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Yeztugo® (lenacapavir) Injection Site Reactions

This document is in response to your request for information regarding Yeztugo® (lenacapavir [LEN]) and injection site reactions (ISRs). This response was developed according to principles of evidence-based medicine and contains data from phase 3 clinical trials.

The use of FTC/TAF for prevention of HIV-1 in individuals at risk of HIV-1 from receptive vaginal sex is investigational and has not been approved by any regulatory authority.

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Summary

Product Labeling[1]

- The most frequent adverse reactions associated with LEN injection for SUBQ use in PURPOSE 1 and PURPOSE 2 were ISRs.
- In PURPOSE 1, 69% of participants receiving LEN experienced ISRs, compared to 35% receiving placebo injections (and FTC/TAF or FTC/TDF). Most participants who received LEN had mild (Grade 1, 50%) or moderate (Grade 2, 19%) severity ISRs.
- In PURPOSE 2, 83% of participants receiving LEN experienced ISRs, compared to 69% receiving placebo injections (and FTC/TDF). Most participants had mild (Grade 1, 66%) or moderate (Grade 2, 17%) severity ISRs.
- Injection site nodule was reported in 64% (PURPOSE 1) and 63% (PURPOSE 2) of participants who received LEN and resolved more slowly than other ISRs.

Clinical Data on SUBQ LEN and ISRs

In the ongoing phase 3 PURPOSE 1 study comparing the safety and efficacy of twice-yearly SUBQ LEN (n=2138) with those of daily oral FTC/TAF (n=2137) or FTC/TDF (n=1070) as HIV PrEP in CGW, reports of ISRs are as follows[2]:

- At the primary analysis, ISRs occurred in 68.8% of participants with LEN, 35.3% with FTC/TAF, and 33.9% with FTC/TDF. Most ISRs were Grade 1 or 2 in severity, and the most frequently reported ISRs were injection site nodules, injection site pain, and swelling. The frequency of ISRs decreased over time, and 4 ISRs (0.2%) led to LEN discontinuation (nodules, n=4, including 1 participant with nodules and pain).[2]
- Through the end of the RBP, no new discontinuations due to ISRs occurred, and the incidence and severity of ISRs were generally similar to those in the primary analysis.[3]

- Through OLE Week 52, the incidence and severity of ISRs were similar between the continuous LEN and LEN switch groups, and the most frequently reported ISRs were injection site nodule and pain.[4]

In the ongoing phase 3 PURPOSE 2 study comparing the safety and efficacy of twice-yearly SUBQ LEN (n=2179) with those of daily oral FTC/TDF (n=1086) as HIV PrEP in CGM, TGW, TGM, and GNB individuals, reports of ISRs are as follows[5]:

- At the primary analysis, ISRs occurred in 83.2% with LEN and in 69.5% with FTC/TDF. Most ISRs were mild to moderate in severity, and the most frequently reported ISRs were injection site nodules, pain, and erythema. The frequency of ISRs decreased over time, and 26 ISRs (1.2%) led to LEN discontinuation.[5]
- Through the end of the RBP, no new discontinuations due to ISRs occurred, and the incidence and severity of ISRs were generally similar to those in the primary analysis.[6]
- Through OLE Week 52, the incidence and severity of ISRs were similar between the continuous LEN and LEN switch groups, and the most frequently reported ISRs were injection site nodule and pain.[7]

In an analysis of ISRs in PURPOSE 1 and PURPOSE 2 by LEN SUBQ injection site location, a smaller proportion of participants had AEs of injection site nodules and pain with LEN administration in non-abdominal sites than in the abdomen; however, there were fewer participants who received injections in the thigh, upper arm, and upper buttocks than abdominal injections in both studies.[8]

- Injection site nodules and indurations generally resolved more quickly when LEN was administered in non-abdominal sites than in the abdomen, although there was longer follow-up for abdominal injections administered during the RBP.
- LEN administration in the thigh, upper arm, or upper buttocks was generally well tolerated, with no serious ISRs or ISRs that led to discontinuation.

Product Labeling[1]

Adverse Reactions

Clinical trials experience

Injection-associated adverse reactions: local ISRs

The most frequent adverse reactions associated with LEN SUBQ injection use in PURPOSE 1 and PURPOSE 2 were ISRs. The most common ISRs (all grades) in ≥2% of participants who received LEN in either PURPOSE 1 or PURPOSE 2 are presented in Table 1.

