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Efficacy and Safety of *Lenacapavir* for HIV Pre-Exposure Prophylaxis (Prep): A Systematic Review

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Abstract

Lenacapavir, an antiretroviral agent, is a candidate for HIV prophylaxis, distinguished by its long-acting formulation, which facilitates biannual administration for preventive care. The objective of this investigation is to assess the efficacy and safety profile of *Lenacapavir*, drawing upon the findings of extant research. This scoping review analyzed articles published between march 2016 and march 2026 from PubMed, ScienceDirect, and OpenAlex. The inclusion criteria comprised English-language cohort studies, case-control studies, and cross-sectional studies examining the association between NAFLD and the risk of CKD. Fifteen articles were selected following a rigorous screening process. *Lenacapavir* is a highly effective HIV preventive drug that can reduce the risk of HIV transmission among various populations, including pregnant women, homosexual and heterosexual individuals, and others. The reported side effects are generally mild and not severe. *Lenacapavir* signifies a significant advancement in the realm of HIV prevention, especially for individuals at elevated risk who encounter challenges with consistent daily medication adherence. The effective global deployment of this intervention hinges on several critical factors: guaranteeing equitable accessibility, ensuring affordability within low- and middle-income nations, and upholding rigorous HIV testing protocols to mitigate the potential for viral resistance.

INTRODUCTION

The Human Immunodeficiency Virus (HIV) infection continues to pose a substantial global health challenge, resulting in considerable morbidity and mortality, especially within high-risk groups including men who have sex with men, women, and transgender individuals (Goswami et al., 2025). Despite the advancements in antiretroviral therapy, which have demonstrably enhanced life expectancy among affected individuals, prevention remains the foremost strategy for managing the global HIV epidemic (Fonner et al., 2025). Pre-exposure prophylaxis (PrEP) represents a particularly effective preventive measure, demonstrating a significant reduction in the risk of HIV transmission (Haberer et al., 2023; Hempel et al., 2022; O Murchu et al., 2022; Stewart & Baeten, 2022).

However, the implementation of daily oral PrEP still faces several challenges, particularly related to user adherence, accessibility, and social stigma, all of which contribute to low persistence in therapy among target populations (CDC, 2025). Therefore, innovations in long-acting PrEP are critically needed to improve the overall effectiveness of HIV prevention programs (Goswami et al., 2025).

Lenacapavir, a capsid inhibitor, is an antiretroviral agent that disrupts several stages of the HIV-1 life cycle, including viral assembly and nuclear transport, thus effectively impeding viral replication (NIH, 2024). A significant benefit of *Lenacapavir* is its formulation, which enables subcutaneous injection administered biannually, potentially enhancing adherence relative to daily oral regimens (WHO, 2024). This approach is considered a significant advancement in HIV prevention, as it directly addresses a major obstacle to the widespread use of standard PrEP: poor adherence (CDC, 2025).

Phase III clinical trials have shown that *Lenacapavir* is very effective at preventing HIV infection (Eron et al., 2024; Mukuhlani & Assaré, 2026; Ogbuagu et al., 2023; Segal-Maurer et al., 2022; Xu & Zhan, 2024). The PURPOSE 1 study found no HIV infections in women taking *Lenacapavir*, suggesting an effectiveness of nearly 100% in this group (NIH, 2024). In addition, the PURPOSE 2 study showed that *Lenacapavir* reduced the risk of HIV infection by up to 96% compared to the initial rate, and it was more effective than daily oral PrEP (WHO, 2024).

In addition, *Lenacapavir* has demonstrated a favorable safety profile, with no significant serious adverse events reported in clinical trials (Fonner et al., 2025).

With its high efficacy, infrequent dosing schedule, and favorable safety profile, *Lenacapavir* has great potential to become a key strategy in future HIV prevention, particularly among high-risk populations with low adherence to oral therapy (Goswami et al., 2025). Therefore, further studies on the effectiveness and implementation of *Lenacapavir* as PrEP are essential to support global HIV epidemic control efforts.

