

Global Long-Acting HIV PrEP Market Growth (Status and Outlook) 2026-2032

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Abstracts

The global Long-Acting HIV PrEP market size is predicted to grow from US\$ 1177 million in 2025 to US\$ 12826 million in 2032; it is expected to grow at a CAGR of 38.9% from 2026 to 2032.

Long-Acting HIV PrEP refers to long-duration antiretroviral pre-exposure prophylaxis delivered through scheduled injectable formulations to reduce the risk of sexually acquired HIV-1 infection in HIV-negative individuals. This study focuses on commercially established long-acting injectable PrEP based on cabotegravir and lenacapavir, covering intramuscular and subcutaneous administration, dosing schedules ranging from every two months to every six months, and the corresponding integrase strand transfer inhibitor and HIV-1 capsid inhibitor mechanisms. These products are administered through professional healthcare settings and require confirmation of HIV-negative status before initiation and appropriate testing during continued use. The principal downstream settings include hospitals and HIV specialty clinics, sexual health clinics, community health centers and public-health PrEP programs. Compared with daily oral prevention, the defining commercial attribute of Long-Acting HIV PrEP is the extension of effective drug exposure across substantially longer dosing intervals, creating a differentiated prevention option for users seeking lower dosing frequency and for healthcare systems aiming to improve persistence with PrEP programs.

Key Findings

The average gross profit margin of this product is 90%

Commercial Long-Acting HIV PrEP now spans two distinct injectable mechanisms

Current dosing intervals range from every two to every six months

Cabotegravir holds an earlier commercial position in long-acting injectable PrEP

Lenacapavir extends injectable HIV prevention to a twice-yearly dosing schedule

Scheduled HIV testing remains integral to long-acting injectable PrEP delivery

Market Trends

The Long-Acting HIV PrEP market is transitioning from a single long-acting injectable concept toward a differentiated platform defined by dosing duration, administration route and mechanism of action. Cabotegravir established the every-two-month intramuscular model, while lenacapavir has extended the interval to twice-yearly subcutaneous administration, materially changing the competitive benchmark for dosing convenience. The longer-term direction of the market is therefore shifting from simply replacing daily tablets toward reducing the number of prevention-related dosing events while preserving reliable clinical follow-up. At the same time, product innovation is increasingly being linked with simplified HIV testing, differentiated service delivery and integration into broader sexual-health and public-health programs. WHO recommendations covering both long-acting cabotegravir and lenacapavir reinforce the development of a multi-option PrEP environment in which long-acting injectables are positioned alongside other prevention choices rather than as a uniform replacement for all existing PrEP approaches.

Market Dynamics

Drivers

Demand for Long-Acting HIV PrEP is primarily supported by the persistent challenge of maintaining adherence to frequently dosed prevention regimens and by growing emphasis on expanding user choice within HIV prevention. Injectable products reduce the number of medication-taking events required over a year and may be particularly relevant for users who experience difficulties with daily pill adherence, privacy concerns or stigma associated with storing and taking oral medication. Regulatory approvals and inclusion of long-acting injectable options in international HIV prevention recommendations have also strengthened the clinical foundation for broader implementation. In parallel, governments and public-health organizations increasingly view diversified PrEP options as a means of improving effective prevention coverage

rather than relying on a single delivery model.

Restraints

The main restraints arise from the more structured service requirements associated with injectable PrEP. Unlike self-administered daily oral medication, current long-acting injections generally require healthcare-provider administration, scheduled return visits and HIV testing before initiation and during continued use. Missed or significantly delayed dosing may complicate preventive management, while use in individuals with undiagnosed HIV infection can create drug-resistance concerns. These operational requirements increase dependence on clinic capacity, patient tracking, reimbursement and reliable appointment systems. Consequently, the commercial advantage of lower dosing frequency does not automatically translate into easier healthcare delivery, particularly in markets where HIV testing infrastructure, trained providers or financing for preventive services remains limited.