Table 1. ISRs (All Grades) Reported in ≥2%[a] of Participants Receiving LEN in PURPOSE 1 or PURPOSE 2[1]

ISRs	PURPOSE 1		PURPOSE 2	
	LEN (N=2140)	FTC/TAF or FTC/TDF[b] (N=3205)	LEN (N=2183)	FTC/TDF[b] (N=1088)
Nodule	64%	17%	63%	39%
Pain	31%	24%	56%	53%

ISRs	PURPOSE 1		PURPOSE 2	
	LEN (N=2140)	FTC/TAF or FTC/TDF[b] (N=3205)	LEN (N=2183)	FTC/TDF[b] (N=1088)
Induration	4%	<1%	16%	10%
Swelling	4%	5%	7%	10%
Pruritus	2%	1%	3%	3%
Erythema	1%	1%	17%	19%
Bruising	<1%	<1%	3%	4%
Warmth	<1%	<1%	2%	2%

[a]Frequencies are based on all ISRs attributed to study drug (or to the procedure) by the investigator.
[b]Participants received placebo SUBQ injections (polyethylene glycol 400).

PURPOSE 1

In PURPOSE 1, 69% of participants receiving LEN experienced ISRs, compared to 35% of participants receiving placebo injections (and FTC/TAF or FTC/TDF). Most participants who received LEN had mild (Grade 1, 50%) or moderate (Grade 2, 19%) severity ISRs. Grade 3 ISRs were reported in 4 (0.2%) participants, and included ulcer and nodule. LEN was discontinued due to ISRs in 4 (0.2%) participants. None of the ISRs were serious. The incidence of ISRs decreased with subsequent injections.

Nodules: Injection site nodule was reported in 64% of participants who received LEN and resolved more slowly than other ISRs. The median duration of nodule associated with the first injections of LEN was 350 (IQR: 182–470) days. The median of the maximum observed nodule diameter from each participant was 3 (IQR: 2–3.5) cm.

Other ISRs: The other ISRs reported in >2% of participants who received LEN were pain (31%), swelling (4%), induration (4%), and pruritus (2%). The median duration of induration, which resolved more slowly than most ISRs, was 173 (IQR: 22–267) days. The median duration of ISRs, excluding nodules and indurations, was 9 (IQR: 4–30) days.

PURPOSE 2

In PURPOSE 2, 83% of participants receiving LEN experienced ISRs, compared to 69% of participants receiving placebo injections (and FTC/TDF). Most participants had mild (Grade 1, 66%) or moderate (Grade 2, 17%) severity ISRs. Grade 3 ISRs were reported in 14 (0.6%) participants, and included ulcer, pain, erythema, edema, and dermatitis. LEN was discontinued due to ISRs in 26 (1.2%) participants. None of the ISRs were serious. The incidence of reported ISRs decreased with subsequent injections.

Nodules: Injection site nodule was reported in 63% of participants who received LEN and resolved more slowly than other ISRs. The median duration of nodules associated with the first injections of LEN was 297 (IQR: 176–423) days. The median of the maximum observed nodule diameter for each participant was 3 (IQR: 2–4) cm.

Other ISRs: The other ISRs reported in >2% of participants who received LEN were pain (56%), erythema (17%), induration (16%), swelling (7%), bruising (3%), pruritus (3%), and warmth (2%). The median duration of induration, which resolved more slowly than most other ISRs, was 151 (IQR: 15–267) days. The median duration of ISRs, excluding nodules and indurations, was 4 (IQR: 2–8) days.

Clinical Data on SUBQ LEN and ISRs

PURPOSE 1: LEN for PrEP in CGW

Study design[2]

PURPOSE 1 (NCT04994509) is an ongoing phase 3, double-blind, randomized clinical study designed to evaluate twice-yearly LEN SUBQ (n=2138) versus daily oral FTC/TAF (n=2137) or daily oral FTC/TDF (n=1070) for prevention of HIV in CGW. Adolescent girls and women (aged 16–25 years), not previously on PrEP and HIV-negative, were randomized in a 2:2:1 ratio to each cohort.

ISRs

Primary analysis

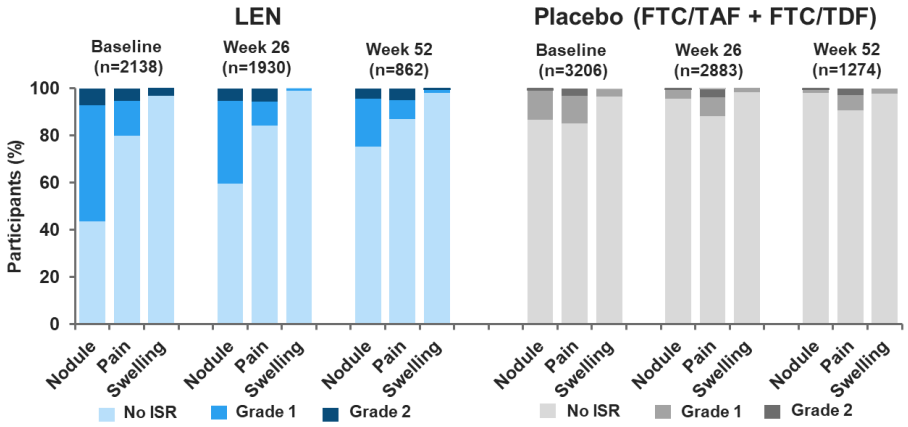
Overall, the most common AEs were ISRs. A total of 25,329 injections were administered, with 10,154 administered to 2138 participants in the LEN group and 15,175 administered to 3206 participants receiving placebo injection in the FTC/TAF and FTC/TDF groups. ISRs were reported by 68.8% of participants in the LEN group, 35.3% in the FTC/TAF group and 33.9% in the FTC/TDF group (Table 2); most ISRs were Grade 1 or Grade 2 in severity, and no serious ISRs were reported. The most common ISRs were SUBQ nodules, pain, and swelling, which occurred in 63.8%, 31.2%, and 4.4% of LEN participants, respectively, and in 16.6%, 23.7%, and 5.4% of participants who received placebo injections.[9] Grade 3 ISRs were rare, with similar rates across all treatment groups, including 3 cases of ulcers and 1 case of nodule in the LEN cohort. No Grade 4 ISRs occurred, and the frequency of ISRs decreased over time (Figure 1). Four ISRs (0.2%) that led to premature discontinuation occurred in the LEN group; all were reported as SUBQ nodules, including 1 that was also reported as injection site pain. No participants who received a placebo injection discontinued due to an ISR. No keloid scars were reported in any group.[2]

