



The Economics of Antibodies for HIV Prevention

A Commercial Assessment of Profitability Potential and Market Strategy in North America and Europe



Motivation

In the context of HIV, multiple bnAbs in the development pipeline show promise of high effectiveness in preventing HIV infection, while directly addressing unmet needs present within the existing pre-exposure prophylaxis (PrEP) landscape. For example, bnAbs may only need to be administered twice annually, have a favorable safety profile, and are unlikely to induce resistance to any HIV treatments on the market today. bnAbs have the potential to greatly expand the number of individuals taking PrEP effectively, bringing us closer to global prevention targets.

Despite this enthusiasm for bnAb PrEP, commercial development of bnAb PrEP faces significant obstacles to practical application. This is in large part due to profitability uncertainty.

The cost of producing bnAbs currently surpasses that of small molecules, both in small and large batches. While bnAbs are extensively used and command high prices as therapies for cancer and a range of immunologic diseases, such as inflammatory bowel disease and psoriasis, their role in infectious disease—particularly in prevention—remains more uncertain. The question of whether a bnAb PrEP can garner sufficient demand from the market, and at what price, to generate commercial profitability has remained unanswered. This lack of evidence understandably contributes to hesitancy among potential manufacturers.

We set out to answer this question, and this report enumerates our findings. We conducted an independent economic analysis of the expected supply and demand for bnAb PrEP, using specific countries as case studies and incorporating learnings from other HIV PrEP programs and monoclonal antibodies (mAbs). We intend for our findings to support biopharma evaluation of bnAb PrEP for incorporation into a complementary asset portfolio. This report focuses on findings for high-income countries (HICs) including North America and Europe. A complementary report illustrates our findings and recommendations for access in middle- and low-income countries (LMICs).

Broadly neutralizing antibodies (bnAbs) are proteins capable of identifying and neutralizing a diverse array of pathogens, including various strains of viruses like HIV. Their adaptability makes them exceptionally valuable in the medical field, offering potential for effective treatments and preventive strategies against infectious diseases. Recent advancements are enhancing the overall potency and longevity of antibodies.

In this report, we will refer to the broadly neutralizing antibody-based pre-exposure prophylaxis approach in HIV as bnAb PreP.

Executive Summary

Our analysis confirms that bnAb PrEP for HIV presents a viable and highly profitable opportunity for a commercial manufacturer, particularly in North America and Europe, where conditions are ripe for product launch, sustained demand, and scalable use.

Despite ongoing global efforts, high-income countries (HICs) continue to fall short of their HIV prevention targets, leaving significant unmet needs within two key populations:

- Individuals not currently using any form of PrEP.
- Individuals using PrEP but experiencing suboptimal outcomes or challenges.

The value proposition for bnAb PrEP in HICs is compelling, with the potential to:

- Increase the population size protected by a PrEP product by around 7%.
- Improve the real-world effectiveness of protection by overcoming adherence barriers.
- Decrease the incidence of unfavorable ART-related side effects, such as bone density loss or breakthrough infection resistance to HIV treatment.

By 2040, an estimated 1.2 million individuals will be eligible for bnAb PrEP in the United States (Total Addressable Market, TAM). We anticipate over 100,000 people using bnAb PrEP each year after launch and initial uptake, representing a 12.5% share of the total PrEP product market. This adoption level is expected to yield more than \$1.8 billion annually in revenue for a pharmaceutical manufacturer (Serviceable Obtainable Market, SOM). In the United States alone, the introduction of a bnAb PrEP product is projected to generate up to \$14 billion in profit within ten years.

These outcomes are achievable through a strategic pricing model that positions bnAb PrEP below branded alternatives, effectively 'flooding the market' to maximize adoption and align incentives across the healthcare system, including reducing overall healthcare expenditures in the US.

Ensuring access in low and middle income countries (LMICs) is achievable with strategic partnerships and subsidies, as elaborated on in our accompanying report.