Opportunities

The principal opportunity lies in expanding PrEP participation among populations that have not been effectively retained by conventional prevention delivery models. Longer dosing intervals create potential for more differentiated service models linking HIV specialty care, sexual-health clinics, community health centers and public-health programs. Simplified testing approaches may further support decentralization of long-acting PrEP services and reduce operational barriers to initiation and continuation. The twice-yearly dosing model also provides a new reference point for future product development, potentially shifting competitive differentiation toward duration of protection, ease of administration and service efficiency. Markets with substantial unmet HIV prevention needs represent an important long-term opportunity, although realization of this potential will depend heavily on national guidelines, procurement mechanisms, reimbursement and access programs.

Challenges

Long-Acting HIV PrEP creates new implementation challenges alongside its adherence advantages. Healthcare systems must maintain accurate HIV-negative confirmation, injection scheduling and follow-up over extended intervals, while providers must manage individuals who miss injections or discontinue treatment. The prolonged pharmacologic activity that supports long dosing intervals also makes resistance management and testing strategy particularly important if HIV infection occurs during

periods of declining drug concentration. At the market level, differences in regulatory approval, reimbursement, public-health funding and provider readiness can produce substantial variation in adoption between countries. Manufacturers therefore face the dual task of demonstrating strong prevention performance while building scalable delivery systems that translate clinical efficacy into consistent real-world uptake.

Industry Chain Analysis

The Long-Acting HIV PrEP industry chain begins with antiretroviral active pharmaceutical ingredients, pharmaceutical excipients, formulation materials and sterile injectable manufacturing inputs. The middle of the chain encompasses long-acting formulation development, sterile production and fill-finish, quality control, clinical development, regulatory registration, packaging and product supply. Compared with conventional solid-dose medicines, the technical value of the product is concentrated not only in the active ingredient but also in achieving controlled and persistent drug exposure over extended periods through specialized injectable formulations. This makes formulation technology, clinical evidence, intellectual property and regulatory capability major components of product value.

Downstream value is realized through hospitals, HIV specialty clinics, sexual-health services, community healthcare facilities and public-health PrEP programs. Because the products require HIV testing and professionally managed dosing schedules, manufacturers depend more heavily on healthcare-delivery infrastructure than suppliers of self-administered preventive medicines. Commercial performance is therefore influenced not only by pharmaceutical production costs but also by reimbursement, procurement, clinical workflow integration, patient identification and long-term retention. As dosing frequency decreases, the industry chain is likely to place greater emphasis on reliable patient recall systems and coordinated prevention services rather than prescription volume alone.

Segment Insights

The current Long-Acting HIV PrEP market is structured around two differentiated pharmacological segments. Cabotegravir Long-Acting PrEP is an integrase strand transfer inhibitor delivered through intramuscular injection, with maintenance dosing every two months after initiation. Its earlier regulatory commercialization gives it a comparatively established position in injectable PrEP service models. Lenacapavir Long-Acting PrEP represents the newer HIV-1 capsid inhibitor segment and uses subcutaneous administration with maintenance dosing every six months, introducing a

substantially longer injection interval and a differentiated mechanism of action.

From a product-structure perspective, competition is therefore moving beyond basic injectable versus oral differentiation. Intramuscular and subcutaneous administration, two-month and six-month intervals, and INSTI versus capsid-inhibitor mechanisms form distinct commercial positioning dimensions. Cabotegravir benefits from an earlier market-entry profile and accumulated implementation experience, while lenacapavir raises the benchmark for dosing duration. The relative development of these segments will increasingly depend on patient preference, provider workflow, reimbursement, persistence with scheduled visits and the ability of prevention programs to integrate each dosing model efficiently.