Table 2. PURPOSE 1 Primary Analysis: ISRs[2]

ISRs, n or n (%)	LEN (n=2138)	FTC/TAF (n=2137)	FTC/TDF (n=1070)
Participants who received ≥1 injection	2138	2136	1070
Participants with ≥1 ISR	1470 (68.8)	755 (35.3)	363 (33.9)
Grade 1	1060 (49.6)	563 (26.4)	281 (26.3)
Grade 2	406 (19)	190 (8.9)	80 (7.5)
Grade 3[a]	4 (0.2)	2 (<0.1)	2 (0.2)
Grade 4	0	0	0
Serious ISRs	0	0	0
ISRs that led to premature discontinuation	4 (0.2)	0	0

[a]Grade 3 ISRs consisted of injection site ulcer (LEN, n=3; FTC/TAF, n=2; FTC/TDF, n=1), nodule (LEN, n=1), and pain (FTC/TDF, n=1).
Note: Included trial-related injections only; reactions to other types of injections (eg, vaccines) were excluded. ISRs were categorized according to the MedDRA v27.0.

Figure 1. PURPOSE 1 Primary Analysis: Frequency of Common Grade ≤2 ISRs[10]



End-of-RBP analysis[3]

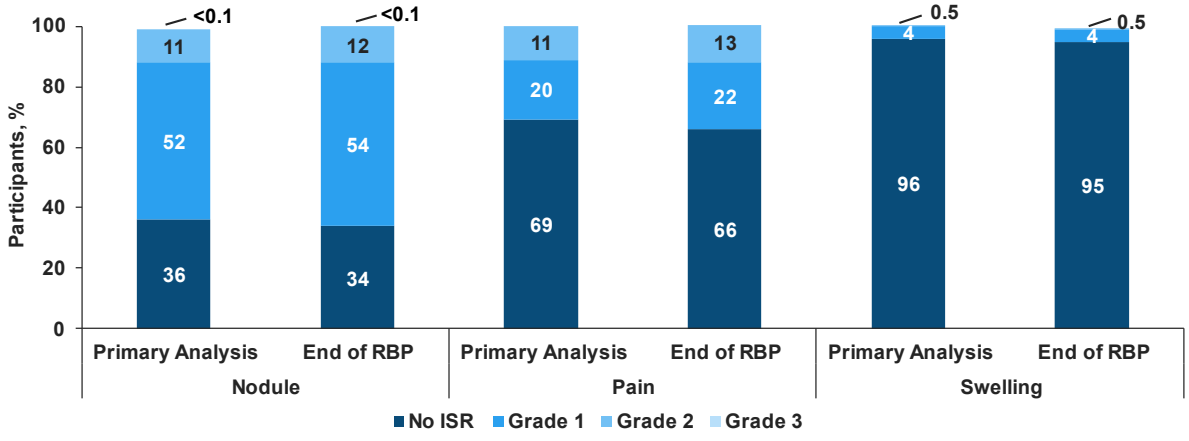
Through the end of the RBP, no new discontinuations due to ISRs occurred (Table 3). The incidence and severity of ISRs were generally similar to those reported in the primary analysis (Figure 2).

Table 3. PURPOSE 1 End-of-RBP Analysis: ISRs in LEN Participants[3]

ISRs, n (%)	End-of-RBP Analysis
	LEN (n=2140)
ISRs	1519 (71)
Grade 2	444 (21)
Grade 3 (highest grade reported)	4 (<1)
Led to LEN discontinuation	4 (<1)

Note: All AEs were coded according to MedDRA v28.0.

