPs may be attractive—especially when considering HICs—commercial partners have a strong preference for later-stage (Phase 2 or later) products to fill their pipelines, citing the cost and uncertainty involved in developing early-stage products. The contraceptive MAP is currently in preclinical studies and would require additional donor commitment and financial support to advance through at least Phase 1/2 clinical studies to generate commercial interest. For products with an intended primary market in LMICs, donor support may be necessary through Phase 3 and introduction, as well.

To date, donors, including the Gates Foundation and USAID, have provided critical support for preclinical development and user evaluations of contraceptive MAPs. Preclinical evidence that contraceptive MAPs can meet target attributes is essential to sustain donor interest in supporting continued development. Clarifying the MAP value proposition through user evaluations and cost-effectiveness studies may also help motivate donors to direct additional resources toward this effort and encourage industry investment. Donors may also be incentivized to invest in contraceptive MAP development as a test case for how to formulate and deliver a sustained-release formulation through a MAP, which maintains drug release over a sustained period of time. These learnings could be applied to other MAP applications targeted for sustained release and help expand the knowledge base to benefit other candidates in development.

## **Addressing cost challenges through product differentiation**

Since products with hormonal active pharmaceutical ingredients require a dedicated manufacturing facility and appropriate containment mechanisms to avoid cross contamination and staff exposure, this increases manufacturing costs. While one strategy discussed for other MAP products, such as vaccines, is potentially having a MAP manufacturing line that could manufacture multiple products, this is not feasible with contraceptive MAPs, as the production line could not be used for other MAP products that use

different active pharmaceutical ingredients.<sup>13</sup> However, it may be feasible to produce hormonal contraceptive MAPs with different durations of protection on the same line if the same progestin is used. While our business case assumes development of one product with six-month duration of protection. Based on product developers that we interviewed and early user feedback from LMICs, other formats such as a one-month or three-month product may also appeal and help expand potential market interest. Women may prefer testing a new product for a shorter period of time to check for side effects and to see how it fits with their lifestyles before committing to a six-month product. Launching multiple versions of the product adds complexity to manufacturing and marketing but may respond to the different needs of women. Additional modeling would be required to understand the financial impact of mixed presentations. More studies would need to be conducted to assess user preferences in different markets regarding duration of protection.

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## Limitations

This business case is a first step at articulating the commercial viability of contraceptive MAPs; however, this analysis has several limitations. The assumptions in this analysis are based on data currently available for contraceptive MAPs in development, as well as input from stakeholders (contraceptive product developers, researchers, donors/funding agencies, MAP manufacturers) and experience from introduction of other contraceptive products. Some of the assumptions are based on MAP products for other indications (such as the COGS based on an analysis of IPV MAPs) and are intended as a placeholder until more information becomes available. This model is also based on assumptions from the introduction of Sayana Press in LMIC, which may or may not be appropriate for a contraceptive MAP.

Since MAP products are still in the early stage of development, the product features and characteristics are still being developed. The business case will benefit from updates as more information becomes available, particularly about product attributes and user acceptability. The model input underpinning this business case can be updated as new data are generated to refine the analysis. We recognize that key topics such as clinical study and regulatory requirements currently are underdeveloped and should also be updated as more information becomes available. PATH's MAP Center for Excellence<sup>14</sup> has a working group looking at regulatory issues, which will help identify some of the quality attributes regulatory agencies will be looking at for MAPs,<sup>12</sup> which also will inform product development, manufacturing, and clinical study requirements. Issues around design, costs, and responsibilities for clinical studies required for product approval are not outlined, as this will depend on when commercial partnerships are achieved. Manufacturing costs and challenges are touched on only at a high level due to the early stage of these products. The business case will benefit from future research to identify user/stakeholder requirements and better define product features and characteristics for various markets, particularly around duration of protection and features that will influence uptake, acceptability, and ease of use. Moreover, some model input, such as pricing (currently based on the public-sector price for Sayana Press), will need further refinement to better articulate the potential returns for contraceptive MAP commercialization partners.

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## Conclusion

The results of this assessment demonstrate that contraceptive MAPs present a potentially viable dual-market opportunity for commercial investment, reaching more than \$100 million in annual revenues four years after launch and a NPV of \$70.2 million in the base case. While LMICs are expected to drive the majority of the demand, the US market would generate the bulk of the revenues due to the presumed high product price in the country under current market assumptions.