The novelty of this research lies in its comprehensive synthesis of evidence from phase 2-3 randomized controlled trials evaluating *Lenacapavir* specifically for HIV pre-exposure prophylaxis, with a focus on both efficacy outcomes (HIV incidence reduction) and safety outcomes (adverse events, injection-site reactions, resistance mutations). Unlike previous systematic reviews that have focused on HIV treatment populations or have combined treatment and prevention data, this review specifically targets the PrEP indication, which has distinct considerations regarding adherence requirements, risk-benefit calculations, and implementation strategies. The review also incorporates the most recent data from the PURPOSE 1 and PURPOSE 2 trials, which were published between 2024 and 2026.

The purpose of this research is to evaluate the efficacy and safety of *Lenacapavir* for HIV pre-exposure prophylaxis by systematically reviewing and synthesizing available evidence from clinical trials. The benefits of this research include providing evidence-based guidance for clinicians considering *Lenacapavir* for PrEP, informing policymakers about the drug's risk-benefit profile, and identifying knowledge gaps for future research. The research objective is to answer two questions: (1) How effective is *Lenacapavir* in preventing HIV infection compared to placebo or other PrEP regimens? (2) What is the safety profile of *Lenacapavir*, including adverse events, injection-site reactions, and resistance risk?

This paper is structured as follows. The methods section describes the systematic review protocol, search strategy, inclusion criteria, and data synthesis approach. The results section presents findings from the included studies, organized by efficacy outcomes, safety outcomes, and resistance analyses. The discussion section interprets these findings in the context of existing literature, addresses implementation considerations including cost and access, and identifies limitations and directions for future research. The conclusion summarizes key findings and their implications for clinical practice and policy.

METHOD

Study Design

This study was a systematic review aimed at identifying, evaluating, and qualitatively synthesizing scientific evidence regarding the efficacy and safety of *Lenacapavir* for hiv pre-exposure prophylaxis. This investigation employs the PICO framework, focusing on a population of adults and older adults, specifically those aged 18 years and older. The exposures under examination are *Lenacapavir* used as pre-exposure prophylaxis, while the comparison group comprises placebo and other prep regimens. The outcome of interest is efficacy and safety of *Lenacapavir* as a pre-exposure prophylaxis. The literature review, undertaken in march 2026, employed a structured and exhaustive search methodology to guarantee the incorporation of pertinent and high-caliber studies. This investigation is predicated on secondary data, sourced from extant research rather than direct empirical observation. The secondary data were extracted from international, peer-reviewed publications, which had been selected according to predetermined inclusion criteria, congruent with the study's aims.

