UNITED REPUBLIC OF TANZANIA

NATIONAL AIDS, STIs AND HEPATITIS CONTROL PROGRAM

OPERATIONAL GUIDE FOR THE INTRODUCTION OF LONG-ACTING INJECTABLE LENACAPAVIR (LEN) FOR HIV PREVENTION IN TANZANIA

JULY, 2026

Dodoma, Tanzania

UNITED REPUBLIC OF TANZANIA

NATIONAL AIDS, STIs AND HEPATITIS CONTROL PROGRAM

OPERATIONAL GUIDE FOR THE INTRODUCTION OF LONG-ACTING INJECTABLE LENACAPAVIR (LEN) FOR HIV PREVENTION IN TANZANIA

JULY 2026

Dodoma, Tanzania

UNITED REPUBLIC OF TANZANIA

NATIONAL AIDS, STIs AND HEPATITIS CONTROL PROGRAM

OPERATIONAL GUIDE FOR THE INTRODUCTION OF LONG-ACTING INJECTABLE LENACAPAVIR (LEN) FOR HIV PREVENTION IN TANZANIA

JUNE 2026

Dodoma, Tanzania

National AIDS, STIs and Hepatitis Control Program (NASHCoP)
Ministry of Health
P.O. Box 784, Dodoma, Tanzania
Kilimani Area, NASHCoP and NTLP Building
Tel: +255 22 2131213
Fax: +255 22 2138282
E-mail: info@nacp.go.tz
Website: www.nacp.go.tz

ISBN: 978-9987-835-17-____

Copyright Notice

FOREWORD

The health and wellbeing of all Tanzanians remain central to our national development agenda. As we continue to strengthen our response to HIV, it is imperative that we embrace innovations that enhance the quality, accessibility, and effectiveness of prevention services while responding to the evolving needs of our communities.

The introduction of long-acting injectable Lenacapavir (LEN) reflects Tanzania's commitment to advancing evidence-informed public health interventions and ensuring that individuals at risk of HIV infection have access to a wider range of prevention choices. The availability of innovative prevention technologies presents an opportunity to further strengthen our efforts toward achieving national and global targets for HIV epidemic control.

The successful introduction of any new health intervention requires more than the availability of a product. It demands strong leadership, effective coordination, adequate health system preparedness, meaningful community participation, and sustained commitment from all stakeholders. This Operational Guide has been developed to support these efforts by providing a framework for coordinated implementation and accountability across all levels of the health system.

The Ministry of Health recognizes that the success of this initiative will depend on the collective efforts of government institutions, healthcare workers, development partners, civil society organizations, researchers, communities, and the individuals who will ultimately benefit from these services. We therefore call upon all stakeholders to work collaboratively to ensure that the introduction of LEN is implemented with the highest standards of quality, safety, equity, and respect for human rights.

As Tanzania continues to pursue Universal Health Coverage and the goal of ending AIDS as a public health threat, strategic investments in prevention remain essential. The introduction of LEN represents an important step in strengthening our prevention response and reaffirming our commitment to delivering people-centered health services that leave no one behind.

I commend all those who contributed to the development of this Operational Guide and encourage its effective utilization in supporting the successful introduction and scale-up of LEN services across the country.

Dr. Grace Magembe
Chief Medical Officer
Ministry of Health
United Republic of Tanzania

PREFACE

The National AIDS, STIs and Hepatitis Control Program (NASHCoP) has the mandate to provide technical leadership and coordination of HIV prevention, care, treatment, and support services in Tanzania. As the HIV prevention landscape continues to evolve, there is a need to ensure that national programs are equipped to effectively introduce and implement emerging evidence-based interventions that can further strengthen the country's HIV response.

This Operational Guide for the Introduction of Long-Acting Injectable LEN for HIV Prevention in Tanzania has been developed to support the translation of policy and scientific evidence into practical implementation. The guide provides operational direction to program managers, healthcare providers, implementing partners, community organizations, and other stakeholders involved in delivering HIV prevention services. It is intended to promote standardized implementation while allowing flexibility to respond to local contexts and service delivery realities.

The development of this guide was informed by a comprehensive review of global evidence, international normative guidance, national policies and strategic priorities, as well as extensive consultations with technical experts, implementing partners, healthcare providers, development partners, civil society organizations, and representatives of communities that will benefit from these services. This collaborative process has ensured that the guidance provided is practical, relevant, and responsive to the needs of the Tanzanian context.

As implementation progresses, valuable lessons and experiences will emerge from different service delivery settings. NASHCoP remains committed to continuously reviewing and updating this guidance to reflect new evidence, implementation experiences, technological advancements, and evolving programmatic needs. The guide should therefore be regarded as a dynamic implementation resource that will continue to evolve alongside the national HIV prevention program.

The successful introduction of LEN will require commitment, collaboration, and accountability from all stakeholders. NASHCoP encourages all implementers and service providers to utilize this guide in promoting quality service delivery, safeguarding client safety, strengthening program performance, and ensuring that individuals at risk of HIV infection are able to make informed choices regarding available prevention options.

We extend our sincere appreciation to all individuals and institutions whose expertise, dedication, and support contributed to the development of this Operational Guide. Their contributions have been invaluable in ensuring the production of a practical and high-quality resource that will support implementation efforts across the country.

Dr. Prosper Njau
Program Manager
National AIDS, STIs and Hepatitis Control Program (NASHCoP)
Ministry of Health

ACKNOWLEDGEMENTS

The Ministry of Health of the United Republic of Tanzania (MoH) expresses its sincere appreciation to all institutions, organizations, and individuals whose commitment, expertise, and support made the development of this Operational Guide for the Introduction of Long-Acting Injectable LEN for HIV Prevention in Tanzania possible.

The development of this Operational Guide was undertaken through a consultative process involving technical experts, implementing partners, development partners, civil society organizations, academic institutions, healthcare providers, and community representatives. Their contributions were instrumental in ensuring that this guide reflects global evidence, national priorities, and implementation realities within the Tanzanian context.

The Ministry extends special appreciation to the National AIDS, STIs and Hepatitis Control Program (NASHCoP) for providing leadership, coordination, and technical oversight throughout the development process. The Ministry further recognizes the dedication of members of the HIV Prevention Technical Working Group, whose expertise and guidance greatly enriched the content and strategic direction of this document. The Ministry also acknowledges the contributions of the drafting team, technical reviewers, and members of the LEN Technical Task Team for their role in the preparation and review of this document.

The Ministry further acknowledges the valuable collaboration of key national stakeholders, including the Tanzania Commission for AIDS (TACAIDS), the Prime Minister's Office – Regional Administration and Local Government (PMO-RALG), Regional Health Management Teams (RHMTs), Council Health Management Teams (CHMTs), civil society organizations, community-led organizations, and representatives of key and vulnerable populations. Their participation ensured that the guide remains responsive to the needs of communities most affected by HIV in Tanzania.

Special recognition is extended to development partners and international agencies for their technical and financial support during the development of this Operational Guide. The Ministry sincerely appreciates the contributions of the World Health Organization (WHO), United Nations Program on HIV/AIDS (UNAIDS) the United States Government and its agencies, including the Centers for Disease Control and Prevention (CDC), Department of State (DoS) and Department of War (DoW), as well as implementers such as Amref Health Africa, Family Health International 360, HJF Medical Research International, Inc., ICAP at Columbia University, KVP Forum, and Tanzania Health Promotion Support. Their technical expertise, guidance, and collaboration were instrumental in supporting the development and review of this Operational Guide.

Finally, while it is not possible to mention every individual who contributed to this undertaking, the Ministry extends its heartfelt gratitude to all stakeholders who participated in the development, review, and validation of this Operational Guide. Your commitment and dedication were instrumental in ensuring its timely completion.

EXECUTIVE SUMMARY

Long-acting injectable LEN represents a major advancement in HIV prevention. Administered every six months, LEN provides sustained protection against HIV acquisition while reducing challenges associated with daily oral PrEP. Evidence from clinical trials has demonstrated high efficacy and a favorable safety profile, positioning LEN as an important addition to HIV prevention options. In line with World Health Organization recommendations and Tanzania's commitment to expanding prevention choices, LEN will be introduced as an additional PrEP option within the national HIV prevention program.

This Operational Guide provides comprehensive programmatic, clinical, and operational guidance for the phased introduction and scale-up of LEN in Tanzania. The guide outlines the policy and regulatory framework, service delivery models, clinical protocols, eligibility and screening procedures, injection administration requirements, follow-up schedules, pharmacovigilance, commodity management, capacity building, monitoring and evaluation, demand creation, governance, and risk management.

Implementation will be phased over the period 2027–2029. Initial rollout will begin at National, Specialized, Zonal Referral, and Regional Referral Hospitals, followed by expansion to District Hospitals and Designated District Hospitals, and subsequently to lower-level health facilities and community-based service delivery platforms based on implementation readiness and lessons learned. LEN will be offered to individuals at substantial risk of HIV acquisition as part of a comprehensive HIV prevention package. Priority populations include adolescent girls and young women, people who inject drugs, HIV-negative partners in sero-discordant relationships, pregnant and breastfeeding women at substantial risk, and selected mobile and occupational populations. PrEP eligibility will be determined through individualized risk assessment and clinical screening in accordance with national guidelines.

Successful implementation will require strong leadership, effective coordination, adequate provider capacity, reliable health commodity systems, meaningful community engagement, and continuous program monitoring.

