



PURPOSE

Prevention with PURPOSE



AIDS 2026
26–31 July

Endorsement and Anticipated Challenges to Adopting Twice-Yearly Lenacapavir for HIV Pre-exposure Prophylaxis (PrEP) Among Cisgender Men Who Have Sex With Men (MSM): Qualitative Insights From the PURPOSE 2 Trial

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Acknowledgments and Presenter Disclosures

Acknowledgments

The research team expresses immense gratitude for PURPOSE 2 trial participants' openness and willingness to share their perspectives and lived experiences

Disclosures

- Steven Meanley has no conflicts of interest to disclose
- Gilead Sciences, Inc. funded and designed the study with input from the PI and the Global Community Advisory and Accountability Group. The PIs and study staff gathered data; Gilead Sciences monitored the conduct of the trial, received the data, and performed analyses
- Medical writing support was provided by Tom Williams, PhD (Aspire Scientific Ltd, UK), and was funded by Gilead Sciences, Inc.



Summary

What are your main questions?

- What were the experiences with, and acceptability of, SC LEN among a racially and ethnically diverse sample of adult cisgender gay, bisexual, and other men who have sex with men from PURPOSE 2 across US clinical sites?

What did you find?

- Among participants who took part in interviews, there was a consistent preference for twice-yearly LEN injections versus daily oral PrEP due to the peace of mind it offers, reduced pill burden, and its protection window
- Participants expressed concerns over potential costs and lack of insurance coverage. The perceived benefits of a twice-yearly injection outweighed concerns around side effects, including injection site pain

Why is it important?

- The experiences of participants from this study highlight LEN's potential to support gay, bisexual, and other men who have sex with men, and improve PrEP uptake in these populations

PURPOSE 2 Demonstrated the Efficacy and Safety of Twice-Yearly SC LEN for PrEP Across Diverse Populations, Including Gay, Bisexual, and Other Men Who Have Sex With Men¹



Acquisition of HIV among gay, bisexual, and other men who have sex with men remains high due to gaps in PrEP use and persistence, particularly among Black and Latino men²⁻⁴



LAI PrEP can address many barriers to PrEP persistence (eg, daily pill burden, stigma)⁵ and, as new PrEP modalities emerge, it is critical to understand how they will be received by people who could benefit from them and what factors may shape equitable access and real-world use



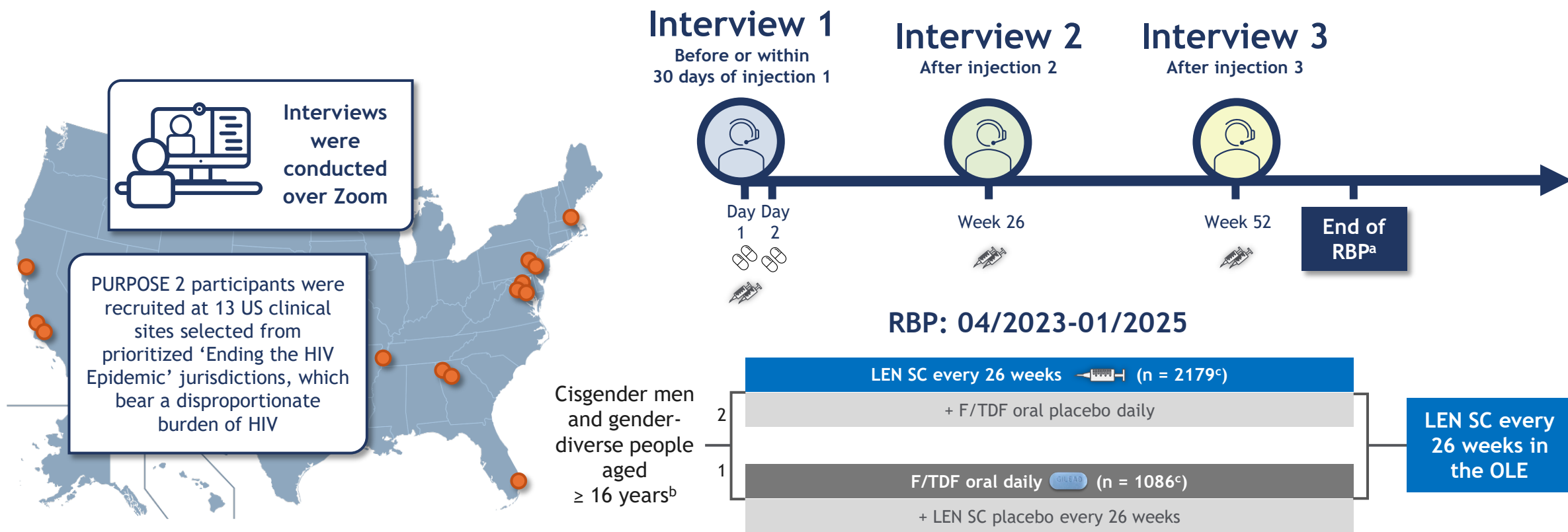
An ancillary **qualitative study** during the PURPOSE 2 trial provided perspectives directly from US participants who come from the communities disproportionately affected by HIV and not benefiting from oral PrEP

