National Department of Health

Pre-Exposure Prophylaxis overview and Lenacapavir roll out plan

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HIV AND AIDS & STIs
14 OCTOBER 2025

PRESENTATION OUTLINE

- Oral PrEP Overview
- Oral PrEP Target Setting Methodology & Targets
- Lenacapavir roll out plan
- Lenacapavir population and geographic coverage
- Commodity and resource requirements
- Next Steps

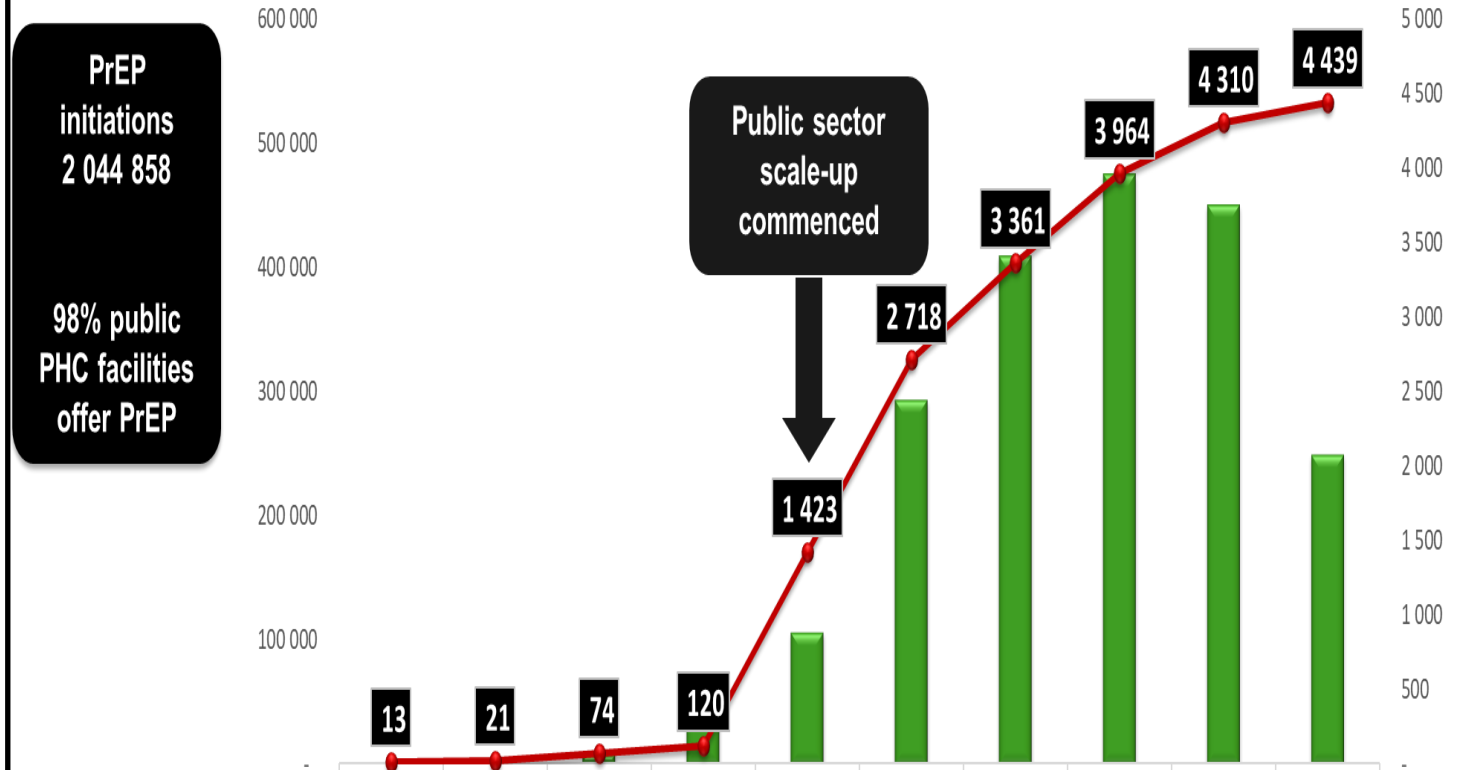
STATUS OF SOUTH AFRICA'S ORAL PREP PROGRAMME (JUNE 2016-AUGUST 2025)

Since the launch of oral PrEP in 2016, South Africa :

- **2,04 million** people have started using oral PrEP.
- **98%** of public primary healthcare facilities now provide PrEP services.
- **4,439** service delivery locations actively provide oral PrEP throughout the country (PHCs, partner sites, hospitals, correctional facilities, campus health facilities).

In 2024 alone, over **450,000** new users were introduced to PrEP.

The key to South Africa's success is that PrEP is embedded within an integrated primary healthcare service and users are offered a comprehensive package of services including combination HIV prevention and SRH services.