This Operational Guide provides a framework for the safe, equitable, and coordinated introduction of LEN in Tanzania. Through its implementation, Tanzania seeks to expand HIV prevention choices, improve access to effective prevention services for populations at substantial risk of HIV infection, and accelerate progress toward ending AIDS as a public health threat by 2030.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS AND ACRONYMS

AE	Adverse Event
ADR	Adverse Drug Reaction
AGYW	Adolescent Girls and Young Women
AHD	Advanced HIV Disease
AIDS	Acquired Immunodeficiency Syndrome
AMREF	Amref Health Africa
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
CAB	Cabotegravir
CAB-LA	Long-Acting Injectable Cabotegravir
CDC	Centers for Disease Control and Prevention
CHMT	Council Health Management Team
CSO	Civil Society Organization
DHIS2	District Health Information System 2
DoS	United States Department of State
DSD	Differentiated Service Delivery
EID	Early Infant Diagnosis
EMR	Electronic Medical Records
FBO	Faith-Based Organization
FHI 360	Family Health International 360
FTC	Emtricitabine
GC8	Global Fund Grant Cycle 8
GoT	Government of Tanzania
HBsAg	Hepatitis B Surface Antigen
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HJFMRI	Henry M. Jackson Foundation Medical Research International
HMIS	Health Management Information System
HTS	HIV Testing Services
ICAP	ICAP at Columbia University
IPC	Infection Prevention and Control
KVP	Key and Vulnerable Population
KVP Forum	Key and Vulnerable Populations Forum
LEN	Lenacapavir
LMIS	Logistics Management Information System
MARPs	Most-at-Risk Populations
M&E	Monitoring and Evaluation
MoH	Ministry of Health
MSD	Medical Stores Department
NASHCoP	National AIDS, Sexually Transmitted Infections and Hepatitis Control Programme
OPD	Outpatient Department
PEP	Post-Exposure Prophylaxis
PEPFAR	President's Emergency Plan for AIDS Relief
PHC	Primary Health Care
PLHIV	People Living with HIV
PMO-RALG	Prime Minister's Office – Regional Administration and Local Government

PMTCT	Prevention of Mother-to-Child Transmission
PrEP	Pre-Exposure Prophylaxis
PWID	People Who Inject Drugs
RCH	Reproductive and Child Health
RHMT	Regional Health Management Team
SAE	Serious Adverse Event
SBCC	Social and Behaviour Change Communication
SOP	Standard Operating Procedure
SRH	Sexual and Reproductive Health
STI	Sexually Transmitted Infection
TACAIDS	Tanzania Commission for AIDS
THPS	Tanzania Health Promotion Support
TMDA	Tanzania Medicines and Medical Devices Authority
ToT	Training of Trainers
TWG	Technical Working Group
UNAIDS	Joint United Nations Programme on HIV/AIDS
USG	United States Government
WHO	World Health Organization

CHAPTER ONE: INTRODUCTION

1.1 Background

Tanzania has made significant progress in its response to HIV and AIDS over the past two decades through sustained investments in prevention, treatment, care, and support services. HIV prevalence among adults aged 15–49 years has declined substantially, and the country has achieved notable progress towards the global UNAIDS 95-95-95 targets. According to the Tanzania HIV Impact Survey (THIS) 2022–2023, approximately 1.7 million people are living with HIV in Tanzania, with 83% aware of their HIV status, 98% of those diagnosed receiving antiretroviral therapy (ART), and 92% of those on treatment achieving viral suppression. Despite these achievements, new HIV infections continue to occur, particularly among populations at elevated risk, including adolescent girls and young women (AGYW), key and vulnerable populations (KVPs), and other individuals experiencing social, structural, and behavioral vulnerabilities.

To accelerate progress towards ending AIDS as a public health threat by 2030, Tanzania has implemented a comprehensive combination HIV prevention approach that includes HIV testing services, voluntary medical male circumcision, condom promotion, behavioral interventions, prevention of mother-to-child transmission, harm reduction services, and biomedical prevention interventions such as pre-exposure prophylaxis (PrEP). Since its introduction in 2017, oral PrEP has become an important component of the national HIV prevention program, offering effective protection against HIV acquisition for individuals at substantial risk of HIV infection.

Although oral PrEP has expanded access to HIV prevention services, challenges related to daily pill-taking, adherence, persistence, stigma, mobility, and individual preferences continue to affect its optimal utilization. Experience from Tanzania and other HIV high burden countries has demonstrated that no single HIV prevention option can adequately meet the diverse needs of all populations at risk. Expanding prevention choices is therefore essential to increase uptake, improve adherence, and strengthen the effectiveness of HIV prevention program.

Despite the expansion of oral PrEP services, PrEP coverage among populations at substantial risk of HIV infection remains below national targets, with challenges related to initiation, adherence, persistence, stigma, frequent clinic visits, and mobility contributing to suboptimal program outcomes. Evidence from Tanzania has shown that many individuals discontinue oral PrEP within the first few months of initiation, underscoring the need for additional HIV prevention options that better align with clients' preferences and lifestyles. Introducing long-acting injectable LEN will expand prevention choices and support a more client-centered approach to HIV prevention.

The development of long-acting HIV prevention technologies represents a major advancement in biomedical HIV prevention. In 2025, the World Health Organization (WHO) recommended long-acting injectable Lenacapavir as an additional HIV pre-exposure prophylaxis (PrEP) option for individuals at substantial risk of HIV acquisition. LEN, a first-in-class capsid inhibitor, offers sustained protection against HIV acquisition through a subcutaneous injection administered once every six months. Clinical trials have demonstrated high efficacy, favorable safety profiles, and strong acceptability among diverse populations, including women, priority populations, and

other individuals at substantial risk of HIV infection. By reducing the need for daily medication, LEN addresses one of the most important barriers to effective PrEP use and has the potential to substantially increase prevention coverage and adherence.

In line with emerging global evidence and recommendations from the WHO and experience from high HIV burden countries, the Government of Tanzania, through the Ministry of Health and the National AIDS, STIs and Hepatitis Control Program (NASHCoP), is introducing long-acting injectable LEN as an additional HIV prevention option within the national PrEP program. The introduction of LEN reflects Tanzania's commitment to expanding prevention choices, promoting client-centered care, and ensuring equitable access to innovative HIV prevention technologies.

This Operational Guide has been developed to provide practical guidance for the phased implementation and scale-up of LEN in Tanzania. The guide complements existing national HIV prevention policies, PrEP implementation frameworks, and Integrated management of HIV, Syphilis and Hepatitis 'B' guidelines by outlining the programmatic, clinical, operational, and health system requirements necessary for successful implementation.

1.2 Purpose of the Operational Guide

The purpose of this Operational Guide is to provide comprehensive technical and programmatic guidance for the safe, effective, and coordinated introduction of long-acting injectable LEN for HIV prevention in Tanzania. The guide serves as a practical reference for policymakers, program managers, healthcare providers, implementers, community organizations, and other stakeholders involved in HIV prevention service delivery.

Specifically, the guide provides direction on program planning and coordination, service delivery models, client eligibility and screening procedures, clinical management, commodity management, provider capacity building, pharmacovigilance, monitoring and evaluation, demand creation, community engagement, and governance arrangements required for successful implementation. The guide is intended to support standardized implementation while allowing flexibility for adaptation to different service delivery settings and local contexts.

1.3 Scope of the Operational Guide

This guide covers the introduction, implementation, and phased expansion of LEN services within Tanzania's national HIV prevention program. It applies to national, regional, council, facility, and community levels involved in HIV prevention programming and service delivery.

The guide supports implementation across multiple service delivery platforms, including health facilities, reproductive and child health clinics, HIV testing services, sexually transmitted infection clinics, community-based programs, outreach services, and differentiated service delivery models targeting priority populations.

The scope of the guide includes program planning and coordination, clinical service delivery, site readiness, workforce development, supply chain management, infection prevention and control, pharmacovigilance, monitoring and evaluation, community engagement, demand creation, and quality improvement. The guide should be

implemented alongside the existing NATIONAL PREP IMPLEMENTATION FRAMEWORK, COMPREHENSIVE HIV PREVENTION AND TESTING, AND THE INTEGRATED MANAGEMENT OF HIV, SYPHILIS, HEPATITIS GUIDELINES' and does not replace any current national policies or regulatory requirements.

1.4 Policy and Regulatory Framework

The introduction of LEN is guided by Tanzania's national health policies, HIV prevention strategies, and regulatory frameworks. Implementation aligns with the 'NATIONAL INTEGRATED GUIDELINES FOR THE MANAGEMENT OF HIV, STIS AND VIRAL HEPATITIS, THE CONSOLIDATED HIV PREVENTION GUIDELINE, NATIONAL PREP IMPLEMENTATION FRAMEWORK' and other relevant national strategic documents that support the expansion of evidence-based HIV prevention interventions.

Confirming LEN's quality, efficacy and safety for use, the Tanzania Medicines and Medical Devices Authority (TMDA) approved LEN for HIV prevention use in Tanzania in November 2025. The introduction is further supported by global recommendations, including WHO guidance endorsing LEN as an additional PrEP option within comprehensive HIV prevention programs.

The Government of the United Republic of Tanzania through NASHCoP at the Ministry of Health will provide leadership and oversight of provision of LEN in collaboration with the Prime Minister's Office – Regional Administration and Local Government (PMO-RALG) and Tanzania Commission for AIDS (TACAIDS). LEN implementation will be done by the Government of Tanzania (GoT) in partnership with the development partners, implementers, healthcare providers and civil society/beneficiaries/population at risk/recipients of care.

1.5 PrEP Options and the Need for Prevention Choice

Tanzania currently offers oral PrEP as part of its HIV prevention package and continues to expand access through facility-based and community-based service delivery models. While oral PrEP remains highly effective when taken consistently, differences in client preferences, lifestyles, risk patterns, and adherence challenges necessitate the availability of multiple prevention options.

The introduction of LEN expands the national HIV prevention portfolio by providing a long-acting alternative for individuals who prefer less frequent dosing, require greater privacy, experience challenges with daily pill-taking, or may benefit from more discreet prevention methods. Expanding prevention choices supports informed decision-making, improves user satisfaction, and increases the likelihood of sustained engagement in prevention services. Evidence from the PURPOSE 1 study demonstrated that LEN provides exceptionally high protection against HIV acquisition and offers a practical option for populations who may not achieve optimal adherence with daily oral PrEP. The availability of multiple prevention options strengthens Tanzania's combination prevention strategy and contributes to reducing HIV incidence across diverse populations and settings.

1.6 Guiding Principles for Implementation

The introduction of LEN in Tanzania will be guided by principles of equity, human rights, quality, and person-centred care. LEN services will be integrated within comprehensive HIV prevention and testing services and delivered through approaches that promote accessibility, acceptability, and informed choice.

Implementation will ensure that individuals can voluntarily select the HIV prevention method most appropriate for their needs and circumstances without coercion, stigma, or discrimination. Service delivery models will be responsive to local epidemiology, community needs, and health system capacity while maintaining high standards of safety and quality. The introduction of LEN will adopt a multisectoral approach that actively engages communities, civil society organizations, healthcare providers, implementing partners, and government institutions throughout planning, implementation, monitoring, and evaluation processes. Lessons learned from oral PrEP implementation and emerging evidence from long-acting prevention programs will be continuously applied to strengthen service delivery and support sustainable scale-up.

CHAPTER TWO: NATIONAL IMPLEMENTATION STRATEGY

2.1 Goal and Objectives

2.1.1 Goal

To provide operational guidance for the safe, effective, client centered and equitable implementation and scale-up of long-acting injectable LEN for HIV prevention in Tanzania.