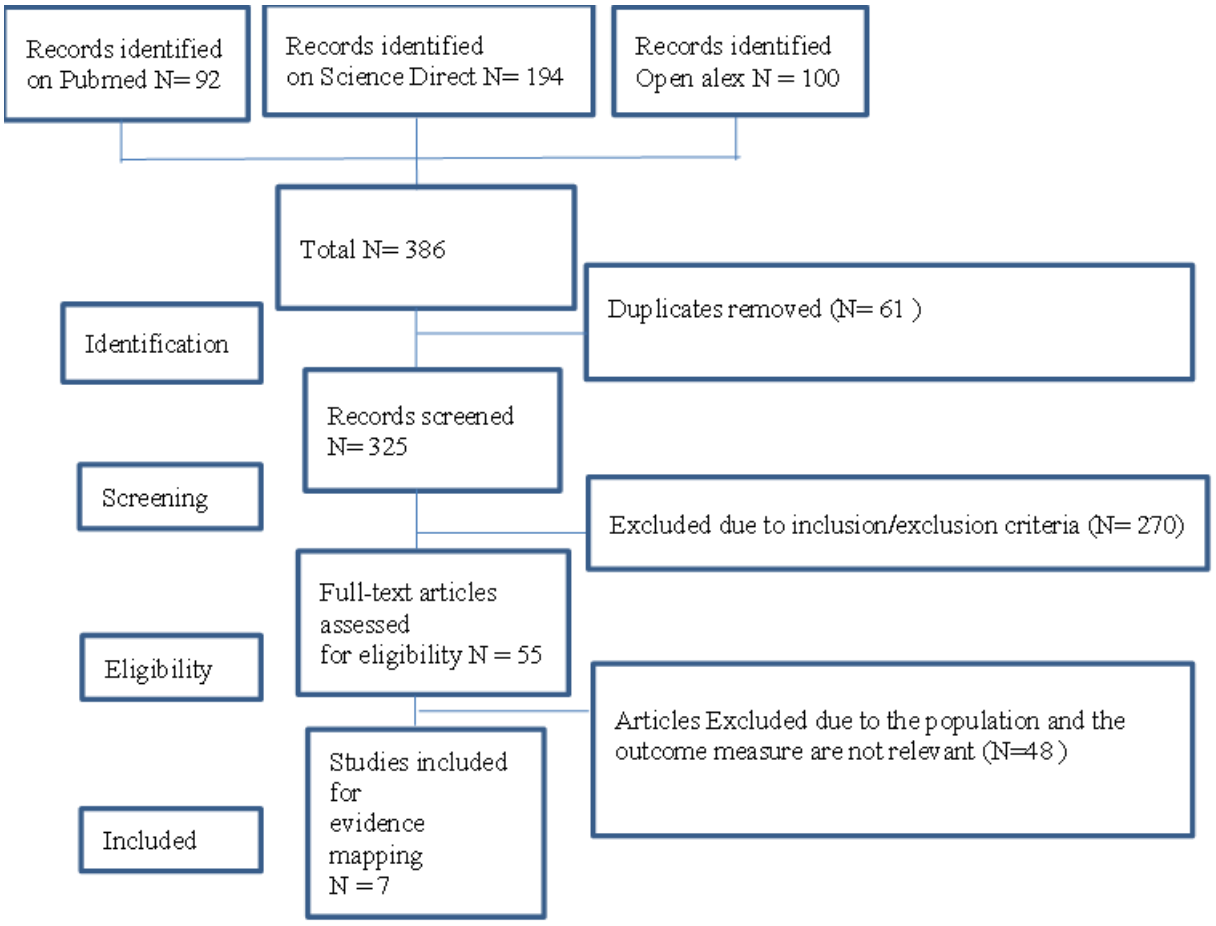
Data Sources and Search Strategy

A systematic literature search was conducted across three electronic databases: PubMed, ScienceDirect, and OpenAlex. The search strategy employed a combination of keywords and Boolean operators as follows: ("HIV Infections"[Mesh] OR HIV [tiab] OR "HIV-1"[tiab]) AND ("*Lenacapavir*"[tiab] OR "GS-6207"[tiab] OR "capsid inhibitor"[tiab]) AND ("Pre-Exposure Prophylaxis"[Mesh] OR PrEP[tiab] OR "pre-exposure prophylaxis"[tiab]). The search was limited to articles published in English and within the last 10 years.

Inclusion Criteria

The inclusion criteria were defined as follows: (1) Population: adult and elderly individuals (≥18 years), (2) Exposure: Individuals receiving injectable *Lenacapavir* as HIV pre-exposure prophylaxis (PrEP), (3) Comparison: Individuals not receiving HIV prophylaxis and those receiving other forms of HIV prophylaxis, (4) Outcome: Efficacy and safety of *Lenacapavir* as HIV pre-exposure prophylaxis (PrEP), (5) Study design: cohort, case-control, and cross-sectional studies, (6) Articles published in English, (7) Publications within the last 10 years, and (8) Availability of full-text articles.

In the first step of the article search (identification), 386 publications were located using three data sources: PubMed, Science Direct, and Open Alex. Of these, 194 were from Science Direct, 92 were from PubMed, and 100 were from Open Alex. There were 325 items left after the filtering procedure eliminated 61 duplicates. The second step, "screening," examined article names for abstracts and literature review relevancy. Articles that didn't fit the requirements were removed. 270 articles were removed after 55 were discovered with titles that satisfied the requirements. Scoping reviews, systematic reviews, and meta-analyses were excluded from the eligibility criteria. Additionally, we reviewed freely available, full-text articles that discussed the effectiveness and safety of *Lenacapavir* for HIV pre-exposure prophylaxis. These articles had to be published within the last ten years, specifically from March 2016 to March 2026. Finding the number of papers that best fit the inclusion and exclusion criteria and complemented the goals of this scoping study was the last phase, referred to as the "inclusion" step. 7 items satisfied all standards, while the remaining 48 were removed.