Figure 2. PURPOSE 1 Primary and End-of-RBP Analyses: ISRs in LEN Participants[3]



OLE Week 52 analysis[4]

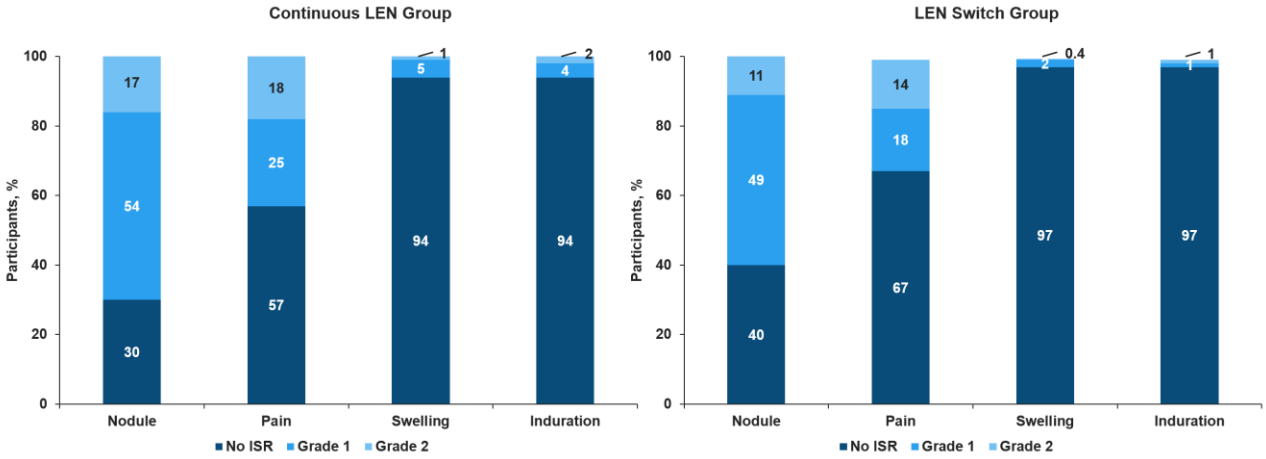
Through OLE Week 52, the incidence and severity of ISRs were generally similar between the continuous LEN and LEN switch groups (Table 4 and Figure 3).

Table 4. PURPOSE 1 OLE Week 52 Analysis: ISRs[4]

ISRs, n (%)	OLE Week 52 Analysis	
	Continuous LEN (n=2140)	LEN Switch (n=2501)
ISRs	1632 (76)	1637 (65)
Grade 2	612 (29)	568 (23)
Grade 3 (highest grade reported)	7 (<1)	5 (<1)
Led to LEN discontinuation	4 (<1)	2 (<1)

Note: All AEs were coded according to MedDRA v28.0.

Figure 3. PURPOSE 1 OLE Week 52 Analysis: ISRs[4]



Note: In the continuous LEN group, <0.1% of participants each experienced Grade 3 nodule and induration. In the LEN switch group, <0.1% of participants each experienced Grade 3 pain, swelling, and induration.

PURPOSE 2: LEN for PrEP in Men and Gender-Diverse Individuals

Study design[5]

PURPOSE 2 (NCT04925752) is an ongoing phase 3, double-blind, randomized, controlled clinical study comparing the efficacy and safety of twice-yearly SUBQ LEN with daily oral FTC/TDF for PrEP in CGM, TGW, TGM, and GNB individuals who were sexually active with partners assigned male at birth. Eligible participants who were HIV-negative and not on PrEP were randomly assigned 2:1 to receive SUBQ LEN (n=2179) or oral FTC/TDF (n=1086).

ISRs

Primary analysis[5]

Overall, 10,094 SUBQ LEN and 5145 SUBQ LEN placebo injections were administered, and ISRs were reported in 1816 participants (83.2%) who received LEN and 756 participants (69.5%) in the FTC/TDF group who received placebo injections (Table 5). Most ISRs were mild to moderate in severity, and nodules, pain, and erythema were the most common ISRs. Nodules were reported more frequently in the LEN group than in the placebo injection group (63.4% vs 39.2%, respectively), with a median (IQR) duration of 183 (89–274) days in the SUBQ LEN group and 64 (19–98) days in the placebo injection group. The median (IQR) duration of induration was 84 (8–190) days in the SUBQ LEN group and 8 (5–57) days in the placebo injection group. The incidence of pain was similar between groups (SUBQ LEN,

56.4%; placebo injection, 53.4%). There were no reports of keloid formation. Overall, the frequency and severity of ISRs decreased over time. AEs of ISRs led to study drug discontinuation in 29 participants (LEN, n=26 [1.2%]; FTC/TDF, n=3 [0.3%]).

Table 5. PURPOSE 2 Primary Analysis: ISRs[5]

ISRs, n or n (%)	LEN (n=2183)	FTC/TDF (n=1088)
Participants who received ≥1 injection	2183	1088
Participants with ≥1 ISR	1816 (83.2)	756 (69.5)
Grade 1	1441 (66)	594 (54.6)
Grade 2	361 (16.5)	161 (14.8)
Grade 3[a]	14 (0.6)	1 (<0.1)
Grade 4	0	0
Serious ISRs	0	0
ISRs that led to premature discontinuation	26 (1.2)	0

[a]Included 7 ulcers in the LEN group.
Note: ISRs were categorized according to the MedDRA v27.0.