	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Oral PrEP Initiations	771	3 196	8 593	45 576	106 402	293 310	410 237	476 272	450 887	249 614
Facilities Offering Oral PrEP	13	21	74	120	1 423	2 718	3 361	3 964	4 310	4 439

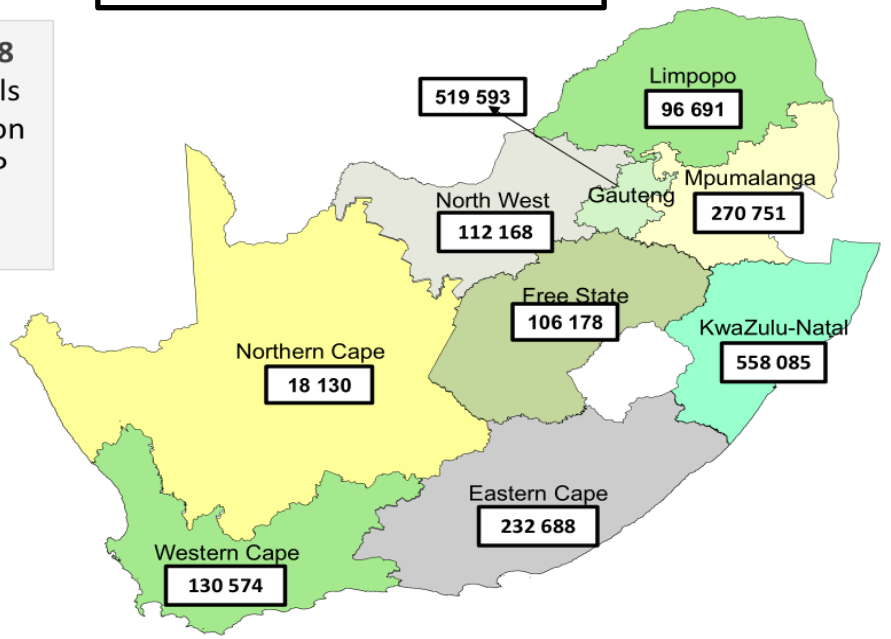
ORAL PREP FACILITY COVERAGE AND INITIATIONS

Province	PHC Facility Implementation Targets	PHC Implementing Facilities (Jun '16 – Aug'25)	PHC Facility Coverage (Jun '16 – Aug'25)
EC	776	774	**100%**
FS	219	219	**100%**
GP	372	372	**100%**
KZN	610	610	**100%**
LP	477	465	**97%**
MP	295	295	**100%**
NC	162	150	**93%**
NW	318	315	**99%**
WC	260	211	**81%**
SA	**3 489**	**3 411**	**98%**

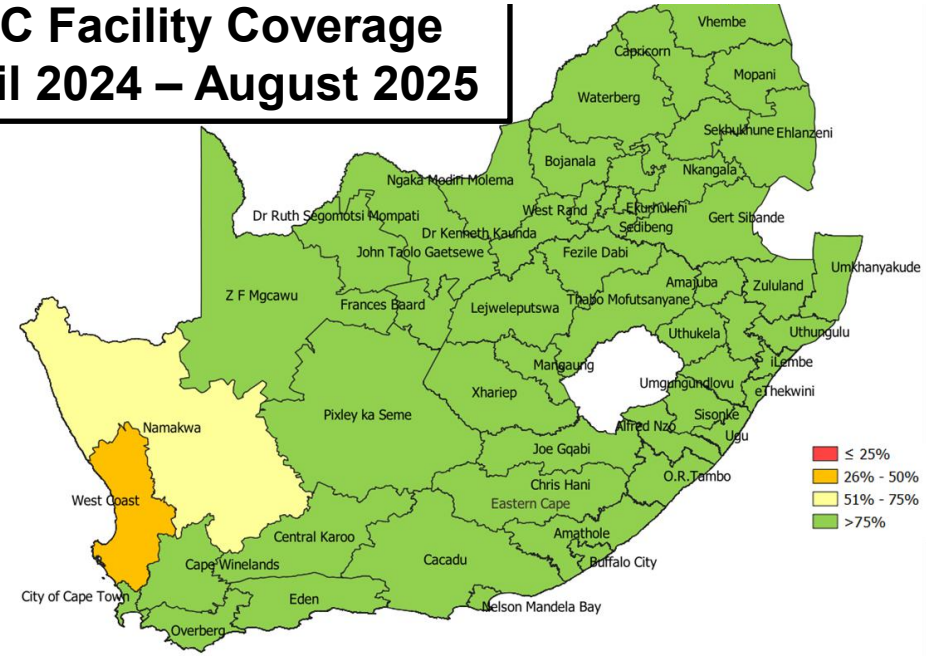
Source:
Consolidated from DHIS, TIER and implementing partner reports.