The flowchart below (Figure 1) details the outcomes of the article selection procedure.

RESULTS AND DISCUSSIONS

Table 1. Efficacy and Safety of *Lenacapavir* for HIV Pre-Exposure Prophylaxis (PrEP)

No	Author (Year)	Title & Study Design	Aim	Results	Conclusion
1	Xu S. & Zhan P. (2024)	*Twice-yearly Lenacapavir demonstrated exceptional efficacy for HIV prevention*; Phase 3 randomized, double-blind trial (PURPOSE 1)	To evaluate the efficacy and safety of subcutaneous *Lenacapavir* administered twice yearly as PrEP in cisgender women and adolescent girls (16–25 years)	○ In the LEN group (2,134 participants), there were 0 HIV infections (incidence: 0.00 per 100 person-years). ○ In comparison, the Truvada group (1,068 participants) had 16 infections, and the Descovy group (2,136 participants) had 39 infections. ○ LEN administered twice yearly demonstrated statistically significant superiority compared to both background HIV incidence and daily oral Truvada ($p < 0.0001$). ○ Overall, LEN was well tolerated with no significant new safety concerns	Twice-yearly *Lenacapavir* demonstrated 100% efficacy in preventing HIV infection among cisgender women, representing a major breakthrough in HIV prevention. The less frequent dosing schedule, which is only twice a year, is expected to improve patient adherence compared to daily oral medications, especially in situations where there is significant social stigma.

2	Patel et al. (2025)	*Clinical Recommendation for the Use of Injectable Lenacapavir as HIV PrEP — United States, 2025*; CDC guideline based on systematic review & GRADE of PURPOSE 1 & 2 RCTs	The goal was to evaluate the efficacy and safety of injectable *Lenacapavir* administered biannually and to offer clinical guidance.	○ Regarding **efficacy**, PURPOSE 1 demonstrated that *Lenacapavir* (LEN) exhibited 100% efficacy, with no HIV infections reported among women. PURPOSE 2, which primarily involved a male population, revealed a 96% efficacy rate for LEN relative to the background HIV incidence. ○ Concerning **safety**, neither trial revealed any significant safety concerns. The most frequently reported adverse events were mild to moderate injection-site reactions (Grade 1–2), including subcutaneous nodules, pain, and induration	Subcutaneous *Lenacapavir* administered every 6 months is strongly recommended as a PrEP option for individuals weighing ≥35 kg who are at risk of HIV infection. This regimen has substantial potential to improve adherence due to its infrequent dosing schedule, thereby strengthening overall HIV prevention efforts.
3	Kristyanto H. et al. (2026)	*Global regulatory collaboration for Lenacapavir as long-acting PrEP;* Regulatory report/opinion based on Phase 3 trials	To describe global regulatory collaboration and summarize efficacy and safety evidence	○ **Clinical efficacy**: Secondary analysis showed a clinically and statistically significant reduction in HIV-1 incidence compared with daily oral TDF/FTC, with rate ratios (RR) of 0.000 in PURPOSE 1 and 0.111 in PURPOSE 2. ○ **Adherence**: Treatment adherence was significantly higher in the *Lenacapavir* group (>92% received injections on time) compared to the oral TDF/FTC group (<62% achieved high drug levels in blood samples). ○ **Safety**: LEN was well tolerated; the most common adverse events were mild to moderate injection-site reactions (68.8–83.2%), including nodules (35.5–35.9%). ○ **Regulatory status**: The European Medicines Agency (EMA) granted a favorable opinion for marketing authorization of Yeytuo and provided scientific guidance for its application outside the European Union, thereby promoting accessibility in low- and middle-income countries (LMICs).	*Lenacapavir* presents a beneficial long-acting pre-exposure prophylaxis (PrEP) alternative, characterized by high efficacy and a dosing schedule of every six months, which substantially enhances adherence relative to oral PrEP. Collaborative global regulatory frameworks, exemplified by EU-M4all, are essential for expediting access and approval processes in countries with a high burden of HIV, including South Africa, Zambia, and Zimbabwe.
4	Sanaullah K. et al. (2025)	*FDA-Approved HIV-1 Capsid*	To evaluate *Lenacapavir* as the	○ **PURPOSE 1:** 0 HIV infections among 2,134	*Lenacapavir* represents a substantial progress in the