End-of-RBP analysis[6]

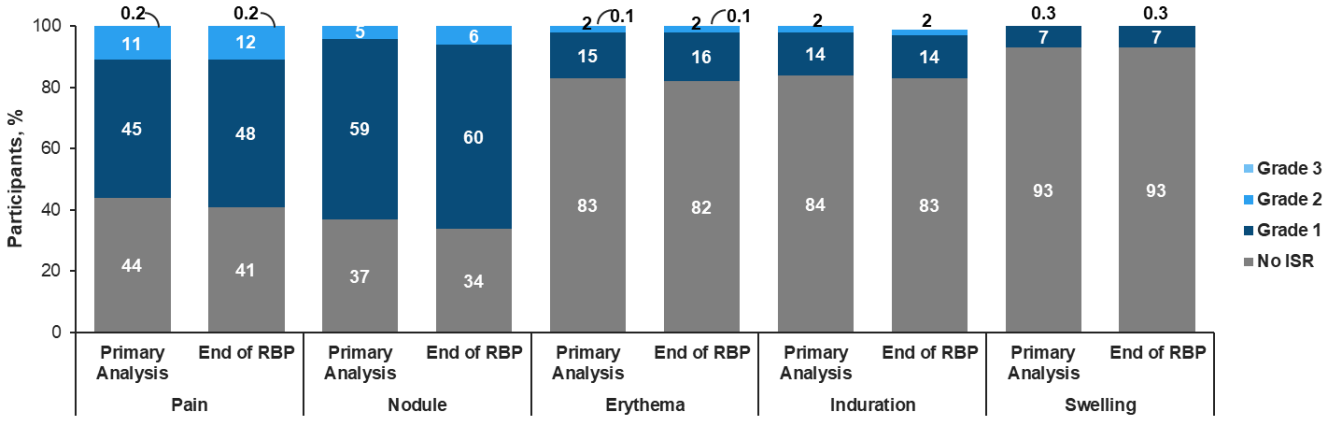
Through the end of the RBP, no new safety concerns were noted, and no additional discontinuations due to ISRs occurred (Table 6). The incidence and severity of ISRs were generally similar to those observed in the primary analysis (Figure 4).

Table 6. PURPOSE 2 End-of-RBP Analysis: ISRs[6]

ISRs, n (%)	End-of-RBP Analysis
	LEN (n=2183)
ISRs	1851 (85)
Grade 2	390 (18)
Grade 3	14 (1)
ISRs that led to LEN discontinuation	26 (1)

Note: All AEs were coded according to MedDRA v28.0.

Figure 4. PURPOSE 2 Primary and End-of-RBP Analyses: Severity of ISRs[6a]



[a]Included ISRs that occurred in ≥100 participants.

OLE Week 52 analysis[7]

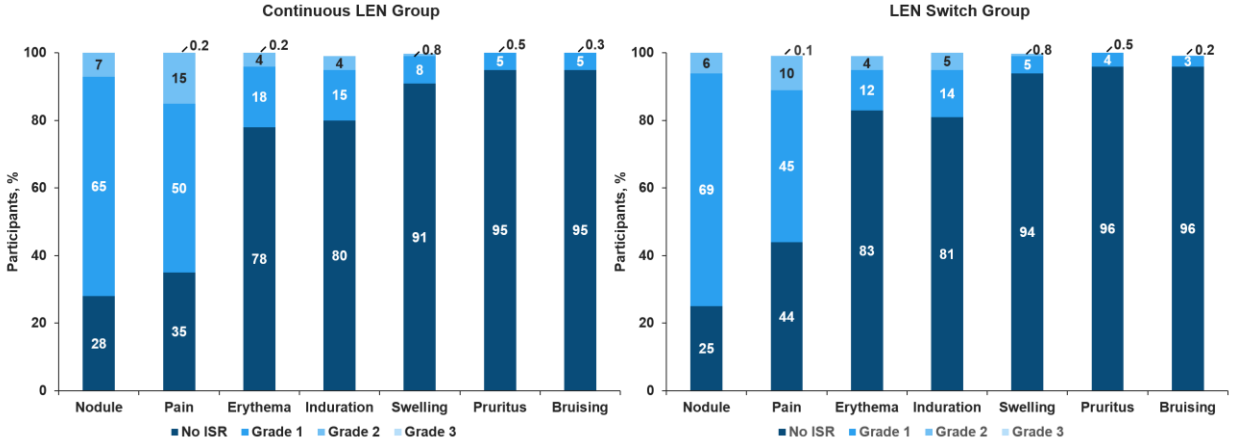
Through OLE Week 52, incidence and severity of ISRs were similar between the continuous LEN and LEN switch groups (Table 7 and Figure 5).