2.1.2 Objectives

1. To standardize client-centered LEN service delivery, including eligibility assessment, initiation, administration, follow-up, and discontinuation.
2. To provide guidance on the management of adverse events, drug–drug interactions, active safety and toxicity monitoring, and pharmacovigilance for clients receiving LEN in accordance with national guidelines and WHO recommendations.
3. To support integration of LEN into existing HIV prevention and related health services and HIVDR monitoring.
4. To strengthen health system readiness through capacity building, commodity management, and quality assurance systems.
5. To provide guidance on community engagement, demand creation, monitoring and evaluation, and phased scale-up of LEN services.

2.2 Program Scale-Up Phases

The scale-up of new PrEP options will follow a phased implementation approach. Product introduction will be based on geographical coverage (regions), with regional selection guided by the following criteria:

1. High HIV incidence rates
2. Low levels of HIV status awareness
3. Low viral load suppression rates
4. Higher estimated populations of MARPs
5. Lower PrEP adherence and retention rates
6. Regions with high MTCT rates

To ensure effective preparation, capacity building, and high-quality service delivery across the selected regions and facilities, the phased implementation will be coordinated in collaboration with TACAIDS, the Ministry of Health (MoH), implementing partners, and civil society organizations (CSOs).

Figure 1. Phases of LEN Introduction and Scale-Up in Tanzania

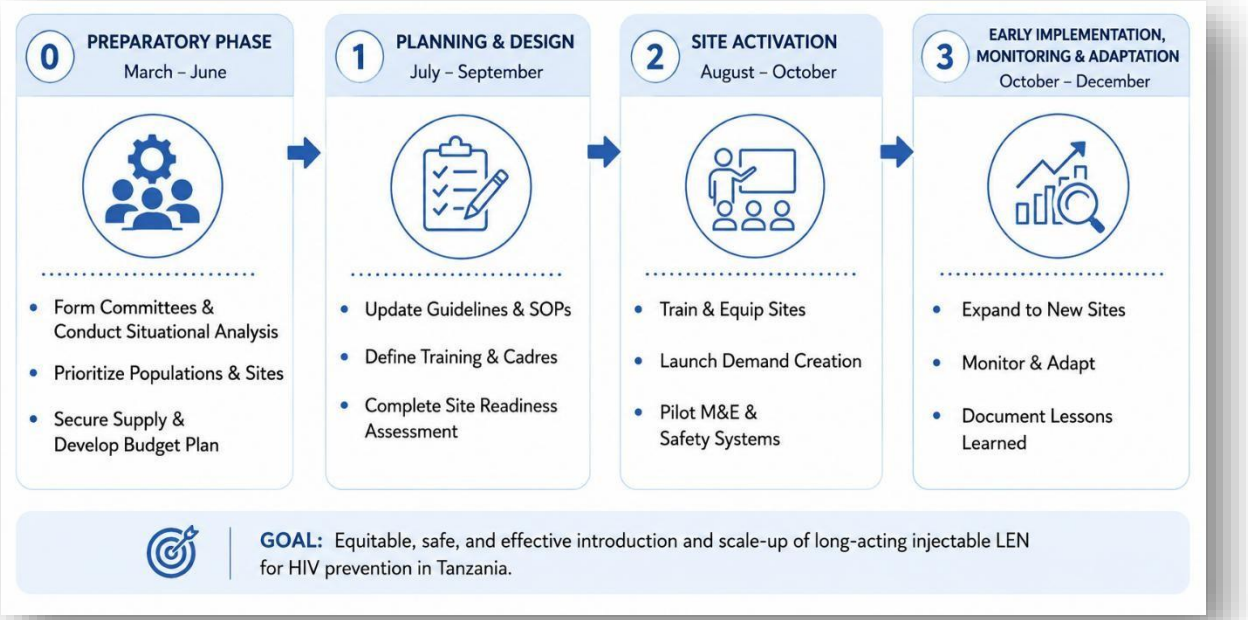


Table 2.1: Detailed Activities by Implementation Phase

Phases of Program Rollout	Task Requirements
Phase 0: Preparatory phase	• Establish National LEN Implementation Committee (as a sub-group of Prevention TWG) and Community Advisory Board (CAB); define terms of reference and meeting flow.
	• Conduct a situational analysis covering epidemiology, policy/regulation, workforce, service delivery platforms, supply chain, financing, data systems, and community engagement.
	• Agree preliminary prioritization: target populations, geographic focus, delivery models, and initial site list; finalize criteria and documentation.
	• Secure supply allocations and finalize inclusion in GC8 request; develop preliminary budget and resource mobilization plan.
	• Design communications and demand creation strategy in partnership with community-led organizations.

Phases of Program Rollout	Task Requirements
Phase 1: Planning and Design	• Update national guidelines and clinical SOPs; integrate LEN within method-mix frameworks; finalize provider job aids.
	• Define provider cadres and task-shifting approach; develop competency-based training curricula and cascade plan.
	• Complete site readiness assessments; confirm activation sequence and go/no-go criteria.
	• Integrate essential LEN indicators into national HMIS; configure data capture and dashboards for sentinel sites and routine reporting.
	• Finalize quantification, procurement budget, storage, waste management, and distribution micro-plans; set buffer stock policies.
	• Complete investment case and budget impact analysis for GC8; align domestic and partner financing.
Phase 2: Pre-Implementation readiness/Site activation	• Deliver cascade training and certification (initiation and follow-up tiers) for prioritized sites; deploy mentorship and supervision plan.
	• Equip sites with required commodities, supplies, safety boxes, and data tools; test client flow and recall systems.
	• Launch demand creation with community partners; activate peer navigation and client support mechanisms.
	• Pilot dashboards and adverse event reporting; validate active pharmacovigilance and safety monitoring workflows, SoPs and referral pathways.
	• Initiate service delivery with soft launches at sentinel sites; refine protocols and logistics based on early feedback.
Phase 3: Early Implementation, Monitoring, Learning, and Adaptation	• Progressively expand to additional sites based on readiness and supply; maintain equity guardrails and transparent criteria.
	• Run monthly initiation task team meeting reviews for first 6 months; adjust delivery models (facility/community/mobile) and staffing as needed.

Phases of Program Rollout	Task Requirements
	• Track essential indicators: initiations, on-time injections (±2 weeks), continuation at 6/12 months, adverse events, seroconversions with HIVDR monitoring, and user satisfaction.
	• Document lessons; update SOPs and micro-plans; produce a national learning brief each quarter.

Important Considerations for LEN Introduction in Tanzania

- The introduction of LEN will follow a phased implementation approach from 2027 to 2029, beginning with higher-level health facilities and progressively expanding to lower-level facilities and selected community service delivery platforms based on readiness and lessons learned.
- Geographical and facility selection will be guided by HIV epidemiological burden, population needs, service readiness, human resource capacity, commodity security, and existing HIV prevention program performance.
- LEN will be offered to eligible individuals at substantial risk of HIV acquisition as part of the national PrEP method mix, following clinical eligibility assessment, HIV testing, counselling, and informed client choice.
- Service delivery will utilize both facility-based and community-based models, including OPD, HTS, ANC, PMTCT, STI, RCH, ART clinics, outreach services, mobile clinics, and other approved differentiated service delivery platforms.
- National PrEP training curricula, implementation tools, job aids, and standard operating procedures (SOPs) will be revised to incorporate LEN-specific clinical and operational guidance.
- Healthcare providers from selected implementation sites will receive competency-based training, mentorship, and supportive supervision to ensure safe and effective LEN service delivery.
- National recording and reporting tools, electronic medical records, pharmacovigilance systems, and monitoring and evaluation platforms will be updated to capture LEN-specific indicators and support routine program monitoring.
- Commodity forecasting, quantification, procurement, storage, distribution, and waste management systems will be strengthened to ensure uninterrupted availability of LEN commodities throughout implementation.
- Demand creation, community engagement, and social and behaviour change communication interventions will be implemented to increase awareness, promote informed choice, and support uptake and continuation of LEN services.
- Continuous program monitoring, pharmacovigilance, quality improvement, and implementation learning will be conducted to inform adaptation and national scale-up

2.3 Geographical Roll-Out and Phased Scale-Up of Long-Acting Injectable LEN

2.3.1 Roll-Out Methodology

The introduction of Long-Acting Injectable LEN in Tanzania will follow a phased, tiered health system approach to ensure safe, efficient, and equitable access to HIV prevention services. Implementation will commence at higher-level health facilities with advanced clinical capacity, established HIV prevention and treatment services, and the ability to support provider mentorship and program learning.

The phased scale-up strategy is guided by health facility level and service readiness. This approach will facilitate gradual expansion of services while ensuring adequate provider competency, quality assurance, commodity security, pharmacovigilance and active safety monitoring, and program monitoring systems are established before wider implementation.

Facilities selected during the initial phases will serve as centres of excellence for LEN implementation, generating lessons learned and best practices that will inform subsequent expansion phases. The phased approach is intended to reduce geographical inequities in access to HIV prevention services and ensure that eligible individuals throughout the country can benefit from LEN.

In addition, all parastatal hospitals will commence LEN implementation during Phase I of the national rollout.

Table 2.2 Phased National Roll-Out Plan

Phase	Period	Facilities Targeted
Phase I	April – June 2027	• National Hospitals
		• Specialized Hospitals
		• All Zonal Referral Hospitals
		• 17 Regional Referral Hospitals
		• All Parastatal Hospitals
Phase II	July – September 2027	• Remaining 13 Regional Referral Hospitals
		• Selected high-volume Council Hospitals
Phase III	October – December 2027	• All Council Hospitals (92)
		• All Designated District Hospitals (DDHs)
Phase IV	January – March 2028	• High-volume Health Centres
		• Selected Faith-Based Organization (FBO) Facilities
		• Selected Private Health Facilities
Phase V	April – June 2028	• Stand-alone Pharmacies (subject to regulatory approval and readiness requirements)
		• Additional private and community-based service delivery platforms

2.3.2 Regional Expansion Approach

Geographical expansion within each region will follow a hub-and-spoke model whereby Regional Referral Hospitals and high-capacity facilities established during earlier phases provide technical mentorship, supportive supervision, and quality assurance support to lower-level facilities joining implementation during later phases.

The MoH reserves the right to adjust the sequencing of facility enrollment based on service readiness assessments, commodity availability, human resource capacity, and lessons learned during implementation.

CHAPTER THREE: CLINICAL AND SERVICE DELIVERY COMPONENTS

3.1 Service Delivery Model(s)

The delivery of long-acting injectable LEN for HIV prevention in Tanzania will be integrated within existing HIV prevention platforms to ensure efficient, accessible, and client-centred service delivery. Integrating LEN into established service delivery systems will allow the program to leverage existing infrastructure, trained health care providers, community networks, and monitoring systems developed for HIV prevention and PrEP services.