While the contraceptive MAP investment case is compelling, it is crucial to emphasize that the high NPV is driven by a singular high-income market and contingent upon success in that highly saturated and competitive market. The possibility that a manufacturer might provide the MAP at lower cost to the LMIC market through cross-subsidizing from HIC revenue is uncertain and would require successful product launch in both LMICs and HICs. A cross-subsidization model has also not yet been demonstrated in the contraceptive space. Making this business model sustainable would require substantial alignment and collaboration between donors, public health stakeholders, the MAP developer, and the commercialization partner(s).

Finally, it is important to note that the hormonal contraceptive MAP is still in very early stages of development and has not yet completed preclinical proof-of-concept studies. This analysis does not account for failure rates and technical challenges that may arise during the process of adopting a complex new technology at an industrial scale.

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# Appendix

**Supplemental Figure 1.** Scenario 1: Sayana Press countries – introduction order.

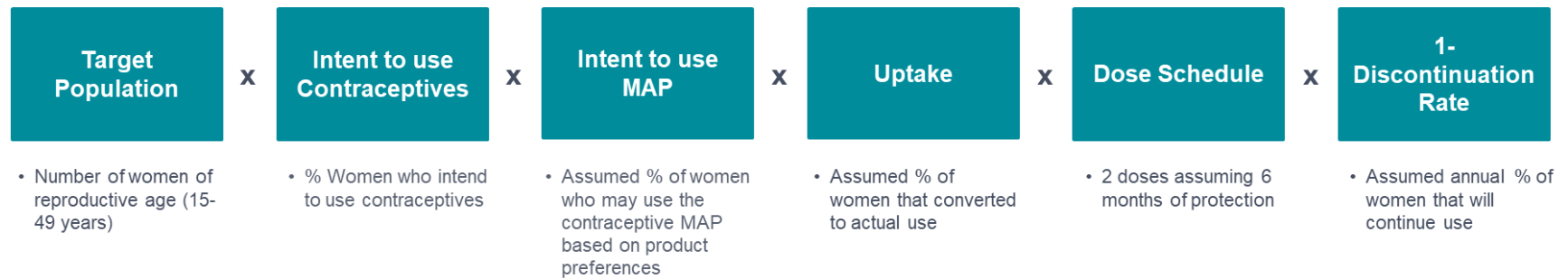
2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040
DRC Ethiopia Ghana Mozambique Nigeria	Benin DRC Ethiopia Ghana Haiti Mali Mozambique Nigeria Togo Uganda	Angola Benin DRC Ethiopia Ghana Haiti Liberia Madagascar Mali Mozambique Nigeria Senegal Tanzania Togo Uganda	Angola Benin Cote d'Ivoire DRC Ethiopia Ghana Guinea Haiti Liberia Madagascar Mali Mozambique Nepal Nigeria Senegal Sierra Leone Tanzania Togo Uganda Zambia	Angola Afghanistan Benin Burkina Faso Cameroon Cote d'Ivoire DRC Ethiopia Ghana Guinea Haiti Liberia Madagascar Mali Mozambique Nepal Nigeria Pakistan Senegal Sierra Leone Tanzania Togo Uganda Zambia	Angola Afghanistan Bangladesh Benin Burkina Faso Cameroon Chad Cote d'Ivoire DRC Ethiopia Ghana Guinea Haiti Kenya