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Unmet Need & Value of HIV bnAbs

Unmet need assessments are essential for evaluating and quantifying the magnitude of impact for HIV prevention products and interventions in communities. Despite the availability of existing HIV preventative measures, including ART-based PrEP, significant gaps in HIV prevention remain. Many countries continue to fall short of their targets for reducing HIV transmission rates. In the United States, for example, only 30% of eligible individuals have initiated ART-based PrEP.

To achieve global HIV prevention goals, two key adult populations need further attention:

- Individuals not currently using any form of PrEP.
- Individuals using PrEP but experiencing suboptimal outcomes or challenges.

Social, behavioral, and logistical barriers associated with existing PrEP options hinder their adoption and consistent use. These challenges are detailed in the table below. The bnAb product profile addresses many of these barriers, offering distinct advantages even when compared to long-acting injectable PrEP.

How On-Market PrEP and bnAb PrEP Products Address or Exacerbate Factors Affecting Global Adoption

		A LIVE A	
	Antiretroviral-based PrEP (oral)	Antiretroviral-based PrEP (injected)	bnAb-based PrEP (infused)
Required adherence to pill taking	CONCERN	BENEFIT	BENEFIT
Reliance on HIV-negative person's ability to assess risk for HIV acquisiti	on CONCERN	BENEFIT	BENEFIT
Discretion	CONCERN	BENEFIT	BENEFIT
Side effects and interactions with other drugs	CONCERN	CONCERN	BENEFIT
Risks of HIV drug resistance, particularly after discontinuation	CONCERN	CONCERN	BENEFIT
HIV testing requirements	CONCERN	CONCERN	BENEFIT
Frequency of clinic visits may be burdensome for some clients	CONCERN	CONCERN	BENEFIT
Costs	BENEFIT	CONCERN	CONCERN
Increased pressure on providers due to more complicated and time-consuming administration and reliance on physicians for injections	BENEFIT	CONCERN	CONCERN
Difficulty of delivery in non-clinic settings and remedicalization of PrEP	BENEFIT	CONCERN	CONCERN

Adapted and expanded on Henderson et al. AIDS and Behavior (2023) 27:3755-3766.

If bnAbs are made available, we project a significant impact on internationally defined HIV prevention targets:

Expanding Coverage: bnAb-based PrEP has the potential to significantly expand the coverage of individuals at risk of HIV. We anticipate that introducing a bnAb PrEP option will lead to a 6.8% increase in the total number of people protected by PrEP in North America and Europe.

Improving Effectiveness: Some individuals currently on existing forms of PrEP may choose to switch to bnAbs, in consultation with their healthcare providers. Our projections include an estimated switch rate of 7% among current PrEP users in high-income countries. For these individuals, bnAbs could enhance real-world efficacy and reduce adverse events.



Product Profile Highlights

The proposed bnAb PrEP product consists of a cocktail of three monoclonal antibodies, each targeting conserved regions of the HIV virus: the CD4 binding site, the V3-glycan, and the V2-apex. These antibodies work together to provide broad protection against various HIV strains, reducing the likelihood of resistance.

Current clinical trials are focused on adult populations, with administration via intravenous infusion requiring only two doses per year. This next-generation bnAb cocktail is anticipated for US FDA regulatory approval in 2030.



Concerns Addressed by Product Profile

HIV researchers and community members have extensively documented the barriers to adoption and real-world effectiveness of daily oral HIV PrEP options currently available. A bnAb product profile addresses many of these challenges, bolstering confidence in its potential to meet the demand projected in this report.

The burden of adherence to daily oral medication significantly diminishes the real-world effectiveness of oral PrEP for many users, despite it being the most prescribed and payer-reimbursed option. While oral PrEP performs well in clinical trials, daily adherence remains a substantial barrier to its real world effectiveness in everyday use. Compounding this issue, individuals who contract HIV while on oral PrEP may remain unaware of their infection for some time. This, combined with the fact that the first three months of HIV infection are associated with the highest transmission rates, creates a particularly concerning scenario for transmission and the risk of developing resistance to treatment.