This qualitative study explored the acceptability of LEN among a racially and ethnically diverse sample of men during the randomized blinded phase (RBP) of PURPOSE 2 at US clinical sites

LAI, long-acting injectable; LEN, lenacapavir; PrEP, pre-exposure prophylaxis; RBP, randomized blinded phase; SC, subcutaneous.

1. Kelley CF, et al. *N Engl J Med*. 2025;392:1261-76. 2. HIV.gov. <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics> (accessed July 02, 2026). 3. CDC.gov <https://www.cdc.gov/hiv/data-research/facts-stats/gay-bisexual-men.html> (accessed July 10, 2026). 4. Chapin-Bardales J, et al. *J Acquir Immune Defic Syndr*. 2023; 93(1):34-41. 5. Keddem S, et al. *J Acquir Immune Defic Syndr*. 2024;95:370-6.

PURPOSE 2 Serial Qualitative Interview Design



- **Interview topics:** Included attitudes toward and experiences with twice-yearly injection, comparisons with daily oral and bimonthly LAI PrEP, and anticipated challenges taking LEN post-trial
- **Codebook thematic analysis:** Transcripts analyzed cumulatively

ClinicalTrials.gov: NCT04925752

^aParticipants who declined LEN OLE were offered up to 78 weeks of open-label F/TDF if they were on blinded LEN in the RBP. ^bCisgender men and gender-diverse people aged ≥ 16 years who have sex with men and are at risk of HIV acquisition.

^cIncluded in the full analysis set for primary efficacy analyses (additional participants are included in the safety analysis).

F/TDF, emtricitabine/tenofovir disoproxil fumarate; LAI, long-acting injectable; LEN, lenacapavir; OLE, open-label extension; RBP, randomized blinded phase; SC, subcutaneous.

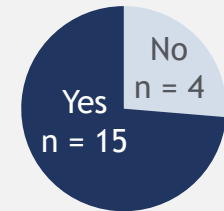
Participants Interviewed During the RBP Were Racially and Ethnically Diverse, and Many Had Prior PrEP Experience



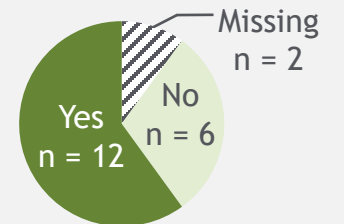
	Interview 1 (N = 19)	Interview 2 (N = 20)	Interview 3 (N = 19)
Age, years, median (IQR)	36 (19-57)	31 (19-57)	31 (19-57)
Race and ethnicity, n (%)			
Non-Hispanic Black	9 (47)	10 (50)	10 (53)
Non-Hispanic White	2 (11)	1 (5)	1 (5)
Hispanic, all races	8 (42)	8 (40)	7 (37)
Non-Hispanic Other	0	1 (5)	1 (5)
Sexual orientation, n (%) ^a			
Gay	15 (79)	14 (70)	13 (68)
Bisexual	3 (16)	5 (25)	5 (26)

Pre-PURPOSE 2 Oral PrEP Use^b

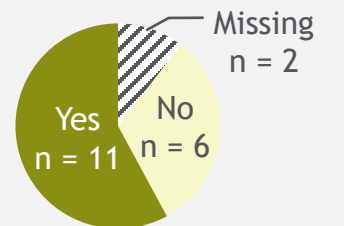
Interview 1
(N = 19)



Interview 2
(N = 20)



Interview 3
(N = 19)



Condomless receptive anal sex with partners assigned male at birth was a key eligibility criterion for cisgender men, transgender women, transgender men, and gender nonbinary people enrolling in PURPOSE 2.

^aAt each interview, there was one participant (5%) who had a sexual orientation categorized as 'Other'. ^bPeople with prior use of cabotegravir were not allowed to enroll in PURPOSE 2.