Oral PrEP Initiations (Jun16 – Aug25)

2 044 858 Individuals Initiated on oral PrEP
4 439 Sites



PHC Facility Coverage (April 2024 – August 2025



health
Department:
Health
REPUBLIC OF SOUTH AFRICA

LESSONS FROM ORAL PREP FOR LENACAPAVIR IMPLEMENTATION

Precision targeting	Disaggregated goals	Strategic alignment	Incidence-led focus	Replicable Framework
• Set ambitious, evidence-based PrEP targets	• Aligned planning to the epidemiological risk of each population group.	• Ensured programmes match population need and facility capacity, while optimising resources for demand creation, testing, and supply chain.	• Directs proportionally greater attention and resources to higher-risk geographic areas and populations.	• Prepares the system for long-acting PrEP by strengthening upstream targeting, demand forecasting, and downstream service delivery.

ORAL PREP TARGET SETTING METHODOLOGY

INPUTS

1. DHIS catchment area data: 3505 PHC facilities	Males & females age ≥15 years within catchment areas: **43.5m**
2. Imperial College London/UCT district level HIV prevalence applied to catchment population	HIV negative males and females age >15 years: **36.4m**
3. HIV prevention demand generation – adjustable input	HIV negative males and females age ≥15 years, eligible for PrEP, reached with demand generation activities based on HIV incidence risk categorization: **14.3m**
4. HIV testing target for those reached with demand creation (adjustable input)	HIV negative males and females age ≥15 years to be tested (in alignment with 95-95-95): **13.6m**
5. National PrEP M&E data Using weighted average, 6.3%	Oral PrEP targets calculated using national oral PrEP data: new PrEP initiations **693 214**
6. National PrEP M&E data- based on programme perfomance (20% of previous year's targets)	Estimated continuations based on national oral PrEP data from previous year: **80 286**

OUTPUTS

ORAL PREP INITIATION TARGETS BY POPULATION CATEGORY
1 APRIL 2025 - 31 MARCH 2026

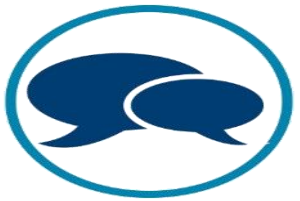
Population	Demand creation (combination HIV prevention)	HIV Testing	Projected choice on PrEP initiation targets
General Population	14 379 759	13 660 771	693 214
GBMSM (Gay, bisexual and other men who have sex with men)	273 590	259 910	155 946
Sex workers	87 249	87 249	69 799
Transgender people	47 321	47 321	37 857
Antenatal (1st ANC HIV test negative results 2023-24)	673 546	673 546	324 792

INTEGRATED PACKAGE OF HEALTH SERVICES

PrEP is provided within the context of combination HIV prevention and an integrated package of services including SRH, gender-based violence and intimate partner violence services

Condoms

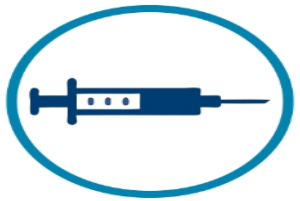
PrEP



Counselling

Post-Exposure Prophylaxis

Healthy lifestyles



Treatment for STIs

Male medical circumcision

ART for partners living with HIV

Introduction of Long-Acting PrEP Methods

PROGRAMMATIC OBJECTIVES LENACAPAVIR IMPLEMENTATION

- Align with national HIV prevention goals, WHO guidance, and SAHPRA regulatory requirements.
- Improve PrEP adherence and expand prevention options by offering long-acting choices.
- Focus resources on populations at highest risk, informed by epidemiological and service delivery data.
- Demonstrate cost-effectiveness and prepare for sustainability through future generic procurement.
- Strengthen systems for integrated service delivery, monitoring, and community engagement.

ROLLOUT GUIDING PRINCIPLES

Equity	Ensure equitable access across priority populations (AGYW, KPs, pregnant/postpartum women, men, adolescents).
Integration	Embed delivery in routine care integrating Lenacapavir within PHC, ANC/PNC, SRH, Youth Zones, and campus/school health; extend via community outreach.
Innovate	Innovate service models to reach priority groups (youth-friendly hours, mobile/outreach, fast-track visits, peer navigators).
Efficiency	Phase by risk and performance starting in high-incidence districts and high-performing facilities; cluster rural sites to achieve meaningful catchment coverage.
Data	Use data to expand apply readiness assessments, continuation data, and client feedback to guide scale-up and expansion.
Systems	Strengthen systems through the rollout supporting supply chain discipline, M&E coherence, HR capacity building, and clinical mentorship.
Community	Engage communities, youth and women, youth, women, and KP-led groups for co-design, demand creation, and accountability; counter stigma with peer education and trusted messengers.
Evidence	Embed evidence & learning using routine data and rapid feedback for adaptive management and policy refinement.

SERVICE DELIVERY INTEGRATION & COMMUNITY LINKAGES FOR LENACAPAVIR

Integration into PHC

- LEN embedded in comprehensive HIV prevention at PHC facilities.
- Facilities as nodal points for commodities, initiation, monitoring, and follow-up and data capturing and reporting.