The long-lasting nature of the bnAb profile offers the potential to close the gap between RCT performance and real-world effectiveness by alleviating the behavioral, cultural, and logistical challenges associated with daily pill regimens.

Adherence to daily oral medication is challenging. The real world effectiveness of branded and generic options for daily oral PrEP medications are limited by human behavior. Remembering to take a daily pill is a barrier for many users. While the efficacy in closely monitored clinical trials has been high, the adherence observed in the real world has been less consistent. Lower adherence to the medication reduces its real world effectiveness in preventing HIV transmission.

Existing PrEP options risk resistance to HIV treatment in breakthrough infections. Previously approved PrEP products are antiretroviral-based, and individuals who experience breakthrough HIV acquisition while using these medications intermittently can develop resistance to antiretroviral therapy (ART) for use as a treatment option. One major advantage of bnAb PrEP is that bnAbs have not been shown to cause resistance to antiretroviral drugs used in HIV treatment, and their mechanism of action makes this unlikely. This characteristic positions bnAb PrEP as a promising alternative to ART-based options. "Offering a choice of PrEP products is another critical aspect of differentiated service delivery as it allows clients to choose the product that best suit their needs and preferences. This may make services more acceptable and thus improve uptake and effective use of PrEP, but implementation research is needed on how to effectively integrate new PrEP products."

-The Future of Pre-Exposure Prophylaxis (PrEP) for HIV Prevention: A Global Qualitative Consultation on Provider Perspectives on New Products and Differentiated Service Delivery

Current PrEP options also carry the risk of adverse events.

Individuals using existing ART-based PrEP products have reported both local adverse effects, such as pain at the injection site for intramuscular (IM) injections and nodules from subcutaneous (SC) injections, as well as systemic effects with prolonged use, like bone density loss. bnAb products are expected to cause fewer adverse events, making them more appealing to prescribers, payers, and patients alike.

Stigma remains a barrier for many. Both current and potential PrEP users report experiencing or perceiving stigma associated with using a PrEP product that is also approved for HIV treatment. For some, the discomfort extends to storing evidence of their PrEP use, such as keeping a labeled bottle in their medicine cabinet at home.

The range of PrEP choices is still limited for prescribers and the community. Providers express a need for more options to address individual lifestyle needs and support differentiated service delivery. In certain cases, providers are hesitant to prescribe pill-based PrEP due to concerns about adherence, particularly among high-risk individuals such as intravenous drug users. Some people also express a preference for long-acting or infusion-based approaches over daily pill regimens.

This situation can be likened to the evolution of contraceptive options, where varying formulations and routes of administration have been adopted differently across life stages, populations, and geographies.

Prior PrEP options have faced challenges due to the perception that vaccines or chemical preventions are unnatural, which can deter some individuals from using them. However, focus groups and early clinical trials suggest that many people view antibodies as more natural substances, making them feel safer compared to drugs or chemical-based preventions. The extensive use of COVID-19 bnAbs has also increased familiarity with antibody-based treatments, even in southern states in the US, potentially making the adoption of bnAb PrEP easier and more widespread than previous estimates suggest.



COMPETITIVE LANDSCAPE Potential new entrant to HIV PrEP market: Lenacapavir (Gilead Sciences, Inc.)

In June 2024, Gilead announced the results of a Phase 3 HIV prevention trial, PURPOSE 1, for Lenacapavir, a twice-yearly (every 6 months) injectable HIV-1 capsid inhibitor. The trial demonstrated 100% efficacy for the investigational use of Lenacapavir in HIV prevention among cisgender women, showing superior efficacy compared to the daily oral PrEP alternatives, Descovy and Truvada. Lenacapavir has a subcutaneous route of administration and nodules at the injection site are common.

The annual wholesale acquisition cost of Lenacapavir for HIV treatment was approximately \$42,000 per year in 2023. If Lenacapavir is priced similarly for HIV prevention, we anticipate significant barriers to widespread reimbursement and adoption.