Table 7. PURPOSE 2 OLE Week 52 Analysis: ISRs[7]

ISRs, n (%)	OLE Week 52 Analysis	
	Continuous LEN (n=2140)	LEN Switch (n=2501)
ISRs	1922 (88)	745 (90)
Grade 2	524 (24)	172 (21)
Grade 3 (highest grade reported)	17 (1)	4 (<1)
Led to LEN discontinuation	27 (1)	0

Note: All AEs were coded according to MedDRA v28.0.

Figure 5. PURPOSE 2 OLE Week 52 Analysis: ISRs[7]



Note: Included ISRs that occurred in ≥100 participants who received LEN injections through OLE Week 52.

PURPOSE 1 and PURPOSE 2: Analysis of ISRs by Injection Site Location[8]

In both PURPOSE 1 and PURPOSE 2, participants randomly assigned to LEN in the RBP could continue on LEN in the OLE phase; participants randomly assigned to FTC/TAF or FTC/TDF who continued into the OLE switched to LEN. Participants received LEN SUBQ injections in the abdomen during the RBP; pregnant participants in PURPOSE 1 could choose to receive LEN administration in the thigh. Participants who continued in the OLE phase could choose to receive LEN SUBQ injections in the abdomen, thigh, upper arm, or upper buttocks.

Safety and tolerability of LEN by SUBQ injection locations

An analysis was conducted to assess the safety and tolerability of LEN SUBQ injections in non-abdominal sites (ie, thigh, upper arm, and upper buttocks) compared with abdominal sites. All participants who received LEN SUBQ in the RBP or OLE phase were included (Table 8). Outcomes included investigator-reported ISRs and AEs that were associated with LEN SUBQ administration across all injection sites.

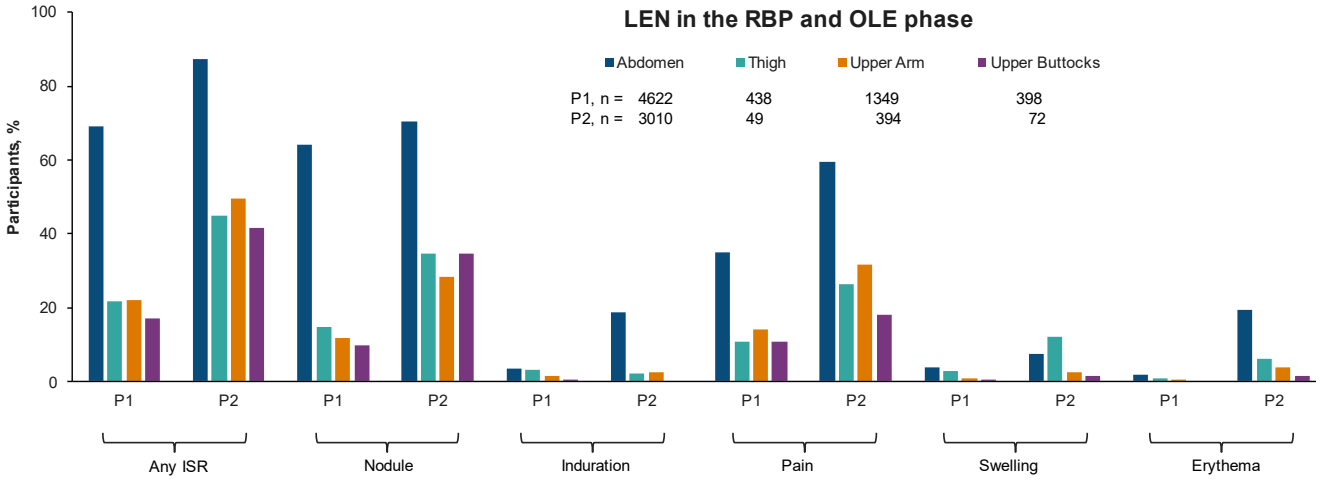
Table 8. PURPOSE 1 and PURPOSE 2 Analysis: Baseline Demographics[8]

PURPOSE 1	Abdomen (n=4622)	Thigh (n=438)	Upper Arm (n=1349)	Upper Buttocks (n=398)
Female sex at birth, %	100	100	100	100
Body weight, median (IQR), kg	65.2 (55.9–79.5)	63.5 (55.8–75)	69.8 (59–84)	66.8 (56.6–81.6)
BMI, median (IQR), kg/m^2	26 (22.3–31.5)	25.6 (22.6–30)	27.8 (23.6–33.3)	26.8 (23–32)