Community Resource Mapping

- Identify & leverage community-based structures and services.
- Link LEN to outreach, mobiles, and existing HIV prevention platforms.

Partnerships

- Higher Health, DSD
- Civil society and CBOs, religious organisations and traditional authorities.
- Community healthcare workers.

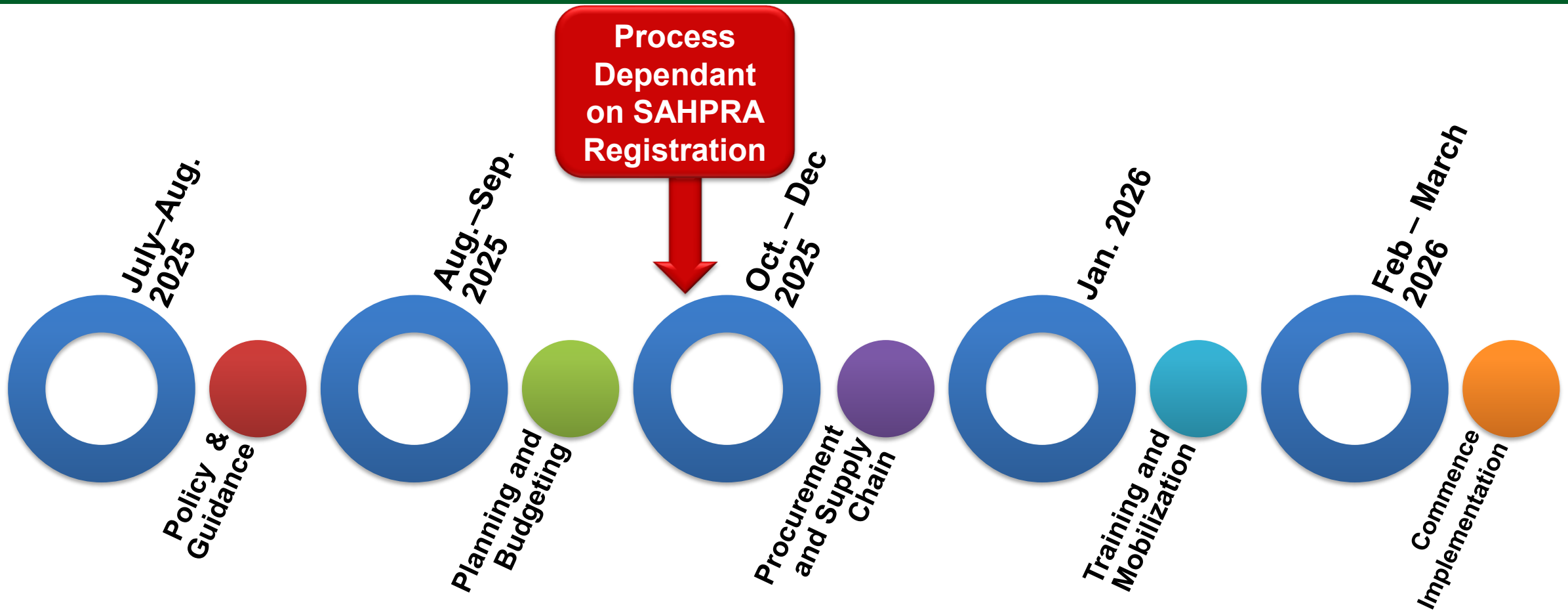
Reaching Priority Populations

- AGYW: TVETs, universities, high schools.
- Pregnant & postpartum women: early ANC and PNC community health worker outreach.
- Key populations: size estimation, hotspot mapping in the geographic catchment area .
- Community entry points: sports, recreation, shopping malls.
- Urban and rural reach based on incidence and clustering of rural areas to improve coverage.

PRIORITISATION CRITERIA FOR LENACAPAVIR ROLLOUT

Epidemiological Burden	• Districts with the highest HIV incidence and antenatal HIV positivity rates.
Health Service Catchment	• Facilities serving a large catchment of priority populations in high-burden areas. • Facilities with wide geographic coverage across provinces.
Priority Populations	• Pregnant and postpartum women. • Key Populations (sex workers, MSM, transgender people, PWID). • Adolescent Girls & Young Women (AGYW).
Programme Performance	• Sites with high PrEP uptake and retention, demonstrating readiness to integrate LEN.