Target Northern Markets for Access

Selecting the right markets for launching bnAbs is crucial for determining pricing, utilization, and financial returns. G7 countries are priority markets. Biopharma manufacturers must assess the scale of unmet need (i.e., the addressable market) and each country's history with PrEP adoption. Additionally, commercialization should be planned in countries where phase III trials are conducted.

As a case study, we analyzed targeting the United States and France among Northern markets due to their significant unmet needs and strong track record in adopting new PrEP solutions. These markets provide valuable insights into potential bnAb performance in similar regions.

In a supplementary report, we also explore market strategy in middleand low-income countries (LMICs) using South Africa, Brazil, Kenya, and Malawi as case studies, offering a comprehensive view of the challenges and opportunities bnAbs might encounter globally.



Launch Pricing Considerations

A solid launch pricing strategy is crucial and determines both the rate of adoption and the sustainability of supply. If the pricing of a new bnAb asset fails to meet or stay below a market's cost-effectiveness threshold, it could significantly hinder its adoption in relevant markets.

We recommend that a future bnAb program establish a wholesale acquisition cost (WAC) per dose that is below the cost-effectiveness threshold and incrementally lower in annual cost to payers than that of long-acting injectable PrEP options, which are offered at the same dosing frequency. This competitive strategy is intended to 'flood the market,' thereby driving high financial returns through a profile that will be attractive to healthcare payers. In turn, this strategy is likely to drive wider adoption.

In the United States, we suggest launching with a WAC to healthcare payers as \$14,000 per person per year, distributed across two doses. For the remaining G7 countries (Canada, France, Germany, Italy, Japan, the United Kingdom), a competitive WAC is recommended to be closer to \$6,000 annually for the healthcare payer.

PrEP Product	Cost to US Healthcare Payer, Annual (USD)
Generic daily oral PrEP (TDF/FTC)	\$8,300
bnAb twice-yearly infusions	\$14,000
Branded daily oral PrEP (TAF/FTC)	\$16,600
Injectable PrEP (CAB-LA) every other month	\$25,800
Twice yearly injectable PrEP, expected launch	\$42,250

*Assumptions used in the base case for this economic evaluation



COMPETITIVE LANDSCAPE Existing long-acting PrEP option: Cabotegravir (ViiV Healthcare)

Cabotegravir, the only long-acting PrEP option on the market as of August 2024, provides important insights into the challenges of achieving widespread adoption. Costing more than \$25,000 per year in the U.S. (WAC), this injectable method is significantly more costly than daily oral options, such as Truvada or Descovy. This price point not only exceeds the financial capacity of many potential users but also triggers commercial healthcare insurance prior-authorization requirements, that can delay or prevent access.

Studies and reports highlight the financial burden associated with Cabotegravir has led to lower-than-expected uptake, particularly among populations that are already underserved by existing PrEP options. The situation underscores the critical need for more affordable and accessible long-acting PrEP solutions, particularly if we are to achieve broader HIV prevention goals. "...the imperative is to spend time, resources, and political will on access, implementation, and delivery. And that plan must include a mechanism to finance these drugs so that the women who have borne an unacceptably high HIV infection burden and who have volunteered for decades in studies of HIV prevention can reap the PrEP benefits and remain HIV free."

-The Real PURPOSE of PrEP — Rochelle Walensky and Lindsey Baden in "Effectiveness, Not Efficacy"

Demand Forecast

The serviceable addressable market (SAM) for PrEP continues to expand, representing the population likely to adopt any PrEP solution. In 2023, the SAM was valued at approximately \$7 billion, encompassing 380,000 individuals in the U.S. and \$5.7 million globally. By 2030, we project this figure will exceed 10 million people worldwide.

In evaluating the potential uptake and demand for bnAb-based PrEP, we considered the significant unmet need in HIV prevention alongside the anticipated value that bnAbs could provide.