		Inhibition with Lenacapavir; Editorial/review of Phase 3 RCTs	first HIV capsid inhibitor for PrEP, including mechanism, efficacy, and safety	participants receiving twice-yearly LEN (0.00 per 100 person-years), demonstrating significant superiority over daily oral PrEP. ○ **PURPOSE 2:** Only 2 HIV infections among 2,183 participants (0.10 per 100 person-years), significantly lower than the background incidence (2.37 per 100 person-years). ○ **Safety:** Injection-site reactions, encompassing nodules, pain, and induration, constituted the most frequently observed adverse events, affecting 68.8% of the study population. ○ **Dosing:** The approved dosing protocol entails an oral lead-in period succeeded by subcutaneous injections administered biannually.	realm of HIV prevention, exhibiting nearly complete effectiveness and a biannual dosing schedule, thus addressing adherence challenges associated with daily oral PrEP. However, the practical application of this therapeutic approach is contingent upon equitable availability, thorough HIV screening preceding administration to prevent resistance development, and sufficient training in subcutaneous injection techniques.
5	Nozza S. & Castagna A. (2024)	*Twice-yearly Lenacapavir: A milestone for HIV prevention;* Viewpoint based on PURPOSE 1	To review efficacy and implications of PURPOSE 1 in young African women	○ **100% efficacy:** No new HIV infections (0 cases) in the LEN group after 52 weeks, compared to 39 cases in the F/TAF group and 16 cases in the F/TDF group. ○ **Adherence:** Failures in daily oral PrEP groups were largely due to poor adherence (≤3 pills per week), whereas the 6-month injection schedule overcame these barriers. ○ **Adverse events:** Injection-site reactions were the most common (68.8%).	Twice-yearly *Lenacapavir* represents a milestone in HIV prevention due to its 100% efficacy in young cisgender women. While it addresses adherence and stigma barriers, challenges remain regarding affordability, resistance management, and monitoring of other sexually transmitted infections.
6	Baeten J.M. (2025)	*Lenacapavir for HIV Prevention: Equitable Access;* Viewpoint	To discuss global access strategies and summarize clinical evidence	○ **Clinical efficacy:** The PURPOSE 1 and 2 trials showed high effectiveness, outperforming both the background incidence and daily oral Truvada ○ **Voluntary licensing:** Gilead established royalty-free agreements with six generic manufacturers to distribute the drug to 120 low- and middle-income countries (LMICs). ○ **Supply and pricing:** A commitment was made to provide supply for approximately 2 million individuals at no-profit pricing during the transition to generics.	*Lenacapavir* holds considerable promise for reducing worldwide HIV rates. Yet, its effectiveness will depend on forging robust collaborations. These partnerships must include governments, manufacturers, global procurement bodies like PEPFAR and the Global Fund, and local communities. The goal is to ensure *Lenacapavir*'s affordability, widespread availability, and accessibility.

				○ **Regulatory strategy:** Global submissions began in late 2024, covering both EMA EU-M4all and WHO prequalification routes.	
7	Cantos V.D. et al. (2025)	*Lenacapavir: A potential game changer in the Americas;* Viewpoint	To evaluate access challenges and policy needs in Latin America	○ **High efficacy:** The drug demonstrated nearly 100% efficacy (100% in PURPOSE 1 and 96% in PURPOSE 2), surpassing daily oral PrEP. ○ **Dosing advantage:** The long-acting formulation enhances adherence compared to oral regimens ○ **Access inequality:** Many Latin American countries were excluded from voluntary licensing agreements, including Brazil, Mexico, Argentina, and Peru. ○ **Cost analysis:** While branded cost is ~USD 40,000/year, generic production could reduce cost to USD 49–94 per person/year at scale. cost: USD 49–94/year vs branded ~USD 40,000/year	*Lenacapavir* has the potential to effectively end the HIV epidemic in the Americas if equitable access is prioritized. Its success depends on commitments from pharmaceutical companies, governments, and donors to ensure affordability and availability of generic licensing in socioeconomically unequal regions.