PHASE 1 PROJECTED TIMELINE LENACAPAVIR IMPLEMENTATION



PROGRESS WITH PREPARATION FOR THE INTRODUCTION OF LENACAPAVIR IMPLEMENTATION

Regulatory Approval & Policy	Implementation & Financial Planning	Service Delivery Preparation	Communication and Social Mobilisation
WHO PQ approval	Demand Forecasts and Impact Models (presented to NEMLC)	Develop National and Provincial Implementation Plans	Dev. social mobilisation & Demand Generation Strategy
SAHPRA approval	Investment Case	Identify and delivery sites and health care providers required for delivery	Effective Interventions for Uptake & Continued Use
Draft National Policy and Guidelines	Costing and Budget Phase 1	Develop M&E Indicators and Systems	Dev. of communication, education and social mobilisation materials
National Health Council Approval	Procurement/ Supply Chain/Global Fund	Draft Implementation tools, job aids & Training Materials	Commence implementation

POLICY AND REGULATORY STATUS

- **WHO** Lenacapavir implementation guidelines launched in July 2025. WHO pre-qualification finalised in October 2025.
- **SAHPRA registration-** national rollout is contingent on registration of Lenacapavir for PrEP anticipated by 31 October 2025.
- **Essential medicines list/NEMLC:** Alignment and listing processes have been initiated to ensure longer-term sustainability.
- **Oversight and governance:** A national technical team with clear terms of reference, together with technical workstreams (policy, supply chain, service delivery/training, demand generation, and M&E), will oversee phased implementation and issue periodic updates.

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A national technical team with technical workstreams (policy, supply chain, service delivery/training, demand generation, and M&E), will oversee phased implementation and issue periodic updates.

FINANCING AND PROCUREMENT

- The Global Fund has identified South Africa as an early-adopter country and allocated US$29.2 million for LEN commodities under GC7, with support for the first two years.
- Commodities will be procured via Global Fund's central pooled mechanism using the rapid supply chain mechanism.
- Quantification assumes equal number of initiations in Year 1 and 2 at facilities that demonstrate readiness and demand.
- A domestic sustainability pathway will be articulated during 2026-27, including options for price reductions, potential generic entry when feasible, and integration into routine provincial budgets.
- The two generic manufacturers have announced an initial price of generic Lenacapavir injectable to be $40 and $17 for oral loading dose (excl distribution cost) from 2027 for 120 countries including South Africa.
- Preliminary budget lines include commodities, implementation resources, training and mentorship, demand generation, and M&E.

COMMODITY PROCUREMENT AND SUPPLY CHAIN MECHANISM

Global Fund pooled procurement mechanism for Lenacapavir

- Lenacapavir commodities will be procured through the Global Fund Pooled Procurement Mechanism (PPM), utilizing the Rapid Supply Mechanism (RSM) option.
- The National Department of Health (NDoH) will place orders for Lenacapavir directly with the Global Fund. The first order was placed on 30 September 2025.
- The Global Fund will then submit the order to Gilead (USA) for processing and shipment.
- The commodities will be shipped by Gilead (USA) to South Africa.
- In South Africa, Gilead (South Africa), in collaboration with its logistics partner DSV, will be responsible for:
  - Importation and customs clearance,
  - Post-importation testing, and
  - Securing SAHPRA approval for the packing deviation applicable to the initial consignment.

Distribution of the commodities

- NDoH will send out letters to the provincial HODs offering them the donated commodities
- The HODs will be required to accept the donated commodities
- The letters of acceptance and the commodity distribution list will be supplied to Gilead
- DSV will deliver the commodities as per NDoH instruction to the respective pharmaceutical depots

PHASED IMPLEMENTATION OF LENACAPAVIR 2026-2029 IN THE 3 474 PUBLIC PRIMARY HEALTH CARE FACILITIES

Phase 1
April 2026– March 2028
360 (10%) facilities in 22 districts and 6 provinces

Phase 2
April 2027 – March 2028
650 Facilities
1034 (30%)

Phase 3
April 2028– March 2029
2 440 Facilities
3 474 (100%)

Global Fund Support (2 Years)