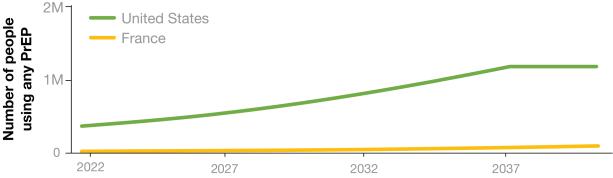
Our projections assume uptake from two key populations with unmet need:

- 10% of those not currently using any form of PrEP who could be reached with bnAb PrEP.
- 5-20% of current PrEP users who may be motivated to switch to bnAbs due to preferences.

Given the numerous advantages of bnAb PrEP, we believe these estimates to be conservative.

bnAb PrEP is anticipated to sustain the current growth rate of PrEP adoption in target markets, continuing until the target ratio of 40 people on PrEP for every new HIV infection is reached. This 40:1 ratio aligns with the UNAIDS target and reflects similar outcomes achieved by other successful HIV prevention programs.

In terms of market share, we project that the introduction of bnAb PrEP will result in a 6.8% increase in the total number of people taking PrEP in high-income countries.



Annual PrEP Adoption Projections (2030-2040) Across Case Study Markets

This data is based on an independent analysis conducted by Infectious Economics, with funding and intellectual partnership from the HIV Vaccine Trials Network (HVTN), supported by the National Institute for Allergy and Infectious Diseases (NIAID).

By 2040, 1.2 million individuals are expected to be eligible for bnAb PrEP, forming the total addressable market (TAM). We estimate that by this time, adoption will include 100,000 people in the United States. Given the numerous advantages of bnAb PrEP, we believe these estimates to be conservative.

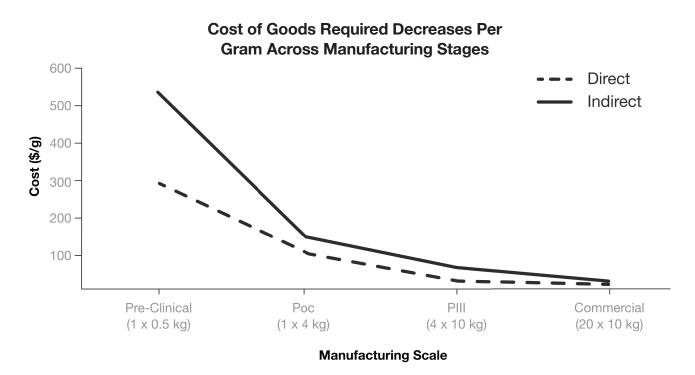
Cost of Production

Antibodies remain more costly to produce than small molecules, particularly when manufacturing the volumes required for infusion-based treatments. To meet projected demand by 2035, the US will need at least 221,000 doses annually, with France requiring 27,000 doses.

For North American and European markets, our supply model estimates an initial fixed cost of \$10 million for clinical trial manufacturing, followed by an additional \$50 million to scale production for commercialization at launch.

The marginal cost per dose in commercial production is currently estimated at \$50 per gram, with an added 30% cost for bottling and packaging. This results in an estimated marginal production cost of \$195 per dose for a 3-gram antibody cocktail, having 1 gram each of 3 different antibodies.

As the program scales and technology advances, we expect production efficiencies to improve over time, reducing the overall cost per dose. Our sensitivity analysis explores these potential cost reductions in more detail, highlighting the positive impact of technology innovations and a multinational launch on long-term manufacturing costs.



Pollock J, Coffman J, Ho SV, Farid SS. Integrated continuous bioprocessing: Economic, operational, and environmental feasibility for clinical and commercial antibody manufacture. Biotechnology progress. 2017 Jul;33(4):854-66.

Revenue & Profitability Projections

From the perspective of the commercial manufacturer, after product launch and successful market uptake, meeting the projected demand could yield \$1.3-1.8 billion in annual revenue in the United States and \$70-120 million annually in France.