PURPOSE 1	Abdomen (n=4622)	Thigh (n=438)	Upper Arm (n=1349)	Upper Buttocks (n=398)
Pregnant or postpartum at time of injection, n (%)	384 (8.3)	225 (51.4)	126 (9.3)	25 (6.3)
PURPOSE 2	**Abdomen (n=3010)**	**Thigh (n=49)**	**Upper Arm (n=394)**	**Upper Buttocks (n=72)**
Male sex at birth, n (%)	2953 (98.1)	46 (93.9)	390 (99)	72 (100)
Body weight, median (IQR), kg	75.7 (65–89)	77.9 (65.6–88.4)	81.7 (70.5–97.1)	76.5 (68.9–88.2)
BMI, median (IQR), kg/m^2	25.3 (22.1–29.1)	24.5 (22.7–28.9)	26.9 (23.6–31)	25.4 (22.7–28.8)

A smaller percentage of participants across both studies had ISRs in the thigh, upper arm, or upper buttocks than in the abdomen (Figure 6). Note that the sample sizes of thigh, upper arm, and upper buttocks injections were smaller than that of abdomen injections in both studies.

Figure 6. PURPOSE 1 and PURPOSE 2 Analysis: LEN-Related ISRs by Injection Site in the RBP and OLE Phases[8]

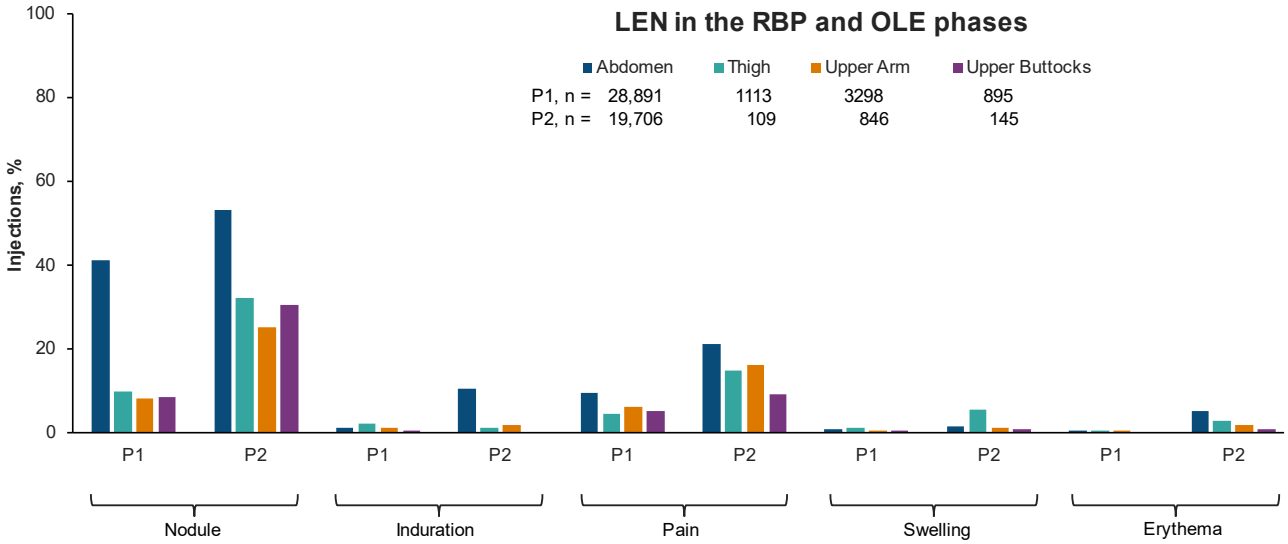


Note: Each LEN 927 mg SUBQ dose was administered as 2 × 1.5 mL injections. For nodules and indurations, bilateral events from the same injection visit were counted as separate AEs; all other ISRs were not counted separately, and all events with the same AE onset date were counted as 1 event.

A smaller proportion of participants had AEs of injection site nodules and pain with LEN administration in non-abdominal sites than in the abdomen; however, there were fewer participants who received injections in the thigh, upper arm, and upper buttocks than abdominal injections in both studies (Figure 7).

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Figure 7. PURPOSE 1 and PURPOSE 2 Analysis: LEN-Related ISRs by Injection Site in the RBP and OLE Phases[8]



Note: Each LEN 927 mg SUBQ dose was administered as 2 × 1.5 mL injections. For nodules and indurations, bilateral events from the same injection visit were counted as separate AEs; all other ISRs were not counted separately, and all events with the same AE onset date were counted as 1 event.

Injection site nodules and indurations generally resolved more quickly when LEN was administered in non-abdominal sites than in the abdomen, although there was longer follow-up for abdominal injections administered during the RBP (Table 9).
LEN administration in the thigh, upper arm, or upper buttocks was generally well tolerated, with no serious ISRs or ISRs that led to discontinuation (Table 10).