Domestic Funding Support with cost-effective generics

Domestic Funding Support with cost effective generics

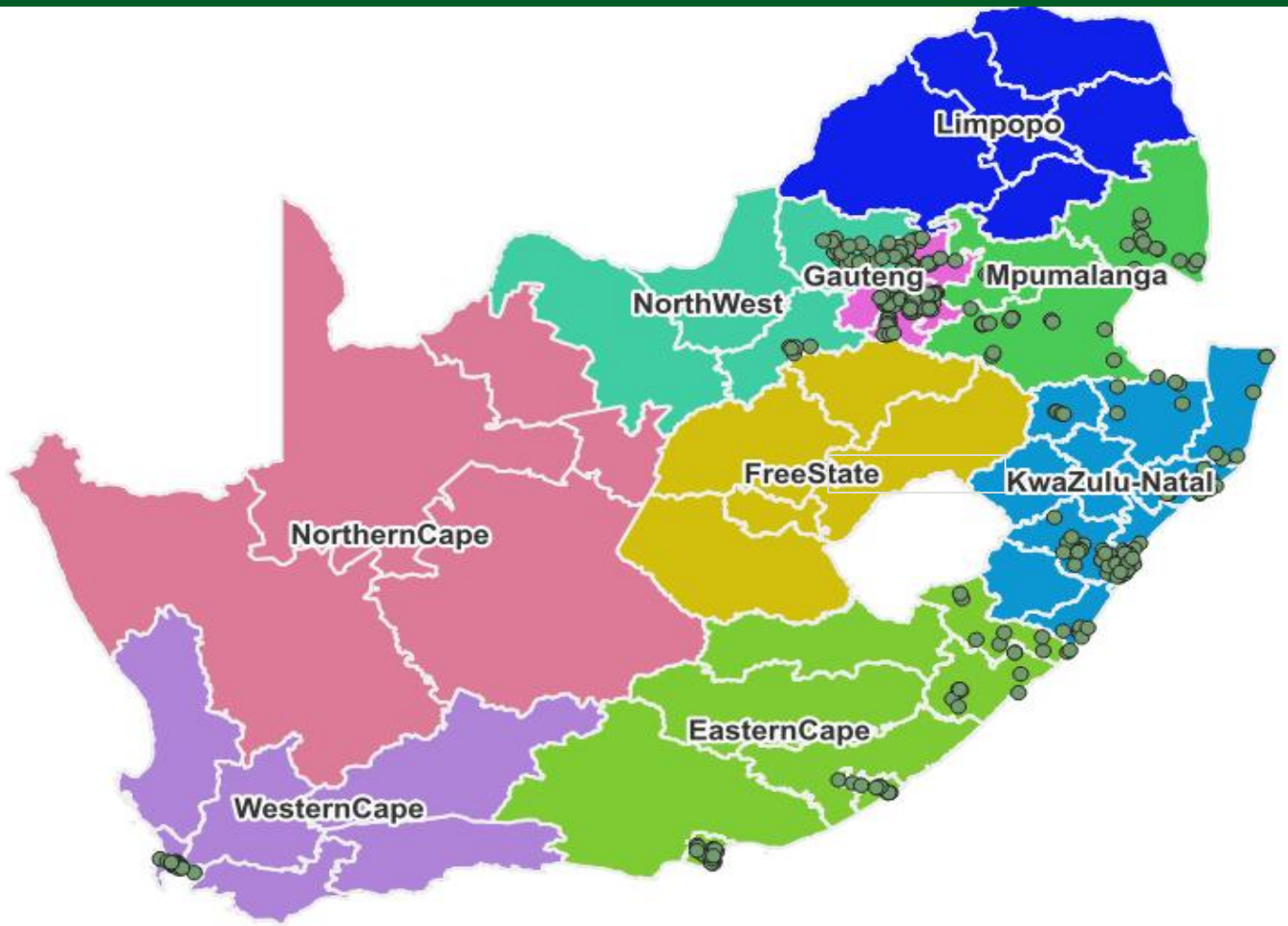
PROPOSED COVERAGE

Provinces/Districts	Facilities	Gen AGYW Initiations Y1 - Y2	Antenatal Initiations Y1 - Y2	FSW Initiation Y1 - Y2	MSM Initiations Y1 - Y2	TG Initiations Y1 - Y2	Total Initiations Y1 - Y2	Total Continuations Y1 - Y2
ec Eastern Cape Province	**49**	**17 040**	**11 940**	**8 240**	**2 940**	**1 680**	**41 840**	**47 600**
ec Alfred Nzo District Municipality	8	2 480	2 560	1 600	420	240	7 300	8 370
ec Buffalo City Metropolitan Municipality	12	3 040	1 700	1 920	620	360	7 640	8 610
ec Nelson Mandela Bay Municipality	20	8 240	4 900	3 120	940	540	17 740	20 180
ec Oliver Tambo District Municipality	9	3 280	2 780	1 600	960	540	9 160	10 440
gp Gauteng Province	**133**	**116 480**	**66 260**	**18 080**	**18 060**	**8 880**	**227 760**	**258 740**
gp City of Johannesburg Metropolitan Municipality	49	49 680	28 460	6 400	6 880	3 380	94 800	107 650
gp City of Tshwane Metropolitan Municipality	30	31 120	15 060	3 280	4 320	2 120	55 900	63 290
gp Ekurhuleni Metropolitan Municipality	44	30 560	19 120	4 560	4 620	2 280	61 140	69 490
gp Sedibeng District Municipality	7	3 600	2 820	1 920	1 140	560	10 040	11 560
gp West Rand District Municipality	3	1 520	800	1 920	1 100	540	5 880	6 750
kz KwaZulu-Natal Province	**94**	**42 080**	**31 600**	**10 240**	**7 340**	**3 300**	**94 560**	**107 380**
kz eThekwini Metropolitan Municipality	49	26 880	19 240	3 120	3 660	1 640	54 540	61 960
kz uMgungundlovu District Municipality	13	5 120	3 200	1 120	920	420	10 780	12 220
kz Amajuba District Municipality	5	2 400	1 580	960	440	200	5 580	6 340
kz King Cetshwayo District Municipality	9	2 960	2 980	1 280	680	300	8 200	9 310
kz Ugu District Municipality	6	1 680	1 480	1 440	620	280	5 500	6 260
kz Umkhanyakude District Municipality	6	1 520	1 360	1 360	440	200	4 880	5 550
kz Zululand District Municipality	6	1 520	1 760	960	580	260	5 080	5 740
mp Mpumalanga Province	**31**	**13 280**	**8 880**	**3 200**	**4 160**	**2 020**	**31 540**	**35 870**
mp Ehlanzeni District Municipality	13	5 200	3 400	1 200	1 400	680	11 880	13 480
mp Gert Sibande District Municipality	14	6 320	4 280	800	1 160	560	13 120	14 900
mp Nkangala District Municipality	4	1 760	1 200	1 200	1 600	780	6 540	7 490
nw North West Province	**31**	**15 280**	**9 020**	**2 240**	**2 920**	**1 420**	**30 880**	**34 900**
nw Bojanala Platinum District Municipality	26	13 120	7 800	1 280	2 160	1 040	25 400	28 680
nw Dr Kenneth Kaunda District Municipality	5	2 160	1 220	960	760	380	5 480	6 220
wc Western Cape Province	**22**	**15 520**	**3 780**	**3 600**	**5 380**	**1 500**	**29 780**	**33 600**
wc City of Cape Town Metropolitan Municipality	22	15 520	3 780	3 600	5 380	1 500	29 780	33 600
Grand Total	**360**	**219 680**	**131 480**	**45 600**	**40 800**	**18 800**	**456 360**	**518 090**