The service delivery model will combine facility-based services, community-based platforms, and differentiated service delivery (DSD) approaches to ensure that LEN services are accessible to individuals at substantial risk of HIV infection across diverse settings.

3.1.1 Health Facility–Based Delivery

Health facilities will serve as primary points for the delivery of LEN services, particularly for clinical assessment, HIV testing, and administration of injections. LEN services may be offered through various facility-based platforms where HIV prevention services are already provided, including:

- **HIV clinics:** These clinics provide a key entry point for individuals seeking HIV prevention services, particularly sero-discordant couples and individuals accessing HIV testing and counselling services.
- **Reproductive and Child Health (RCH) clinics:** RCH services provide an important opportunity to identify and reach pregnant, breastfeeding Women Adolescent girls and Young Women (AGYW) at substantial risk of HIV infection. HIV-negative pregnant women, breastfeeding and Adolescent girls who remain at ongoing risk should be assessed for HIV prevention options, including LEN, in accordance with national guidelines. Integration of LEN into RCH platforms will support the delivery of comprehensive sexual and reproductive health services. Pregnancy and breastfeeding are not reasons to discontinue LEN where HIV risk persists.
- **Sexually Transmitted Infection (STI) clinics:** STI clinics are important service delivery points for HIV prevention. Individuals attending STI clinics for screening, diagnosis, or treatment should be routinely assessed for their risk of HIV acquisition and offered appropriate HIV prevention services, including oral PrEP or long-acting injectable LEN, in accordance with national guidelines. Clients presenting with STI symptoms in other service delivery points, such as outpatient departments (OPDs), should similarly be assessed for HIV prevention needs and linked to appropriate PrEP services, including LEN where eligible.
- **HIV Testing Services (HTS) Points**: All HIV testing service delivery points should be considered entry points for LEN. These include standalone HTS sites, provider-initiated testing and counselling (PITC) services, voluntary counselling and testing (VCT) centres, index testing services, and HIV self-testing linkage points. Individuals testing HIV-negative and identified as being at substantial risk of HIV infection should be assessed for LEN eligibility and linked to appropriate prevention services.

- **Outpatient Department (OPD):** General outpatient clinics serve a large and diverse population and offer opportunities to identify individuals who may benefit from HIV prevention services. Clients presenting with recurrent STIs, multiple HIV testing visits, high-risk sexual behaviours, or other HIV risk factors can be screened and referred for LEN services.
- **Family Planning Clinics**: Family planning services frequently serve sexually active women and couples who may benefit from integrated HIV prevention services. Offering LEN information, screening, and referral within family planning settings supports person-centred and integrated care.
- **Tuberculosis (TB) Clinics and TB Screening Services**: Routine HIV testing conducted within TB services can identify HIV-negative individuals who may have ongoing HIV exposure risks. Eligible clients can be counselled and linked to LEN services as part of integrated TB/HIV programming.
- **Gender-Based Violence (GBV) and One-Stop Centres:** Survivors of sexual violence may require comprehensive HIV prevention services, including post-exposure prophylaxis (PEP), ongoing HIV risk assessment, and transition to PrEP services such as LEN when appropriate. These centres should have strong referral pathways to LEN service delivery points.

Health facilities offering LEN services must ensure that trained providers are available to conduct eligibility screening, HIV testing, counselling, injection administration, and follow-up monitoring.

The service package in Tanzania to be offered alongside LEN may include: Hepatitis B Surface Antigen (HBsAg), and screening for STIs. Mental health and substance use assessments, as well as linkage to other combination HIV prevention methods (e.g., condoms, voluntary medical male circumcision, and partner services). This integrated approach reinforces PrEP delivery as part of a comprehensive continuum of care, rather than a standalone intervention.

3.1.2 Community-Based Service Delivery

Community-based platforms will play an essential role in increasing access to LEN services, particularly among key and priority populations who may face barriers to accessing facility-based care. Community service delivery models may include the following:

- **Facility-led community outreach services:** Trained healthcare providers from HFs, supported by peer educators and community organizations, may deliver LEN services through facility-led community outreach services through mobile clinics, motorcycles, vehicles, and on foot. During outreach services, HCPs and peer educators will provide community mobilization, demand creation, HIV testing and eligibility assessment, initiation and administration of LEN injections, follow-up, adherence support, and referral for additional HIV prevention, treatment, and care services as needed.

Community platforms will also play a key role in demand creation, client education, adherence support, and follow-up, helping to strengthen retention in prevention services.

3.2 Application of Differentiated Service Delivery Approaches at facility and community settings

The introduction of LEN will incorporate DSD models designed to improve convenience, accessibility, and client satisfaction. These approaches will ensure that services are tailored to the needs and preferences of individuals and populations at substantial risk of HIV infection.

Key DSD approaches include:

- **Integration within existing PrEP programs:** LEN will be offered alongside oral PrEP as part of the national PrEP method mix, enabling clients to choose the prevention option that best suits their needs and circumstances.
- **Client-centred service delivery:** Providers will support informed choice by counselling clients on available prevention options, including the benefits and potential risks of each method. Services will be delivered in a manner that respects client preferences, privacy, and confidentiality.

Where possible, service delivery models will also incorporate peer support, community navigation, and linkage systems to facilitate access to services and promote continuity of care.

Overall, the integration of facility-based services, community-based delivery platforms, and differentiated service delivery approaches will help ensure that LEN services are accessible, acceptable, and responsive to the needs of diverse populations, thereby strengthening the effectiveness of HIV prevention efforts in Tanzania.

3.3 Package of Services Offered with PrEP

Table 3.1: Package of Services Offered with PrEP

Service	Package of Services
HIV Testing Services	• Confirm HIV-negative status before initiation
	• Regular retesting (upon every visit depending on the PrEP choice)
Risk Assessment and Counselling	• Understand individual HIV prevention and sexual health needs (including potential exposures)
	• Provide information on HIV prevention options
Sexually Transmitted Infection (STI) Screening and Treatment	• Routine screening for STIs
	• Syndromic or lab-based treatment where necessary
Contraceptive Services (especially for women and AGYW)	• Offer a range of contraceptive options
	• Discuss pregnancy intentions and options
Hepatitis Screening and Vaccination	• HBV and HCV testing if available
	• Where feasible, clients initiating PrEP should be screened and tested for hepatitis B and, if positive

Service	Package of Services
	and eligible, link to appropriate treatment. The choice of PrEP should be guided by client preferences, HBV clinical assessment and national HIV and hepatitis B management guidelines. Where indicated, TDF-containing oral PrEP may be the preferred option because it is active against both HIV and HBV
	• Availability of or access to hepatitis B testing should not be a barrier to PrEP initiation or use.
	• Offer Vaccination for Hepatitis B, if available
Mental Health and Psychosocial Support	• Screening for depression, anxiety, GBV, and substance use
	• Referral or in-house support where possible
Harm Reduction Supplies	• Condoms
	• Educational materials
Referrals and Linkages	• Linkage to other services such as support for survivors of sexual violence, substance use treatment, and ART services if HIV-positive

3.4 Eligibility and Screening

Ensuring appropriate client eligibility and thorough screening is essential for the safe and effective use of long-acting injectable LEN for HIV prevention. Health care providers must follow standardized eligibility and screening procedures to confirm that clients are suitable candidates for LEN and to minimize the risk of initiating PrEP in individuals with undiagnosed HIV infection.

LEN should be offered as an additional prevention choice for people at risk of HIV, as part of combination prevention approaches. Prior to initiation, all potential clients must undergo a comprehensive clinical assessment that includes HIV testing, clinical eligibility, and counselling to support informed decision-making

3.4.1 Eligibility Criteria

Clients considered for LEN should meet the following eligibility criteria:

- Confirmed HIV-negative status: Clients must test negative for HIV using the national HIV testing algorithm prior to initiation.
- At substantial risk of HIV infection: This includes individuals whose circumstances, behaviors, or epidemiological context place them at increased risk of HIV acquisition.
- Willingness to use long-acting injectable PrEP: Clients must express interest in and willingness to receive LEN as a long-acting HIV prevention option after receiving appropriate counselling on available PrEP products. They must also be willing to take the oral loading doses as prescribed.
- Ability to adhere to follow-up visits: Clients must be willing and able to return to the health facility or designated service delivery point for follow-up visits and repeat injections according to the recommended six-month (26 weeks +/- 2

weeks) dosing schedule. Regular follow-up is important to ensure continued HIV-negative status and ongoing protection against HIV infection.

In addition, providers should assess the client's overall health status and ensure there are no potential drug–drug interactions such as; anti-TB medications rifampicin to receiving LEN.

3.4.2 Eligibility Requirements Prior to Initiation

Before initiating LEN, health care providers should conduct a comprehensive process to confirm eligibility and ensure safe initiation. Key screening components include:

- HIV testing: All clients must undergo HIV testing using the nationally approved HIV testing algorithm to confirm HIV-negative status. HIV testing should be conducted immediately prior to LEN initiation to minimize the risk of initiating PrEP in individuals with undiagnosed HIV infection.
- HIV self-testing may be used as a complementary testing strategy and reactive test results confirmed according to national HIV testing guidelines.
- Assessment for PEP: Clients who have had a possible exposure to HIV in the previous 72 hours should be offered a 28-day prescription of PEP and advised that they can immediately transition to PrEP after 28 days without a gap.
- Assessment of HIV exposures: Clients requesting PrEP should be offered PrEP as a priority, even if no other risk factors are disclosed, as requesting PrEP is an indicator of substantial risk. Structured risk assessments can help identify additional clients who may benefit from PrEP to reduce the risk of HIV acquisition. This assessment may include discussion of recent sexual behaviors, partner HIV status, condom use, history of sexually transmitted infections, and other contextual risk factors. Risk assessments should not be used as a way to restrict or ration LEN.
- HIV prevention counselling: Providers should offer comprehensive counselling to ensure that clients understand the benefits and limitations of LEN, the importance of maintaining HIV-negative status, and how to start, continue and stop LEN safely, including the importance of returning on time for follow-up injections to maintain protection, and options switch to another PrEP or HIV prevention product if they decide to stop using LEN.
- Counselling should also include information on other HIV prevention options, allowing clients to make informed choices about the method that best meets their needs.
- Screening and management of sexually transmitted infections (STIs): Clients should be offered STI screening and treatment in accordance with national guidelines. Addressing STIs as part of PrEP services supports broader sexual health and helps reduce HIV acquisition risk.

Through careful eligibility assessment and screening, health care providers can ensure that LEN is offered safely and appropriately to individuals who are most likely to benefit from this long-acting HIV prevention option.

The PrEP program specifically targets all populations at substantial risk of acquiring HIV, with an emphasis on those most affected by the epidemic. Healthcare providers offering PrEP should ensure that clients receive thorough education and counseling about its risks and benefits.