Liberia Madagascar Malawi Mali Mozambique Nepal Nigeria Pakistan Rwanda Senegal Sierra Leone Tanzania Togo Uganda Zimbabwe	Angola El Salvador Congo Guinea-Bissau Afghanistan Bangladesh Benin Burkina Faso Cameroon Chad Cote d'Ivoire DRC Ethiopia Ghana Guinea Haiti Kenya Liberia Madagascar Malawi Mali Mozambique Myanmar Nepal Niger Nigeria Pakistan Rwanda Senegal Sierra Leone Tanzania Togo Uganda Zambia Zimbabwe	Angola El Salvador Bolivia Congo Djibouti Guinea-Bissau Lesotho Papua New Guinea Yemen Afghanistan Bangladesh Benin Burkina Faso Burundi Cameroon Chad Cote d'Ivoire DRC Ethiopia Guinea Haiti Kenya Laos Liberia Madagascar Malawi Mali Mauritania Mozambique Myanmar Nepal Niger Nigeria Pakistan Rwanda Senegal Sierra Leone South Sudan Tanzania Togo Uganda Zambia Zimbabwe	Angola Brazil Chile El Salvador Trinidad Bolivia Congo Djibouti Guinea-Bissau Lesotho Mongolia Papua New Guinea Yemen Afghanistan Bangladesh Benin Burkina Faso Burundi Cameroon Chad Cote d'Ivoire DRC Ethiopia Ghana Guinea Haiti Kenya Laos Liberia Madagascar Malawi Mali Mauritania Mozambique Myanmar Nepal Niger Nigeria Pakistan Rwanda Senegal Sierra Leone South Sudan Tanzania Togo Uganda Zambia Zimbabwe	Angola Brazil Chile El Salvador Trinidad Bolivia Congo Djibouti Guinea-Bissau Lesotho Mongolia Papua New Guinea Yemen Afghanistan Bangladesh Benin Burkina Faso Burundi Cameroon Chad Cote d'Ivoire DRC Ethiopia Ghana Guinea Haiti Kenya Laos Liberia Madagascar Malawi Mali Mauritania Mozambique Myanmar Nepal Niger Nigeria Pakistan Rwanda Senegal Sierra Leone South Sudan Tanzania Togo Uganda Zambia Zimbabwe	
<div></div> FP2020 Commitment Maker	<div></div> FP2020									
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■ FP2020 Commitment Maker  
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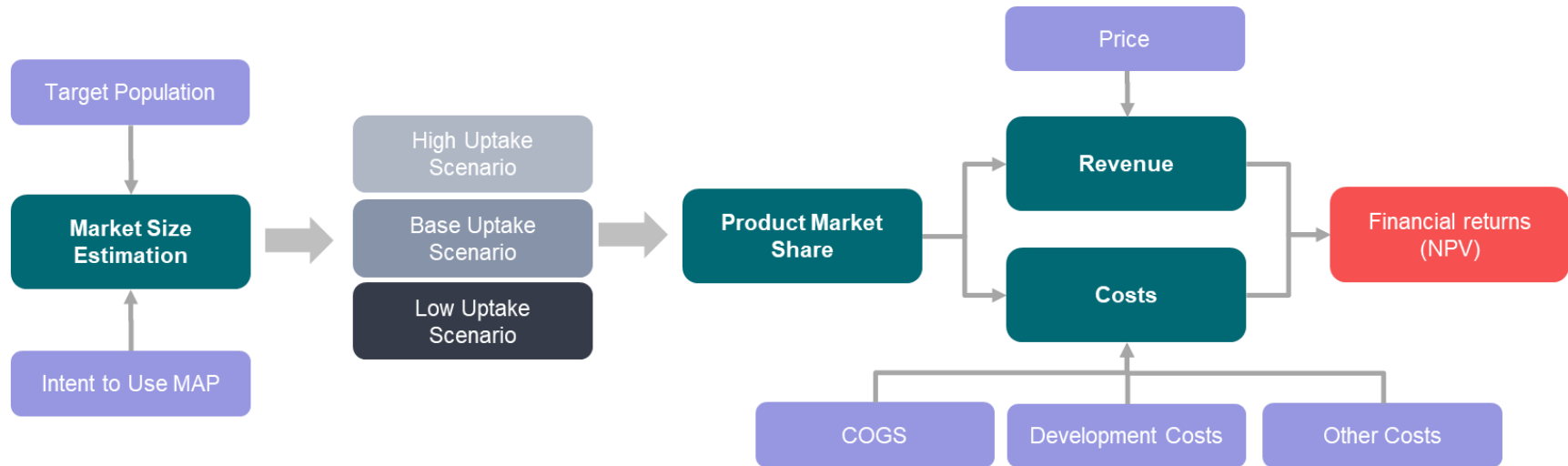
Abbreviation: FP, family planning.



**Supplemental Figure 2.** Contraceptive MAP demand model.



**Supplemental Figure 3.** Net present value model diagram.



**Legend**