Table 9. PURPOSE 1 and PURPOSE 2 Analysis: Duration and Resolution of LEN-Related Nodules and Indurations[8]

PURPOSE 1	Abdomen		Thigh	Upper Arm	Upper Buttocks
	All LEN (n=4622)	Switched to LEN OLE (n=2482)	All LEN (n=438)	All LEN (n=1349)	All LEN (n=398)
Total injections, n	28,891	11,082	1113	3298	895
Nodules, n (%)	11,899 (41.2)	4723 (42.6)	108 (9.7)	268 (8.1)	74 (8.3)
Resolved,[a] n (%)	7326 (61.6)	2275 (48.2)	57 (52.8)	80 (29.9)	19 (25.7)
Time to resolution,[b] median (IQR), days	260 (151–364)	182 (91–275)	90 (80–174)	91 (72–142)	90 (86–97)
Indurations, n (%)	276 (1)	79 (0.7)	22 (2)	30 (0.9)	2 (0.2)
Resolved,[a] n (%)	213 (77.2)	47 (59.5)	13 (59.1)	25 (83.3)	1 (50)
Time to resolution,[b] median (IQR), days	87 (15–262)	53 (17–233)	15 (11–49)	29 (10–55)	95 (NR)

PURPOSE 2	Abdomen		Thigh	Upper Arm	Upper Buttocks
	All LEN (n=3010)	Switched to LEN OLE (n=827)	All LEN (n=49)	All LEN (n=394)	All LEN (n=72)
Total injections, n	19,706	3113	109	846	145
Nodules, n (%)	10,430 (52.9)	1839 (59.1)	35 (32.1)	213 (25.2)	44 (30.3)
Resolved,[a] n (%)	6201 (59.5)	597 (32.5)	10 (28.6)	98 (46)	11 (25)
Time to resolution,[b] median (IQR), days	270 (176–367)	183 (106–273)	116 (82–178)	85 (32–96)	182 (168–184)
Indurations, n (%)	2025 (10.3)	398 (12.8)	1 (0.9)	15 (1.8)	0
Resolved,[a] n (%)	1641 (81)	288 (72.4)	1 (100)	12 (80)	N/A
Time to resolution,[b] median (IQR), days	85 (7–191)	11 (6–115)	93	22 (3–95)	N/A

Abbreviation: NR=not reported.
[a]Denominator was the number of nodules or indurations.
[b]Duration was calculated by subtracting the onset date from the stop date and adding 1 day.

Table 10. PURPOSE 1 and PURPOSE 2 Analysis: ISRs by LEN SUBQ Injection Site[8]

PURPOSE 1, Participants (%)	Abdomen		Thigh	Upper Arm	Upper Buttocks
	All LEN (n=4622)	Switched to LEN OLE (n=2482)	All LEN (n=438)	All LEN (n=1349)	All LEN (n=398)
Any ISRs	3188 (69)	1575 (63.5)	95 (21.7)	295 (21.9)	68 (17.1)
Grade 3 or 4 ISRs	8 (0.2)	3 (0.1)	3 (0.7)	0	1 (0.3)
Any serious ISRs	0	0	0	0	0
ISRs that led to LEN discontinuation	6 (0.1)	2 (<0.1)	0	0	0
ISRs that led to study discontinuation	1 (<0.1)	1 (<0.1)	0	0	0
PURPOSE 2, Participants (%)	**Abdomen**		**Thigh**	**Upper Arm**	**Upper Buttocks**
	All LEN (n=3010)	**Switched to LEN OLE (n=827)**	**All LEN (n=49)**	**All LEN (n=394)**	**All LEN (n=72)**
Any ISRs	2628 (87.3)	723 (87.4)	22 (44.9)	196 (49.7)	30 (41.7)
Grade 3 or 4 ISRs	18 (0.6)	3 (0.4)	0	0	0
Any serious ISRs	1 (<0.1)	1 (0.1)	0	0	0
ISRs that led to LEN discontinuation	27 (0.9)	0	0	0	0
ISRs that led to study discontinuation	3 (<0.1)	0	0	0	0

Clinical Considerations

Injection Techniques Considerations

The provider should use their clinical judgement to make a medically appropriate decision for their patients. The following mitigation techniques are commonly used in routine clinical care and are not specific to LEN.

- Ice may be applied before and after injection and may help with post-injection soreness. Apply ice ~10 minutes before injection to both injection sites.[11]
- Topical analgesics, such as lidocaine and prilocaine cream (not patches), may be used as clinically appropriate. Apply at least 30 minutes before injection to both injection sites if not contraindicated. Cream may be wiped off with alcohol swab during injection site prep.[12]

- Oral analgesics, such as acetaminophen or NSAIDs, may be considered if not contraindicated and as clinically appropriate.[11]

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Abbreviations

AE=adverse event
CGM=cisgender men
CGW=cisgender women
FTC=emtricitabine
GNB=gender nonbinary
ISR=injection site reaction
LEN=lenacapavir
MedDRA=Medical Dictionary for Regulatory Activities
OLE=open-label extension
PK=pharmacokinetic(s)
PrEP=pre-exposure prophylaxis
RBP=randomized blinded phase
SUBQ=subcutaneous(ly)
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TGM=transgender men
TGW=transgender women

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Yeztugo, Descovy, and Truvada US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi; www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi; www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or 🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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