3.4.3 PrEP Product Specific Eligibility Assessment

Product selection shall be guided by clinical eligibility, client preference, safety considerations, and the ability to adhere to the recommended dosing and follow-up schedule.

All clients must meet general PrEP eligibility criteria prior to product-specific assessment. Healthcare providers shall conduct a thorough evaluation to ensure the selected PrEP method is safe, effective, and appropriate for the individual client. Education and counselling for clients considering or already on PrEP is important to ensure they can make informed choices and effectively use PrEP.

Table 3.2: Product-Specific Eligibility Assessment for PrEP Methods

	Oral PrEP	**LEN**
Able/Willing to attend PrEP Visits	For all products, clients should be committed to attend scheduled follow-up appointments	
Age	≥ 15	
Body weight	≥ 35 kg	≥ 35kg
Pregnancy	All available PrEP products are safe to use in pregnant or breastfeeding women.	
Breast Feeding		
Contraindications	Abnormal renal function (i.e. estimated creatinine clearance rate <60ml/min)	No allergy or previous reaction to LEN

3.4.4 Drug–Drug Interactions

LEN has relatively few clinically significant drug–drug interactions compared with some other antiretroviral agents. However, because LEN is metabolized through pathways involving cytochrome P450 (CYP3A), P-glycoprotein (P-gp), and uridine diphosphate glucuronosyltransferase (UGT1A1), concomitant use of certain medications may reduce LEN concentrations and potentially compromise its effectiveness for HIV prevention.

Healthcare providers should routinely assess all prescription medications, over-the-counter medicines, herbal products, and recreational substances before initiating LEN and during follow-up visits.

Table 3.3: Important Drug–Drug Interactions with Lenacapavir

Drug/Drug Class	**Examples**	**Recommendation**
Rifamycin-based tuberculosis treatment	Rifampicin, Rifabutin, Rifapentine	Concurrent use with LEN is not recommended because rifamycin may reduce LEN concentrations and compromise HIV prevention efficacy. Clients starting or already receiving LEN who require rifamycin-based TB treatment should transition to daily oral TDF-based PrEP (TDF/FTC or TDF/3TC) before or at the start of rifamycin therapy and continue throughout treatment and the

Drug/Drug Class	Examples	Recommendation
		recommended transition period after the last LEN injection. LEN may be resumed after rifamycin therapy is completed if the client remains eligible.
Anticonvulsants	Carbamazepine, Phenytoin, Phenobarbital	Concurrent use is not recommended as these agents may significantly reduce LEN exposure. Consider alternative anticonvulsants or alternative PrEP methods.
Herbal preparations	St. John's Wort (Hypericum perforatum)	Contraindicated due to the potential for reduced LEN concentrations.
Erectile dysfunction medications	Sildenafil, Tadalafil, Vardenafil, Avanafil	**Use with caution.** LEN may increase plasma concentrations of phosphodiesterase-5 (PDE-5) inhibitors through CYP3A inhibition, increasing the risk of adverse effects. Counsel clients and monitor for headache, flushing, dizziness, hypotension, visual disturbances, and priapism. **Consider the following dose adjustments:** Sildenafil: initiate at 25 mg; Tadalafil: use no more than 10 mg every 72 hours as needed, or 2.5 mg once daily if administered daily; Vardenafil: do not exceed 5 mg within 24 hours; Avanafil: maximum 100 mg, not more than once every 48 hours. These recommendations should be applied where clinically appropriate and in accordance with national guidance as updated.
Hormonal contraceptives	Oral contraceptives, injectable contraceptives, implants, hormonal intrauterine systems	No clinically meaningful interactions have been identified. Hormonal contraceptives can be used safely with LEN.
Gender-affirming hormone therapy	Estrogen- or testosterone-containing therapies	No clinically significant interactions are currently known. Routine monitoring should continue according to standard clinical practice.

Clinical Considerations

1. A medication history should be obtained before LEN initiation and reviewed at every follow-up visit.
2. Clients receiving treatment for tuberculosis, epilepsy, or other chronic conditions should undergo careful assessment to identify potential interactions before starting LEN.
3. Where a significant drug–drug interaction is identified, healthcare providers should discuss alternative HIV prevention options and ensure continuity of HIV prevention services.
4. Clients should be encouraged to inform healthcare providers whenever new medications, herbal remedies, or supplements are started while receiving LEN.
5. The Ministry of Health and NASHCoP will update this guidance as new evidence on LEN drug–drug interactions become available.

3.5 PrEP Prescription

All PrEP prescriptions shall be based on confirmed HIV-negative status, assessed ongoing risk of HIV acquisition, and clinical eligibility. Healthcare providers must ensure that clients receive adequate counselling, clear instructions on medication use, and appropriate follow-up to optimize effectiveness and safety.

Table 3.4 PrEP Prescription by Product Type

PrEP Method	PrEP Prescription
Oral PrEP	• Eligible clients will be provided PrEP monthly for the first 6 months (Note: gets prescription of 3 months, but picks medicine every month). At the 6th visit, the provider will assess for effective use and presence of continued risk for HIV then consider offering a 3 multi-month dispensing (3MMD) supply to align with the 3 monthly HTS visit.
LEN	**Initiation** • Day 1: Administer two 300 mg LEN tablets orally (600 mg total). • Day 1: Administer LEN 927 mg as two subcutaneous abdominal injections (1.5 mL each). • Day 2: Take two 300 mg LEN tablets orally (600 mg total). **Continuation**

PrEP Method	PrEP Prescription
	• Administer LEN 927 mg as two subcutaneous abdominal injections every 26 weeks (+/- 2 weeks). • No oral loading dose is required for subsequent injections administered within the recommended dosing window.

3.6 PrEP Follow-up Visit

At the time of PrEP initiation, healthcare providers shall schedule the client's first follow-up visit and clearly communicate the appointment date before the client leaves the facility. Clients initiated on oral PrEP shall be scheduled for their first follow-up visit 1 month after initiation. Clients initiated on LEN shall be scheduled for their first follow-up visit 26 weeks (±2 weeks) after completion of the initiation package, with subsequent follow-up visits scheduled every 26 weeks (±2 weeks) thereafter**.**

-***Table 3.5: PrEP Follow-Up Visit Schedule by Product Type***

PrEP Product	Timing of first F/U visit
Oral PrEP	1 month after initiation (earlier F/U visits to emphasize for more efficient integration with other services.)
LEN	6 months +/- 2 weeks (24-28 weeks) after the initiation package

Table 3.6: Recommended Laboratory and Clinical Screening Tests for Clients Receiving LEN Services.

S/N	Test	Frequency	Action to be Taken
1	Conventional HIV Rapid Test	• Initial Visit • Every 6 months	To assess HIV status: ➢ If HIV negative, start PrEP ➢ If the client is HIV positive, initiate ART
2	STI Screening	• At every visit	➢ Diagnose and treat STIs according to national guidelines
3	Hepatitis B Surface Antigen (HBsAg)	• Initial Visit • As per clinician indication	➢ **HBsAg Negative:** Start PrEP and vaccinate against Hepatitis B, if vaccine is available. ➢ **HBsAg Positive:** Refer the client for further assessment and management of HBV infection. The choice of PrEP should be guided by client preferences, HBV clinical assessment and national HIV and hepatitis B management guidelines. Where indicated, TDF-containing oral PrEP may be the preferred option because it is active against both HIV and HBV.

CHAPTER FOUR: STANDARD OPERATING PROCEDURES (SOPS) FOR LEN INJECTION ADMINISTRATION

4.1 Introduction

This section outlines the standardized procedures for the safe and effective administration of long-acting injectable LEN at facility and approved community service delivery points. All providers must adhere to these procedures to ensure quality of care, client safety, and consistency across implementation sites.

4.2 Client Flow and Pre-Injection Procedures

All clients presenting for LEN services should follow a standardized service flow:

1. Registration and Screening
2. HIV Testing
3. Clinical Assessment
4. Counselling and Consent

4.3 Dosing

LEN initiation requires both oral and injectable components. On Day 1, the client receives an oral loading dose of 600 mg (two 300 mg tablets) together with 927 mg of LEN administered subcutaneously as two 1.5 mL injections. On Day 2, a second oral dose of 600 mg (two 300 mg tablets) is administered.

Following completion of the initiation regimen, maintenance dosing consists of 927 mg of LEN administered subcutaneously every 26 weeks (6 months). Subsequent injections should be scheduled at 26-week intervals. To maintain adequate drug concentrations and ensure continued protection against HIV acquisition, repeat injections should not be administered earlier than 24 weeks or later than 28 weeks after the previous injection.

Table 4.1: LEN Initiation Dosing Schedule

Initiation Dose	Oral Tablets	Injections
Day 1	600 mgs (2 x 300mg)	927 mgs (2 x 1.5mL)
Day 2	600 mgs (2 x 300mg)	None

Table 4.2: Lenacapavir Maintenance Dosing Schedule

Timing of Follow-up Injection	Dose
26 weeks (6 months) after the previous injection (not earlier than 24 weeks and not later than 28 weeks)	927 mg (2 × 1.5 mL injections)

Important Dosing Considerations

The second oral loading dose administered on Day 2 is not a directly observed therapy (DOT) dose. Clients should be instructed to take the second oral dose at home within 24 hours of receiving the Day 1 dose. If a client forgets to take the Day 2 oral dose at the scheduled time, they should be advised to take it immediately upon remembering.

The oral loading doses and the initial LEN injections are both essential to achieve adequate drug concentrations and ensure optimal protection against HIV acquisition. Therefore, healthcare providers should emphasize the importance of completing both oral loading doses and receiving the initiation injections as scheduled. Oral reloading is not required for follow-up injections provided that the client returns within this allowable dosing window.

4.5 Management of Missed or Delayed Follow-up LEN Injections

To maintain continuous protection against HIV acquisition, clients should receive follow-up LEN injections every 26 weeks (6 months). Follow-up injections may be administered within an allowable dosing window of 2 weeks before to 2 weeks after the scheduled injection date (24–28 weeks after the previous injection).

4.5.1 Client Presenting Within the Allowable Dosing Window

If the client presents within the allowable dosing window (24–28 weeks after the previous injection):

- Conduct HIV testing according to national PrEP guidelines.
- Assess for signs or symptoms of acute HIV infection.
- If the HIV test result is negative and the client remains eligible for PrEP, administer the scheduled LEN injection.
- Schedule the next follow-up injection appointment for 26 weeks after the current injection date.