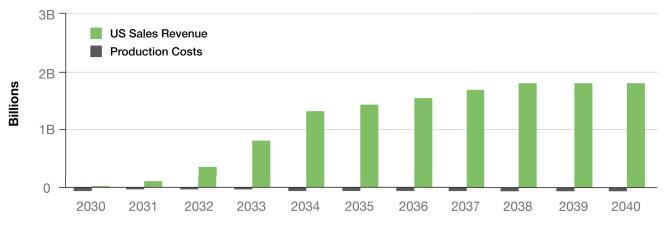
When subtracting anticipated cost of goods from these revenue projections, a clear path to profitability emerges. The program is anticipated to break even, yielding profitability within two years of market access. **By 2035, within five years of launch, a commercial manufacturer could realize an annual profit surpassing \$1.5 billion in the United States and \$76 million in France.** Of course, accurate profitability projections must also take into account holistic costs, specific program strategies, and sponsor manufacturing advantages.

	Expected doses delivered in 2035*	Estimated 2035 revenue minus production cost**
United States	221,000	\$1,507,000,000
France	27,000	\$76,000,000

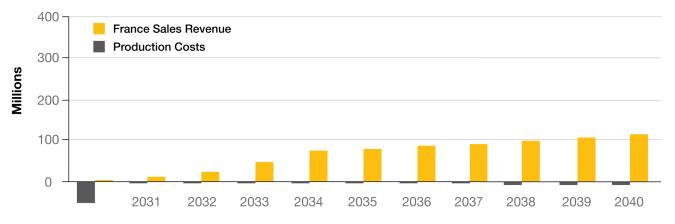
*Assumes market entry in 2030, with three years uptake before reaching optimal adoption

**Perspective of pharmaceutical manufacturer assuming value-based pricing at local cost-effectiveness threshold





Case study: The French Serviceable Obtainable Market (SOM) Exceeds 76 Million USD Annually Within Five Years

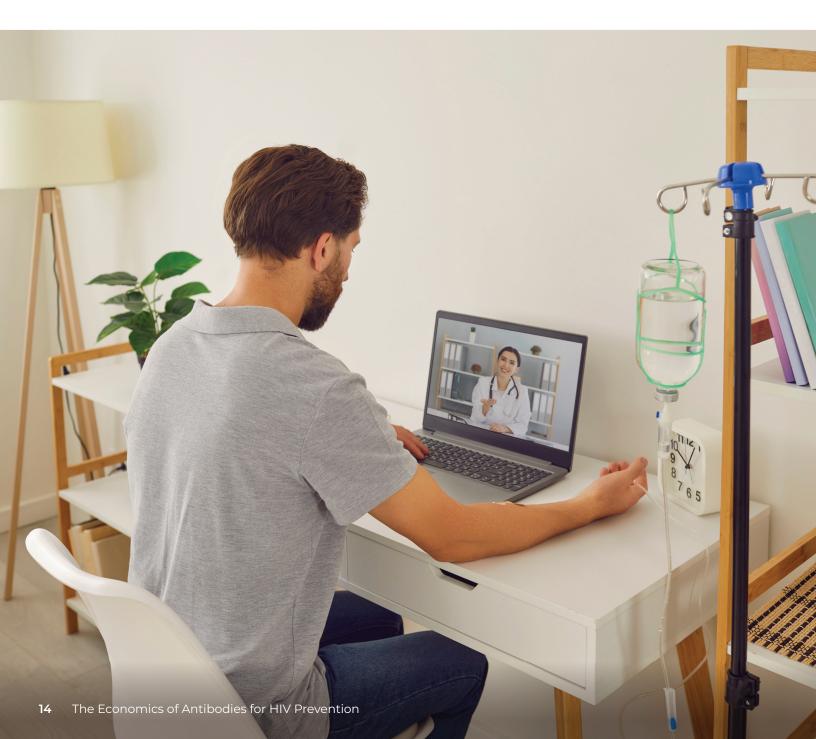


Source: Independent analysis conducted by Infectious Economics, with funding and intellectual partnership from the HIV Vaccine Trials Network (HVTN), supported by the National Institute for Allergy and Infectious Diseases (NIAID).