Participants Consistently Preferred LEN



Interview Topics

1. Experiences in PURPOSE 2 trial
2. Attitudes toward and experiences with twice-yearly injection
3. Comparisons with daily oral and bimonthly LAI PrEP
4. Anticipated challenges taking LEN post-trial
5. Social network discussions and perceptions



Results: Themes and Patterns

Perceived benefits

- Eliminating daily pills
- 6-month window of protection
- Increased confidence
- Peace of mind
- Discreetness



Common side effects

- Injection site nodules
- Injection site pain
- Injection site burning sensation



Recommending LEN to peers

- Convenience
- Duration of protection
- Community safety
- Effectiveness



Anticipated challenges to LEN adoption

- Fear of needles
- Fear of side effects
- Cost/insurance coverage
- Accessibility/logistics
- Stigma
- Misinformation



Feelings Toward and Experiences With LEN Were Generally Positive



Peace of mind



Reduced pill burden



Demonstrated efficacy



“

*There is a, I get up and go about your day version of PrEP and there is a stop and remember to take your pill version of PrEP and I would say that most people would just rather get up and go ... this hasn't been my first rodeo with PrEP, on and off with PrEP probably for six, seven years ... I think there is some fatigue that sets in with popping the pill every day and so, **of course I would recommend the injectable over the daily.***

Non-Hispanic Black participant, age 35-44, at Interview 3

“

The injectable is something that I don't think about after it's done, it's kind of an invisible bullet proof vest in a sense ... with the daily PrEP, it's something that I do have to think about daily, and it is somewhat of a reminder too of the virus and the risk.

”

Non-Hispanic Black participant, age 25-34, at Interview 2

“

*Yeah something that would motivate them to take [is that] **it's been so tested and the results have been like basically 100% positive** ...*

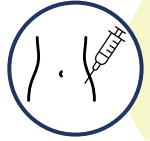
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Non-Hispanic Black participant, age 25-34, at Interview 3

The Perceived Benefits of LEN Outweighed Concerns About Injections



Injection site pain/
burning sensation



Injection site nodules



Cost/insurance coverage



“*The nodules actually went down which was my deepest concern. If they hadn’t gone down, then I probably would not have gone through with the second injection. But they are now pretty undetectable and when I stretch backwards or any way, I don’t feel them anymore. And so yea, I think any concern I had is now gone, and it’s better now.*”

Non-Hispanic Black participant, age 25-34, at Interview 2

“*I think the injectable will eventually have a higher adherence of folks utilizing it. I think that it’s a better option for folks who [have] busy lifestyles and don’t wanna take a daily pill so I think that the benefits outweigh the momentary pain of the injection.*”

Non-Hispanic Black participant, age 35-44, at Interview 2

“*Like if you’re willing to deal with that burn twice a year, it’s definitely worth it because, you know, you’re being protected from- from HIV. That’s good for both your own personal health and for public health to be on PrEP. I would recommend it.*”

Non-Hispanic Black participant, age 25-34, at Interview 1

“*I think the only [barrier] would be the financial ... if insurance covers it, I would definitely use [LEN] ... But if not, I will just take the pills, and it’s gonna be fine.*”

Hispanic White participant, age 25-34, at Interview 2

The Perceived Benefits of LEN Position it as the Preferred PrEP Option Across Diverse Populations, Including Gay, Bisexual, and Other Men Who Have Sex With Men



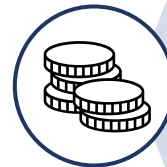
In this ancillary qualitative study, **twice-yearly SC LEN was highly preferred for HIV prevention** and was consistently favored over daily oral PrEP.

Perceived benefits of LEN included:

- **Peace of mind** (reduced need to think about HIV prevention)
- **Reduced burden** (no need to remember to take pills)
- **Demonstrated efficacy** of LEN



Protection over a 6-month window outweighed concerns over injection site pain



Pre-approval concerns over out-of-pocket cost and insurance coverage highlight the **importance of a robust access strategy for LEN for PrEP**

Participants' preference for twice-yearly SC LEN, including its demonstrated high efficacy and long-acting protection, suggests that PrEP uptake could be improved in communities with historically low PrEP uptake

A Growing PURPOSE Portfolio



#preventionwithpurpose

#accesswithpurpose

PURPOSE 1: NCT04994509; PURPOSE 2: NCT04925752; PURPOSE 3: NCT06101329; PURPOSE 4: NCT06101342; PURPOSE 5: NCT06513312; PURPOSE 365: NCT07047716.

LEN, tenacapavir; PrEP, pre-exposure prophylaxis.

PURPOSE studies. <https://www.purposestudies.com> (accessed July 24, 2026).

QR Code

To download this presentation, the infographic summary, other Gilead Lenacapavir for PrEP presentations, and consult the Gilead access strategy for Lenacapavir for PrEP in Low and Middle-Income Countries, scan the QR code^a



Qualitative findings from interviews with transgender and gender-diverse participants from the PURPOSE 2 study will be presented at the Poster Session (Thursday, July 30, 2026)