Downstream Market Opportunities

Downstream demand for Long-Acting HIV PrEP is concentrated in professionally managed HIV prevention settings rather than conventional retail drug channels. HIV specialty clinics and sexual-health clinics are natural early-adoption environments because testing, risk assessment, counseling and injection administration can be integrated within established workflows. Community health centers and public-health PrEP programs represent a broader expansion opportunity as testing and preventive services become more decentralized. The commercial opportunity is particularly significant where providers can identify individuals with substantial HIV exposure risk but low persistence with frequently dosed prevention. Future market expansion will therefore depend on converting long dosing intervals into practical improvements in retention, convenience and continuity of prevention services rather than relying solely on pharmacological differentiation.

Regional Insights

North America currently represents the most mature commercialization environment within the Long-Acting HIV PrEP market, reflecting earlier regulatory introduction of cabotegravir and subsequent launch of twice-yearly lenacapavir in the United States. Europe has also developed a broader long-acting PrEP portfolio following regulatory authorization of cabotegravir and later lenacapavir, providing a second major regulated market for competing long-duration injection strategies. These markets benefit from comparatively established HIV testing networks, specialty care infrastructure and reimbursement mechanisms, although access can still vary by healthcare system.

In other regions, market development is more closely tied to national HIV prevention

policies, public procurement, donor-supported programs, regulatory timelines and healthcare-delivery capacity. WHO recommendations for both cabotegravir and lenacapavir create an important policy foundation for broader adoption, particularly in markets with high unmet prevention needs. However, commercial maturity is likely to remain uneven because clinical availability does not automatically translate into funded and scalable access. For manufacturers, regional expansion will increasingly require differentiated pricing, public-health partnerships and service-delivery models adapted to local testing and follow-up capacity.

Competitive Landscape Analysis

The confirmed commercial landscape of Long-Acting HIV PrEP is highly concentrated around ViiV Healthcare and Gilead Sciences, but their competitive positioning is differentiated rather than directly homogeneous. ViiV Healthcare established the earlier long-acting injectable PrEP model through cabotegravir, building its position around an intramuscular regimen with maintenance injections every two months. Gilead Sciences subsequently entered the market with lenacapavir and differentiated its offering through a novel HIV-1 capsid mechanism and twice-yearly subcutaneous dosing. As a result, competition is increasingly centered on dosing interval, route of administration, implementation convenience, clinical confidence and access rather than price alone. ViiV's earlier commercialization supports accumulated provider familiarity, whereas Gilead's six-month dosing interval creates a strong product-level differentiation point. Future competitive outcomes will depend on how effectively each company converts these pharmacological and dosing characteristics into sustained patient uptake, reimbursement coverage and integration into national and community-based HIV prevention programs.

Report Scope

LPI (LP Information)' newest research report, the "Long-Acting HIV PrEP Industry Forecast" looks at past sales and reviews total world Long-Acting HIV PrEP sales in 2025, providing a comprehensive analysis by region and market sector of projected Long-Acting HIV PrEP sales for 2026 through 2032. With Long-Acting HIV PrEP sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US\$ millions of the world Long-Acting HIV PrEP industry.

This Insight Report provides a comprehensive analysis of the global Long-Acting HIV PrEP landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report

also analyses the strategies of leading global companies with a focus on Long-Acting HIV PrEP portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms' unique position in an accelerating global Long-Acting HIV PrEP market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Long-Acting HIV PrEP and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Long-Acting HIV PrEP.

This report presents a comprehensive overview, market shares, and growth opportunities of Long-Acting HIV PrEP market by product type, application, key players and key regions and countries.

Market Segmentation

Segmentation by Type:

Cabotegravir Long-Acting PrEP

Lenacapavir Long-Acting PrEP

Segmentation by Route of Administration:

Intramuscular Injectable PrEP

Subcutaneous Injectable PrEP

Segmentation by Time of Administration:

Every 2 Months

Every 6 Months

Segmentation by Application:

Hospitals and HIV Specialty Clinics

Sexual Health Clinics

Public Health PrEP Programs

This report also splits the market by region:

Americas

United States

Canada

Mexico

Brazil

APAC

China

Japan

Korea

Southeast Asia

India

Australia

Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

Gilead Sciences

GSK

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