Healthcare Payer Perspective

Furthermore, healthcare systems could experience reductions in total healthcare spending as bnAbs substitute more costly PrEP options. In the United States, this shift is expected to lower overall healthcare spending on PrEP products by approximately 1-2%. This benefit may be particularly pronounced in high-income markets, where brand-name oral PrEP and injectable PrEP are more commonly used prior to a bnAb program launch. This is a vital opportunity to lower healthcare payer spending on PrEP products while at the same time increasing the total number of people using and protected by PrEP.

In the United States, this shift is expected to lower overall healthcare spending on PrEP products by approximately 1-2%.

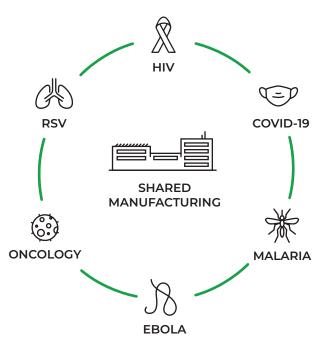


Strategic Recommendations for bnAb PrEP Commercialization

Based on our independent economic evaluation, there remains a compelling unmet need for HIV prevention solutions in high-income countries. The value proposition for bnAb PrEP is clear, with the potential to deliver cost-effective impact by reducing new HIV transmissions.

To ensure the successful commercialization and long-term viability of bnAb PrEP, we offer the following strategic recommendations:

- Collaborate with Manufacturers and Governments: Establish partnerships with commercial manufacturers and government entities to support product development and production for later-phase trials.
- Competitive Pricing Strategy: Launch bnAb PrEP at a price point below that of antiretroviral-based long-acting injectable PrEP options to encourage adoption and market penetration.
- Ongoing Community Engagement: Continue engaging with communities to validate product-market fit and ensure infusion-based HIV prevention aligns with patient preferences and willingness.
- Leverage Existing bnAb Portfolios: Integrate bnAb PrEP production into existing antibody portfolios to capitalize on shared factory maintenance costs, driving cost efficiencies across markets.
- Innovative Manufacturing Techniques: Develop new techniques for more efficient, large-scale antibody production, lowering the overall cost of goods and ensuring competitive pricing.
- Risk-Sharing Agreements: Establish risk-sharing agreements between payers and manufacturers, backed by third-party guarantees, to reduce financial risks and promote investment.
- Advanced Market Commitments: Secure multi-nation advanced market commitments to guarantee demand and mitigate financial uncertainty.
- Fast Track Designation: Pursue Fast Track Designation from the FDA to expedite the development and approval process, ensuring rapid market access.



Conclusion

The analysis presented in this report reveals a significant opportunity for the commercialization of bnAb PrEP for HIV prevention in high-income countries, particularly in North America and Europe. Despite initial skepticism about the profitability of bnAb PrEP, our findings demonstrate a compelling market potential. With a projected total addressable market (TAM) of 1.2 million eligible individuals by 2040, bnAb PrEP has the potential to address critical unmet needs in HIV prevention while generating substantial financial returns.

Market conditions suggest that the introduction of bnAb PrEP could lead to annual revenues of \$1.8 billion in the US alone, supported by a strategic pricing model that optimizes adoption while aligning with healthcare cost-saving goals. The anticipated uptake in key G7 markets underscores a clear incentive for commercial interest, with a clear path to profitability achieved within five years of FDA approval.

Furthermore, as the total number of people indicated to use PrEP in high-income countries increases, pressure on healthcare payers will also rise. We present bnAb PrEP as a cost-effective alternative compared to other long-acting injectable PrEP options, offering substantial savings for healthcare payers, driving advocacy and utilization.

These findings provide a data-driven response to the earlier doubts, highlighting the economic viability of bnAb PrEP and offering a pathway to both public health impact and commercial success within the evolving landscape of HIV prevention.