4.5.2 Client Presenting After the Allowable Dosing Window

If the client presents more than 28 weeks after the previous injection:

- Conduct HIV testing according to national PrEP guidelines and assess for signs or symptoms of acute HIV infection.
- Reassess the client's eligibility for LEN and ongoing HIV prevention needs.
- Determine whether the client used oral PrEP during the period following the missed injection.

Clients who used weekly oral LEN (300 mg) as bridging may receive the next LEN injection without repeating the oral loading doses, provided the injection is administered within 7 days of the last weekly oral LEN dose, in accordance with the manufacturer's prescribing information.

Clients who transitioned to daily TDF-based oral PrEP should be managed as re-initiating LEN and should complete the standard LEN initiation regimen, including the oral loading doses, before resuming injectable LEN, in accordance with national guidelines and the manufacturer's prescribing information.

Clients who did not use weekly oral LEN bridging or who received no oral PrEP should restart the standard LEN initiation regimen, including:

- Day 1: Two oral loading tablets (600 mg total) and LEN 927 mg administered as two subcutaneous injections.
- Day 2: Two oral loading tablets (600 mg total).
- Resume follow-up LEN injections every 26 weeks (±2 weeks).

4.5.3 Follow-up and Retention Measures

Healthcare providers should counsel clients on the importance of adhering to scheduled injection appointments and actively follow up clients who miss appointments to facilitate timely re-engagement in HIV prevention services. Facilities should implement client retention strategies, including:

- Appointment reminder cards.
- SMS reminders.
- Telephone calls.
- Peer navigator outreach.
- Community-based follow-up mechanisms, where available.
- Multi-month appointment planning and client-centred scheduling.

All missed or delayed appointments, follow-up actions, and outcomes should be documented in the client's medical record and the relevant PrEP monitoring tools.

4.6 Injection Preparation

Prior to administering LEN, healthcare providers should ensure that all preparation procedures are completed to promote safe and effective administration.

4.6.1 Pre-administration Checks

- Verify the client's identity and confirm that LEN is the correct product and dose to be administered.
- Review the client's eligibility, injection schedule, and any relevant medical history.
- Check the expiry date and inspect the vial or pre-filled syringe for any signs of damage, leakage, discoloration, or particulate matter.
- Confirm that the client has received the required oral loading doses, where applicable.

4.6.2 Required Supplies

Prepare the following supplies before the procedure:

- LEN injection product

- Sterile syringe and needle (if the products are not supplied in a pre-filled syringe)
- Alcohol swabs
- Non-sterile examination gloves
- Gauze or cotton wool
- Safety box for immediate disposal of sharps

4.6.3 Infection Prevention and Control

- Perform hand hygiene according to national infection prevention and control guidelines.
- Wear appropriate personal protective equipment (PPE).
- Maintain aseptic technique throughout the injection procedure.

4.7 Injection Administration Procedure

LEN is administered as a subcutaneous injection. A complete dose consists of two separate injections of 1.5 mL each (total dose 927 mg). The two injections should be administered at different anatomical sites during the same visit.

4.7.1 Injection Sites for LEN Administration

Abdomen (Preferred Site)

The abdomen is the preferred site for LEN administration.

When administering LEN in the abdomen:

- Each injection should be given at least 5 cm away from the umbilicus (navel).
- The two injection sites should be at least 10 cm apart.
- Avoid the waistline and areas that may be compressed by clothing.

Thigh (Alternative Site)

The thigh may be used as an alternative injection site when abdominal administration is not appropriate or preferred.

When administering LEN in the thighs:

- One injection should be administered in each thigh.
- In pregnant and breastfeeding women, the thigh is the preferred injection site.

Note: Do not administer injections into areas with scars, bruising, inflammation, infection, lipodystrophy, or other skin abnormalities.

4.7.2 Injection Administration Steps

1. Explain the procedure to the client and obtain verbal confirmation to proceed.
2. Position the client comfortably and expose the selected injection site(s).

3. Clean each injection site with an alcohol swab and allow the skin to air dry completely.
4. Gently pinch the skin to create a skin fold.
5. Insert the needle into the subcutaneous tissue at the recommended angle (typically 45–90 degrees depending on needle length and client body habitus).
6. Ensure the needle is placed in the subcutaneous fat layer. Avoid injecting too deeply into muscle tissue or too superficially into the dermis.
7. Administer the injection slowly and steadily until the entire dose has been delivered.
8. Repeat the procedure at the second injection site.
9. Withdraw the needle and apply gentle pressure using gauze or cotton wool if required. Do not massage the injection site.
10. Immediately dispose of all used sharps in a safety box without recapping.

4.8 Post-Injection Monitoring and Documentation

4.8.1 Client Monitoring

- Observe the client for at least 15 minutes following administration for any immediate adverse reactions.
- Assess the injection sites for bleeding, swelling, pain, or other local reactions.

4.8.2 Post-Injection Counselling

Provide counselling on:

- Expected injection-site reactions and other possible side effects.
- Provide client education on injection-site care, including informing the client that a small nodule or lump at the injection site may occur, is usually temporary, and advising them not to massage, rub, or apply excessive pressure to the injection site. Counsel clients to seek medical attention if they experience severe pain, increasing swelling, redness, warmth, drainage, or other signs of infection.
- Signs and symptoms that require medical attention.
- The importance of adhering to scheduled follow-up injections.
- Management of missed appointments and available oral bridging options, where applicable.
- The date of the next injection appointment.

Clients should be informed that follow-up LEN injections are scheduled every 26 weeks (6 months) and may be administered within an allowable dosing window of 24 to 28 weeks after the previous injection.

4.8.3 Appointment Scheduling

- Schedule the next injection appointment before the client leaves the facility.
- Provide appointment reminders through available mechanisms such as appointment cards, SMS reminders, telephone calls, or community follow-up systems.

4.8.4 Documentation

Document all relevant information in the appropriate records, including:

- Date of injection administration.
- Dose administered.
- Injection site(s).
- Batch/lot number and expiry date of the product.
- Next appointment date.
- Any adverse events or side effects reported.

Record the visit in:

- The PrEP register and client record.
- Electronic Medical Record (EMR) systems, where available.

Report all suspected adverse events (mild, moderate, severe, and serious) following LEN administration through the national pharmacovigilance reporting system in accordance with TMDA pharmacovigilance guidelines.

4.9 Safety Monitoring and Management

Healthcare providers should monitor clients receiving LEN for adverse reactions and potential drug–drug interactions at every visit. Adverse reactions should be managed according to their severity, while serious adverse events should be reported through the national pharmacovigilance system in accordance with TMDA guidelines. Table 4.3 summarizes the recommended management

Table 4.3: Safety Monitoring and Recommended Management for Clients Receiving LEN

Category	Clinical Presentation / Examples	Recommended Management
Injection-site pain	Mild pain or tenderness at the injection site	Reassure the client and provide symptomatic treatment (e.g., analgesics) as required.
Injection-site swelling	Localized swelling following injection	Observe and provide symptomatic management. Advise the client to return if symptoms worsen or persist.

Category	Clinical Presentation / Examples	Recommended Management
Injection-site erythema	Localized redness at the injection site	Monitor and reassure the client. Advise the client to return if redness spreads, worsens, becomes increasingly painful, or is accompanied by swelling, fever, or other signs of infection. Conduct a clinical assessment and manage or refer as appropriate.
Injection-site nodules	Persistent palpable lump at the injection site	Conduct a clinical assessment, provide follow-up, and manage or refer according to severity.
Nausea	Mild gastrointestinal discomfort	Provide symptomatic treatment and reassurance.
Headache	Mild to moderate headache	Provide analgesics as clinically indicated and monitor symptoms.
Fatigue	Generalized tiredness	Conduct a clinical assessment and provide supportive management.
Fever	Elevated body temperature	Assess for alternative causes, including infection, and manage or refer as appropriate.
Hypersensitivity reaction	Rash, facial swelling, difficulty breathing, anaphylaxis	Provide immediate emergency management, discontinue further LEN administration, refer urgently, and report through the national pharmacovigilance system in accordance with TMDA guidelines.

Category	Clinical Presentation / Examples	Recommended Management
Injection-site necrosis	Tissue breakdown or ulceration at the injection site	Provide urgent clinical assessment and appropriate medical or surgical management. Report as a serious adverse event through the national pharmacovigilance system.
Active safety monitoring and pharmacovigilance	All clients receiving LEN, with enhanced monitoring at designated sentinel sites	Conduct **active safety and toxicity monitoring** for clients receiving LEN, with targeted assessment for adverse events of special interest, including injection-site reactions, hypersensitivity reactions, drug–drug interactions, and adverse pregnancy outcomes where applicable. At designated sentinel sites, clients should be proactively followed up, preferably **30 days after LEN initiation**, to identify and document adverse events that may occur before the next scheduled injection visit. All suspected adverse events (mild, moderate, severe, or serious) should be documented in the client's medical record and reported through the national pharmacovigilance system in accordance with TMDA guidelines. Information generated through active safety

Category	Clinical Presentation / Examples	Recommended Management
		monitoring should complement routine spontaneous pharmacovigilance reporting and support early detection of potential safety signals.
Drug–drug interactions	Rifampicin, rifabutin, rifapentine	Concurrent use is not recommended. Transition clients requiring rifamycin-based TB treatment to daily oral TDF-based PrEP in accordance with national guidance.
	Carbamazepine, phenobarbital, phenytoin	Avoid concurrent use where possible. Consider alternative anticonvulsants and monitor clinically.
	Ketamine	Assess use and provide counselling regarding the potential for drug interactions.
	Sildenafil, tadalafil, vardenafil, avanafil	Use with caution. LEN may increase PDE-5 inhibitor concentrations. Monitor for headache, flushing, dizziness, hypotension, visual disturbances, and priapism.
	Hormonal contraception	No clinically meaningful interaction. No dose adjustment is required.

4.10 Transitioning Between HIV Prevention Options

Clients may choose to transition between available HIV prevention options based on their preferences, clinical needs, lifestyle considerations, side effects, or changes in HIV risk. Careful planning is required during transitions to ensure continuous HIV protection and to minimize the risk of HIV acquisition.

4.10.1 General Principles for Transitioning Between PrEP Products

Before transitioning from one PrEP product to another, healthcare providers should complete the following steps:

1. **Ensure Continuous HIV Protection**

   When transitioning between PrEP products, it is important to consider the time required for the new product to achieve protective drug levels. Appropriate overlap or timing of initiation should be planned to ensure uninterrupted HIV prevention coverage and safe discontinuation of the previous PrEP product.

2. **Confirm HIV-Negative Status**

   Conduct HIV testing according to the national HIV testing algorithm and confirm a negative HIV test result before initiating the new PrEP product.