LENACAPAVIR ALLOCATION BY AGE AND GENDER

	Lenacapavir Year 1 initiation Targets												
Province /District	**F 15-19**	**F 20-24**	**F 25-34**	**F 35-49**	**F 50+**	**M 15-19**	**M 20-24**	**M 25-34**	**M 35-49**	**M 50+**	**F 15+**	**M 15+**	**Total 15+**
ec Eastern Cape Province	**1 798**	**1 997**	**1 252**	**534**	**134**	**233**	**581**	**696**	**311**	**99**	**5 715**	**1 920**	**7 635**
ec Alfred Nzo District Municipality	255	283	177	76	19	33	82	100	44	13	810	272	1 082
ec Buffalo City Metropolitan Municipality	294	326	203	86	21	38	94	113	51	17	930	313	1 243
ec Nelson Mandela Bay Municipality	905	1 007	632	269	69	116	294	351	157	50	2 882	968	3 850
ec Oliver Tambo District Municipality	344	381	240	103	25	46	111	132	59	19	1 093	367	1 460
gp Gauteng Province	**13 095**	**14 545**	**9 101**	**3 881**	**977**	**1 695**	**4 251**	**5 077**	**2 277**	**723**	**41 599**	**14 023**	**55 622**
gp City of Johannesburg Metropolitan Municipali	5 620	6 243	3 907	1 664	418	729	1 822	2 176	974	310	17 852	6 011	23 863
gp City of Tshwane Metropolitan Municipality	3 524	3 912	2 448	1 043	263	456	1 144	1 366	613	195	11 190	3 774	14 964
gp Ekurhuleni Metropolitan Municipality	3 388	3 766	2 355	1 006	253	438	1 103	1 316	591	187	10 768	3 635	14 403
gp Sedibeng District Municipality	387	429	269	115	30	50	125	150	68	21	1 230	414	1 644
gp West Rand District Municipality	176	195	122	53	13	22	57	69	31	10	559	189	748
kz KwaZulu-Natal Province	**4 552**	**5 056**	**3 158**	**1 348**	**337**	**590**	**1 474**	**1 765**	**788**	**252**	**14 451**	**4 869**	**19 320**
kz Amajuba District Municipality	260	287	180	76	20	35	83	102	45	15	823	280	1 103
kz eThekwini Metropolitan Municipality	2 954	3 282	2 048	874	220	383	959	1 143	513	163	9 378	3 161	12 539
kz King Cetshwayo District Municipality	310	345	215	93	22	41	100	121	53	17	985	332	1 317
kz Ugu District Municipality	178	197	122	53	12	22	57	68	31	11	562	189	751
kz uMgungundlovu District Municipality	552	614	385	163	41	71	179	215	94	30	1 755	589	2 344
kz Umkhanyakude District Municipality	152	169	106	45	11	19	49	59	27	8	483	162	645
kz Zululand District Municipality	146	162	102	44	11	19	47	57	25	8	465	156	621
mp Mpumalanga Province	**1 414**	**1 566**	**980**	**418**	**108**	**183**	**457**	**546**	**243**	**77**	**4 486**	**1 506**	**5 992**
mp Ehlanzeni District Municipality	553	613	383	163	42	73	178	214	95	30	1 754	590	2 344
mp Gert Sibande District Municipality	670	742	464	198	52	86	218	259	115	37	2 126	715	2 841
mp Nkangala District Municipality	191	211	133	57	14	24	61	73	33	10	606	201	807
nw North West Province	**1 661**	**1 843**	**1 152**	**490**	**124**	**216**	**539**	**641**	**289**	**93**	**5 270**	**1 778**	**7 048**
nw Bojanala Platinum District Municipality	1 443	1 601	1 001	426	107	188	469	557	250	81	4 578	1 545	6 123
nw Dr Kenneth Kaunda District Municipality	218	242	151	64	17	28	70	84	39	12	692	233	925
wc Western Cape Province	**1 728**	**1 922**	**1 202**	**509**	**128**	**226**	**559**	**671**	**300**	**97**	**5 489**	**1 853**	**7 342**
wc City of Cape Town Metropolitan Municipality	1 728	1 922	1 202	509	128	226	559	671	300	97	5 489	1 853	7 342
Grand Total	**24 248**	**26 929**	**16 845**	**7 180**	**1 808**	**3 143**	**7 861**	**9 396**	**4 208**	**1 341**	**77 010**	**25 949**	**102 959**
Percentage of PrEP targets allocated to Len	60%	60%	50%	40%	20%	35%	35%	35%	31%	20%	75%	25%	