Methods

We conducted an economic evaluation to estimate the potential costs and revenue from HIV bnAb commercialization in high income countries.

The time horizon for this analysis spans from 2022 to 2040, with a product market launch expected in 2030 following FDA approval.

We forecasted the total number of PrEP eligible and PrEP users in target countries. Our analysis of future PrEP utilization incorporates observed usage data from 2014 to 2022, trend fitting of uptake patterns, extrapolation into future years, and stabilization at country-specific target population sizes. After regulatory approval and product launch, the uptake rate is assumed to increase linearly over three years until the expected market share among all PrEP clients is achieved.

To estimate the expected uptake, including new users and switches from competing PrEP products due to individual preferences, we developed a decision tree model. The decision tree model was employed to compare the incremental differences in Serviceable Obtainable Market (SOM) size and PrEP product share across various categories (branded oral, generic oral, 2-month injectable, and 6-month injectable) in scenarios with and without the introduction of bnAbs.

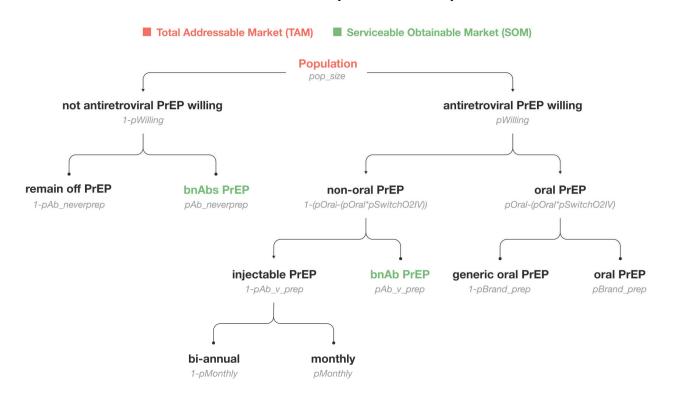
Model inputs were derived from published studies and expert opinion, with assumptions made in areas lacking direct evidence. Within the bnAb access scenario, two types of bnAb initiation were considered: switching and new user adoption. Existing PrEP users are projected to switch from oral (5%) or injectable (20%) PrEP to bnAbs due to factors such as adherence, convenience, or safety. Additionally, a subset of individuals who were previously eligible for PrEP but had not initiated use—due to reasons such as stigma or safety concerns—are expected to begin bnAb treatment as new users, increasing the overall population protected by PrEP products (assumed at 10% of eligible non-users).

The annual per-person cost of PrEP (across categories such as branded oral, generic oral, 2-month injectable, 6-month injectable, and 6-month bnAb) to the US healthcare system was integrated into the decision tree to estimate both total and incremental costs with bnAb access.

For North American and European markets, our supply model assumes an initial facility fixed cost of \$10 million for clinical trial product manufacturing, followed by an additional fixed cost of \$50 million for facility expansion to support commercialization at launch. The marginal cost per dose in commercial production was assumed to be \$50 per gram, with an additional 30% cost allocation for bottling and packaging product. This results in a marginal production cost of \$195 per dose for a bnAb cocktail comprising three antibodies, each at 1 gram.

Over time, technological innovations are expected to enhance production efficiencies and improve profit margins for manufacturers. Given the anticipated scale of a multinational launch, we explored sensitivity analyses that projected manufacturing costs for the bnAb PrEP program will decrease.

Structure of Decision Tree to Estimate Demand for bnAbs in a Competitive Marketplace



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Contact and Acknowledgments

This study was produced independently by Infectious Economics, LLC, with support from the HIV Vaccine Trials Network (HVTN), funded by the National Institute for Allergy and Infectious Diseases (NIAID).

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REFERENCING THIS REPORT

Please use this format when referencing this report: **Infectious Economics, LLC.** The economics of antibodies for HIV prevention: a commercial assessment of profitability potential and market strategy in North America and Europe. September 2024. Available from: www.hvtn.org.