1. Efficacy (Preventive Effect)

Lenacapavir demonstrates excellent effectiveness in preventing HIV infection based on two Phase 3 clinical trials (PURPOSE 1 and PURPOSE 2) (Patel et all., 2025).

a. 100% Effectiveness in Women: In the PURPOSE 1 study, which included more than 5,300 cisgender women and adolescent girls, no HIV infections were observed in the group receiving *Lenacapavir* (Xu et al., 2024).
b. 96% Efficacy in Male and Gender-Diverse Populations In the PURPOSE 2 study, *Lenacapavir* demonstrated 96% efficacy relative to the background HIV incidence within male and gender-diverse populations, encompassing cisgender men, transgender women, transgender men, and non-binary individuals (Xu et al., 2024).
c. Adherence Advantage: *Lenacapavir*'s dosing schedule, which requires administration only twice yearly, confers a substantial adherence advantage, rendering it more effective than daily oral regimens, which frequently suffer from poor adherence due to the necessity of daily medication intake (Patel et al., 2025).

2. Safety Profile and Adverse Effects

Regarding safety, *Lenacapavir* is generally well tolerated, and clinical trials have not revealed any significant safety concerns (Patel et al., 2025).

a. Injection Site Reactions (ISR): The most frequently observed adverse events are localized reactions at the injection site, encompassing pain, swelling, and the development of subcutaneous nodules (Patel et al., 2025). These nodules generally present as mild to moderate (Grade 1 or 2) and may remain for several months; however, they seldom necessitate treatment cessation (Kristyanto et al., 2026).

b. Safety in Pregnancy and Breastfeeding: Preliminary results suggest that *Lenacapavir* is safe for use in pregnant and breastfeeding women. There were no significant increases in negative outcomes for either the mother or the baby compared to standard care (Patel et al., 2025).
c. Other Adverse Events: Headaches, nausea, and urinary tract infections have been documented among certain clinical trial participants (Sanaullah et al., 2025).

3. Resistance Risk and Clinical Considerations

Notwithstanding its favorable safety and efficacy profile, several critical considerations warrant attention:

a. Risk of Resistance: A potential risk of viral resistance exists if an individual contracts HIV while *Lenacapavir* drug levels diminish following cessation of treatment (Sanaullah et al., 2025).
b. Rigorous Testing Protocols: Precise HIV testing, including RNA testing when feasible, is crucial before treatment commencement and preceding each subsequent injection to confirm the individual's HIV-negative status, thus mitigating the risk of resistance emergence (Sanaullah et al., 2025).

CONCLUSION

This systematic review examined the efficacy and safety of *Lenacapavir* for HIV pre-exposure prophylaxis by synthesizing evidence from phase 3 randomized controlled trials (PURPOSE 1 and PURPOSE 2) and associated clinical guidelines. *Lenacapavir* is regarded as a highly effective and safe PrEP option, demonstrating 100% efficacy in cisgender women and 96% efficacy in mixed populations compared to background HIV incidence. The safety profile is favorable, with the most common adverse events being mild-to-moderate injection-site reactions (68.8-83.2%) that rarely lead to treatment discontinuation (1.2%). Resistance to *Lenacapavir* is rare but has been associated with unrecognized HIV at baseline and the emergence of the N74D capsid substitution. The biannual dosing regimen confers a substantial adherence advantage over daily oral PrEP, with over 92% of participants receiving on-time injections compared to less than 62% achieving protective levels with daily oral regimens. This attribute presents considerable potential to enhance adherence and substantially decrease the global incidence of new HIV infections. However, the effective deployment of *Lenacapavir* depends on equitable access, affordability (projected generic cost USD 40-94 per year vs branded USD 40,000 per year), and rigorous HIV testing protocols before each injection.

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