3. **Screen for Acute HIV Infection and STIs**

   Assess for signs and symptoms suggestive of acute HIV infection (AHI) and screen for sexually transmitted infections (STIs) in accordance with national guidelines. Clients with suspected or confirmed acute HIV infection should not initiate or continue PrEP until HIV infection has been excluded.

4. **Assess Hepatitis B Virus (HBV) Status**

   Clients with chronic hepatitis B virus infection who are receiving tenofovir-based oral PrEP should be counselled on the clinical benefits of remaining on TDF oral PrEP, as tenofovir-containing regimens provide treatment-active agents against HBV. Discontinuation of tenofovir in individuals with chronic HBV infection may result in HBV reactivation and hepatic flares.

5. **HBV Testing Prior to Transition from Oral PrEP to LEN**

   Clients transitioning from daily oral TDF-based PrEP to LEN should be offered hepatitis B testing where available. Clients who test positive for chronic HBV infection and meet eligibility criteria for HBV treatment should be advised to remain on daily TDF-based oral PrEP or another appropriate tenofovir-containing regimen, in accordance with national HBV treatment guidelines.

4.9.2 Counselling During Transition

Healthcare providers should counsel clients on:

- The reasons for transitioning to a different prevention option.
- The expected benefits and limitations of the new PrEP product.
- The timing of initiation and discontinuation of PrEP products.
- The importance of adherence during the transition period.
- Potential side effects and follow-up requirements.
- The need for continued HIV testing and clinical monitoring.

All transitions between PrEP products should be documented in the client's medical record and PrEP monitoring tools.

Table 4.3: Clinical Guidance for Switching Between LEN, Oral PrEP, and PEP

Daily Oral PrEP to LEN	• Conduct eligibility assessment to rule out any contraindications
	• Initiate LEN initiation regimen (2 injections, 2 pills - day 1, 2 pills - day 2)
	• Clients should continue using oral PrEP for 2 days after starting LEN
LEN to Daily Oral PrEP	• Conduct eligibility assessment to rule out any contraindications
	• Start Oral PrEP 6 months after the last LEN injection was administered
LEN to PEP	• PEP will only be required if there is a possible exposure to HIV after 28 weeks since the last LEN injection.
	• Offer PEP as per national guidelines.
PEP to LEN	• LEN may be initiated after the completion of the 28-day PEP course and confirmed HIV-negative with consistent substantial HIV risk.

4.11 Infection Prevention and Waste Management

All LEN injections shall be administered in accordance with national infection prevention and control (IPC) standards and safe injection practices.

1. Perform hand hygiene before and after each client encounter in accordance with standard IPC procedures.
2. Use aseptic technique throughout the preparation and administration process to minimize the risk of infection.
3. Use only sterile, single-use needles, syringes, and injection supplies for each client and each injection. Reuse of injection equipment is strictly prohibited.
4. Clean the selected injection site with an appropriate antiseptic solution and allow it to dry completely before administering the injection.
5. Do not recap, bend, break, or manipulate used needles after administration.
6. Immediately dispose of all used needles, syringes, and other sharps into approved puncture-resistant safety boxes located at the point of care.
7. Segregate, handle, transport, and dispose of medical waste according to national healthcare waste management guidelines and facility procedures.
8. Ensure that safety boxes are sealed and replaced when they reach the recommended fill level and are disposed of through approved waste management systems.

9. Any accidental exposure, needlestick injury, or spillage shall be managed and reported according to national occupational health and safety and post-exposure prophylaxis (PEP) procedures.
10. Service providers shall ensure that the injection area is maintained in a clean and safe condition and that all infection prevention supplies are available before providing LEN services

4.12 Roles and Responsibilities

- Clinicians/Nurses: Conduct clinical assessment, pre- and post-HIV testing and counselling, pre- and post-injection counselling and administering LEN injection.
- Pharmacy/Store Staff: Ensure commodity availability and stock management
- Laboratory technician/assistant: Regular follow up with laboratory monitoring for STIs and HBsAg tests.
- Data Clerks: Record and report service data
- Supervisors: Ensure adherence to SOPs and provide supportive supervision

CHAPTER 5: PHARMACOVIGILANCE AND SAFETY MONITORING

5.1 Adverse Events

The introduction of Long-Acting Injectable LEN into the national HIV prevention program requires robust pharmacovigilance systems to ensure the continued safety of clients receiving the intervention. Safety monitoring is an integral component of service delivery and shall be implemented at all levels of the health system.

An Adverse Event (AE) is any untoward medical occurrence experienced by a client following administration of LEN, regardless of whether the event is considered causally related to the product. Adverse events may occur during initiation, maintenance, or follow-up periods and may range from mild, self-limiting symptoms to severe clinical conditions requiring medical intervention.

Healthcare providers shall actively assess clients for adverse events at every client encounter, including scheduled follow-up appointments, unscheduled visits, and community-based encounters. In addition, where feasible, particularly at designated sentinel sites, clients initiated on LEN should receive an active safety follow-up approximately 30 days after the first injection to identify and manage adverse events that may occur before the next scheduled injection visit. All adverse events identified shall be documented in the client's medical record, managed appropriately, and reported through the national pharmacovigilance system in accordance with TMDA guidelines. Active safety monitoring shall complement routine pharmacovigilance reporting to support early detection of potential safety signals.

The most commonly reported adverse events associated with LEN are injection-site reactions, including pain, swelling, erythema, and nodules. Other reported events may include headache, nausea, dizziness, fatigue, and fever. Most adverse events are mild to moderate in severity and resolve without discontinuation of treatment.

5.2 Adverse Drug Reactions

An Adverse Drug Reaction (ADR) is a noxious, unintended, and undesired response to LEN occurring at doses used for HIV prevention. ADRs may be suspected when there is a reasonable possibility that the product contributed to the occurrence of the event.

Healthcare providers should evaluate and report all suspected ADRs and determine the appropriate clinical management based on severity, duration, and impact on the client's health status. In most cases, clients can safely continue LEN while receiving supportive management for mild reactions.

Table 5.1: Management of Common Adverse Drug Reactions Associated with Lenacapavir

Adverse Drug Reaction	Clinical Presentation	Recommended Management
Injection-site pain	Mild pain or tenderness at injection site	Reassure client and provide symptomatic treatment as required
Injection-site swelling	Localized swelling after injection	Observation and symptomatic management
Injection-site erythema	Localized redness at injection site	Monitor, provide reassurance, and advise the client to return if the redness spreads, worsens, becomes increasingly painful, or is accompanied by swelling, fever, or other signs of infection. Conduct a clinical assessment and manage or refer as appropriate.
Injection-site nodules	Persistent palpable lump at injection site	Clinical assessment and follow-up
Nausea	Mild gastrointestinal discomfort	Symptomatic treatment and reassurance
Headache	Mild to moderate headache	Analgesics as clinically indicated
Fatigue	Generalized tiredness	Clinical assessment and supportive management
Fever	Elevated body temperature	Assess for other causes and manage appropriately
Hypersensitivity reaction	Rash, facial swelling, difficulty breathing	Immediate clinical management and referral

Healthcare providers should counsel clients on expected adverse reactions and encourage prompt reporting of any symptoms experienced after receiving LEN.

5.3 Serious Adverse Events

A Serious Adverse Event (SAE) is any adverse medical occurrence that:

- Results in death;
- Is life-threatening;
- Requires inpatient hospitalization or prolongation of existing hospitalization;
- Results in persistent or significant disability or incapacity;
- Results in a congenital anomaly or birth defect;
- Requires medical intervention to prevent permanent impairment or damage; or
- Results in interruption, discontinuation, or inability to receive scheduled LEN doses due to an adverse event, given the potential increased risk of HIV acquisition associated with disruption of HIV prevention.

Although serious adverse events following LEN administration are uncommon, all suspected SAEs, including adverse events leading to interruption or discontinuation of LEN, shall be managed promptly and reported through the national pharmacovigilance system in accordance with TMDA guidelines.

Table 5.2: Examples of Serious Adverse Events and Required Actions

Serious Adverse Event	Immediate Action
Anaphylaxis	Emergency treatment and urgent referral
Severe hypersensitivity reaction	Immediate clinical management and reporting
Injection-site necrosis	Specialist assessment and referral
Hospitalization associated with LEN use	Clinical management and expedited reporting
Death following LEN administration	Immediate notification and investigation

All SAEs shall be reported irrespective of whether a causal relationship with LEN has been established.

Upon identification of an SAE, healthcare providers shall stabilize the client, provide appropriate treatment, arrange referral where necessary, notify facility management, complete the required reporting forms, and submit reports within the prescribed timelines.

5.4 Adverse Event Severity Grading

The severity of adverse events shall be assessed using standardized grading criteria to facilitate appropriate clinical management and reporting.

Table 5.3: Adverse Event Severity Grading

Grade	Severity	Description	Recommended Action
Grade 1	Mild	Transient or mild symptoms; no limitation of normal activities	Continue LEN and provide symptomatic treatment
Grade 2	Moderate	Mild to moderate limitation of activities	Clinical assessment and appropriate management
Grade 3	Severe	Significant limitation of daily activities; medical intervention required	Urgent clinical evaluation and possible referral
Grade 4	Life-threatening	Immediate risk to life	Emergency management and immediate reporting
Grade 5	Death	Death related to an adverse event	Immediate reporting and investigation

Healthcare providers should document the severity grade for all reported adverse events whenever possible.

5.5 TMDA Reporting Procedures

All adverse drug reactions and serious adverse events associated with LEN shall be reported to the Tanzania Medicines and Medical Devices Authority (TMDA) in accordance with national pharmacovigilance requirements.

Reporting enables the continuous monitoring of product safety and supports early detection of rare or unexpected adverse reactions that may emerge during program implementation.