LENACAPAVIR: FACILITY COVERAGE 360 FACILITIES



Province	No. facilities	%
Gauteng	133	37
KwaZulu-Natal	94	26
Eastern Cape	49	14
Mpumalanga	31	9
North West	31	9
Western Cape	22	6
Total	360	100

GEOGRAPHIC AND FACILITY PRIORITISATION CRITERIA

AGYW incidence: HIV incidence among adolescent girls & young women (15–24).	ANC positivity rate: HIV positivity at first ANC test.	Facility population catchment size: AGYW population and ANC first-test volumes.	Consistent oral PrEP performance (FY23/24 & FY24/25): general + antenatal uptake; initiations ≥250 achieved.
Oral PrEP target projected ≥350 initiations in FY25/26.	Stability (Jan–Jun 2025): performance maintained despite USAID withdrawal	Equity & coverage: balanced provincial spread and urban–rural representation; strong PHC catchment coverage.	Priority given to facilities showing strong, consistent uptake in both general and antenatal populations.

MANAGE POTENTIAL RISKS & CHALLENGES

- **Regulatory approval delays**: Maintain close engagement with SAHPRA.
- **Commodity supply delays and pricing**: Use global fund pooled procurement;
- **Data systems (TIER. Net and DHIs) are not aligned to track cohorts and priority groups:** Explore interim data solutions to track cohorts if feasible.
- **Human resources & training load**: Cascade ToT; e-learning modules; mentorship and supportive supervision.
- **Insufficient demand generation & stigma:** Youth-friendly messaging; community partners; strong integration with ANC/PNC and KP services; address myths proactively.
- **Data quality & adverse event monitoring**: national adverse event reporting SOPs; sentinel site reviews; quarterly data quality audits.
- **Funding shifts (**donor reprioritization): Prioritize high-impact sites; protect core lines in provincial budgets; phase expansion to match resources.

SUMMARY OF PHASE 1 LENACAPAVIR TARGETS COMMODITY REQUIREMENTS UPDATED

Target population	No. of Persons Initiated Years 1&2	% Coverage	No. of doses (initiations & continuations) 2 years	Cost USD ($60 per person year)
General Population 15+ (incl AGYW)	219 680 /36 280 268	,61%	458 880	$13 766 400
Pregnant and Lactating Women	131 480/615 583	20,2%	287 490	$8 624 700
Sex Workers	45 600/93 000	46%	100 960	$3 028 800
Gay & Bisexual Men who have Sex with Men	40 800 /28191	14,5%	86 380	$2 591 400
Transgender Individuals	18 800/62 130	30,3%	40 740	$1 222 200
Total	**456 360/ 36 280 268**	**1%**	**974 450**	**$29 233 500**

RESOURCE REQUIREMENTS TO SUPPORT LENACAPAVIR SCALE-UP

Item	ZAR	USD
Lenacapavir (Global Fund)	R271,008,000	$29,220,000
Additional resource requirements		
IEC materials, guidelines and job aids	R900,000	$50,000
Clinical stationery	R500,000	$20,000
Social mobilization	R1,750,000	$100,000
Training (9 provinces 25 districts 350 facilities)	R1,750,000	$100,000
M&E system deployment, equipment, data housing	R2,750,000	$155,000
Total	**R7,650,000**	**$425,000**

WAY FORWARD

- Finalise geographic and facility coverage for Phase 1 implementation of Lenacapavir following consultation with key stakeholders and provinces
- Update the information system
- Commencement date 1 February or 1 April 2026 depending on SAHPRA registration and commodity availability

THANK YOU