Table 5.4: TMDA Reporting Timelines

Event Type	Reporting Timeline
Serious Adverse Event (SAE)	Within 24 hours of awareness
Severe Adverse Drug Reaction	Within 7 days
Non-serious Adverse Drug Reaction	As soon as identified through routine reporting mechanisms

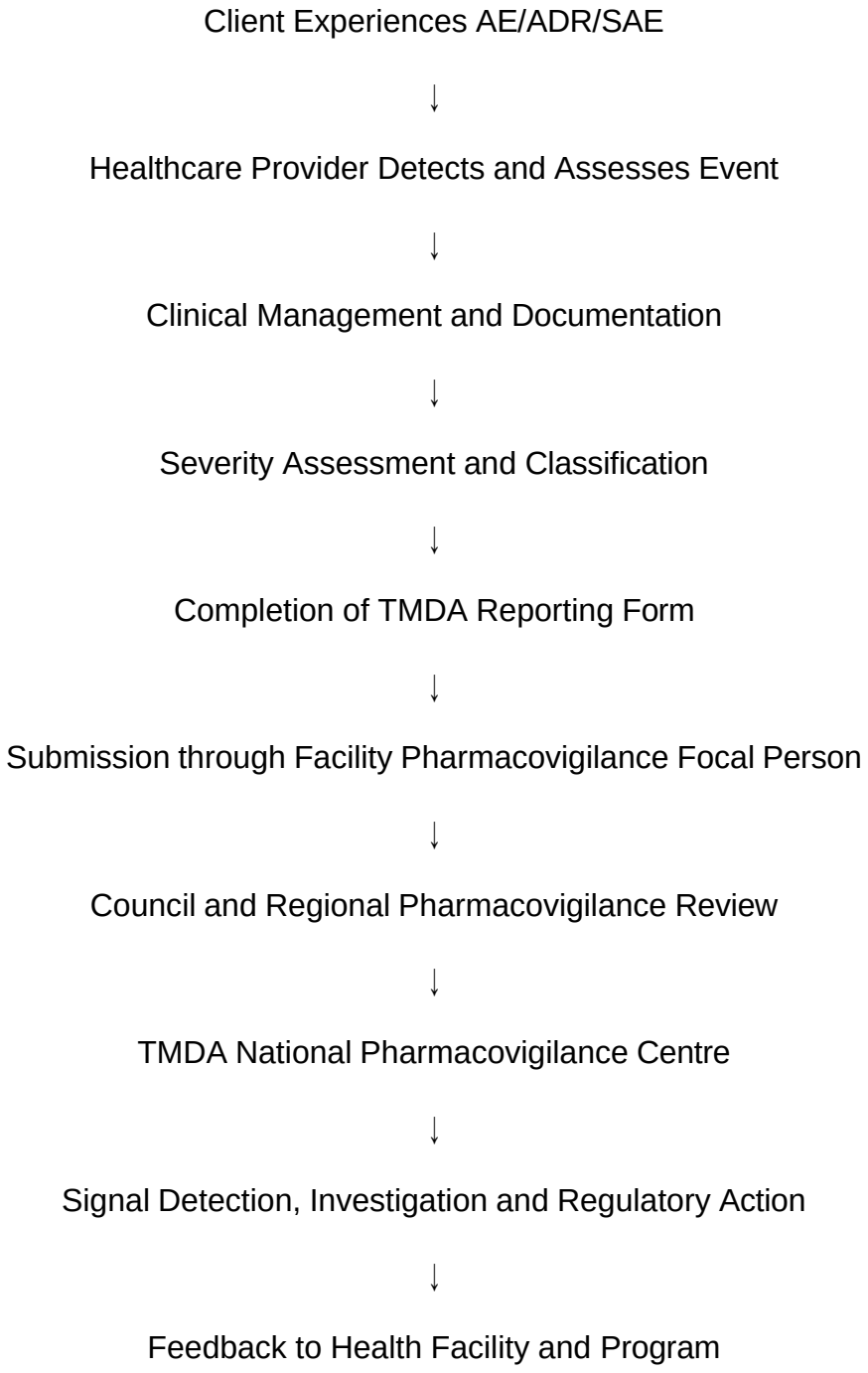
Reports may be submitted using approved TMDA pharmacovigilance reporting tools, including paper-based reporting forms, electronic reporting systems, the Med Safety Mobile Application, and established district, regional, and national reporting channels.

At a minimum, reports should include client information, details of LEN administration, description of the adverse event, clinical management provided, outcome of the event, and reporter information.

5.6 Pharmacovigilance Flowchart

The pharmacovigilance reporting pathway for LEN shall follow existing national pharmacovigilance structures.

Figure 5.1: LEN Pharmacovigilance Reporting Pathway



5.7 Safety Monitoring Responsibilities

Effective pharmacovigilance requires coordinated action by all stakeholders involved in LEN implementation.

Table 5.5: Roles and Responsibilities for Safety Monitoring

Stakeholder	Key Responsibilities
Ministry of Health	Provide policy direction and oversight for LEN safety monitoring
NACP	Coordinate pharmacovigilance activities within HIV prevention programs and monitor reporting performance
TMDA	Receive, review, analyses, and investigate safety reports; conduct causality assessments and issue regulatory guidance
Regional Health Management Teams	Support supervision, mentoring, and monitoring of pharmacovigilance activities
Council Health Management Teams	Ensure reporting compliance and support facility-level implementation
Health Facility In-Charges	Ensure pharmacovigilance systems are functional and reporting requirements are met
Healthcare Providers	Detect, assess, manage, document, and report AEs, ADRs, and SAEs
Pharmacists and Pharmacy Personnel	Support ADR detection, documentation, reporting, and client counselling
Clients	Report adverse symptoms promptly and attend scheduled follow-up visits

Routine safety monitoring shall be conducted at every client encounter, and pharmacovigilance performance indicators shall be reviewed during supportive supervision visits, program review meetings, and quality improvement activities. The information generated through pharmacovigilance systems shall be used to strengthen client safety, improve service quality, and support evidence-based decision-making during the scale-up of LEN in Tanzania.

CHAPTER SIX: HEALTH SYSTEM READINESS

6.1 National level Readiness

The successful introduction of Lenacapavir in Tanzania will build on and strengthen existing HIV prevention platforms, particularly the national PrEP policy and implementation framework, ensuring that its rollout is fully integrated within established policies, service delivery models, and coordination mechanisms. National readiness will require updating HIV prevention and PrEP policies, guidelines, training packages, standard operating procedures, job aids, and monitoring tools to incorporate Lenacapavir recommendations and support standardized service delivery, client monitoring, and program performance. In addition, culturally appropriate information, education, and communication materials will be developed to promote awareness and informed demand, while Regional and Council Health Management Teams (R/CHMTs) will be oriented to strengthen planning, coordination, supervision, and implementation. The Robust existing pharmacovigilance and HIV drug resistance surveillance systems will be optimized to monitor safety and effectiveness, alongside strengthened quantification, procurement, supply chain management, resource mobilization, and sustainability planning to ensure uninterrupted commodity availability and long-term program success.

6.2 Regional/Council level Readiness

At the regional and council levels, readiness will focus on selecting appropriate implementation sites and establishing strong supervision and mentorship teams to provide ongoing technical support, monitor service quality, and facilitate the seamless integration of Lenacapavir into existing HIV prevention and reproductive, maternal, newborn, child, and adolescent health (RMNCAH) service platforms.

6.2.1 Facility Selection

Site selection will follow an evidence-based process that actively engages key stakeholders such as NASHCoP, PMO-RALG, TACAIDS, implementing partners, civil society organizations, and community representatives. This collaborative approach will ensure that local epidemiological patterns, population needs, existing service coverage, and health system capacity are fully considered. Assessments of potential sites will include reviews of infrastructure, human resources, commodity management, data systems, and referral mechanisms.

Site selection will be guided by respective CHMT in collaboration with implementing partners and CSOs using the already defined criteria i.e. prioritizing locations with higher HIV incidence, high MTCT rates, and Most-At-Risk Populations (MARPs) , as identified through surveillance data and program reports.

Additionally, existing health services, such as those for reproductive, maternal, newborn, child and adolescent health, antiretroviral therapy, and tuberculosis should be assessed to promote service integration and operational efficiency.

6.2.2 Facility readiness

Site readiness for PrEP services requires ensuring that facilities are adequately prepared to deliver high-quality prevention interventions. This includes leveraging the existing infrastructure for privacy and confidentiality during counselling and clinical consultations, maintaining functional infection prevention measures, and securing

appropriate storage for medicines and commodities. Reliable access to clean water, electricity, and other essential utilities is also critical to support uninterrupted service delivery.

PrEP services will be delivered in health facility settings by healthcare providers trained in PrEP. Additionally, the health facility should be able to provide other integrated HIV services such as PEP, hepatitis, and STI services. PrEP services will be provided by nurses and clinicians, with capacity for data and supply chain management. Updated clinical guidelines, job aids, and standard operating procedures will be made available to ensure consistency and quality of care.

Table 6.1: Minimum Health Facility Readiness Requirements for PrEP Service Delivery

Domain	Minimum Requirement	Description
Authorization	Approved service delivery point	• The facility must be officially authorized to provide PrEP services in accordance with national guidelines.
Service Integration	Integrated HIV, Maternal and SRH services	• The facility should provide PrEP alongside integrated services, including HIV testing services (HTS), sexual and reproductive health (SRH), condom provision, and antiretroviral therapy (ART).
Human Resources	Healthcare workers trained on injectable LEN and HIV testing	• At least one trained PrEP healthcare workers must be available, could be either: a clinician or nurse,
	Community linkage	• Facilities should be linked to trained community health workers (CHWs) to support demand creation, adherence support, and client tracking for refills.
	Data management staff	• Trained staff on data management to support data entry, reporting, and records.
Pharmacovigilance	ADR reporting capacity	• The facility should have the capacity to detect, document, and report adverse drug reactions (ADRs) using national pharmacovigilance systems.
Monitoring & Evaluation	Use of national M&E tools	• All PrEP services willbe documented and reported using the national monitoring and evaluation (M&E) system.

Domain	Minimum Requirement	Description
Commodity Management	Supply chain capacity	• The facility should be able to forecast, order, store, manage, and report on PrEP commodities and related supplies.
Laboratory Capacity	HIV Rapid Testing	• The facility should have the capacity to provide HTS
	Sample referral system	• Facilities should have the capacity to refer blood samples for HIV Drug Resistance for LEN users who have seroconverted.
Clinical Services	STI management	• The facility should have an added advantage to screen, manage, and/or refer clients with suspected sexually transmitted infections (STIs).

6.3 Human resource and capacity building

Successful introduction and scale-up of long-acting injectable LEN for HIV prevention will require comprehensive training and continuous capacity building of health care providers and program personnel at all levels of the health system. Training will ensure that providers have the necessary knowledge and skills to safely deliver LEN services, counsel clients effectively, monitor outcomes, and maintain high standards of quality care.

The Ministry of Health, in collaboration with implementing partners and technical agencies, will coordinate the development and implementation of standardized training programs aligned with national HIV prevention guidelines and operational procedures. Training activities will be integrated within existing capacity-building platforms for HIV prevention and PrEP services to promote efficiency and sustainability.

PrEP services will be provided by health personnel trained on PrEP, i.e. clinicians and nurses. The R/CHMT will conduct regular supportive supervision and mentorship visits. Trained Community Health Workers and Peer educators will provide information, education and communication for behavioral change and can assist with promotion and demand creation for PrEP to target audiences.

A cascade approach for training of both health workers and peer educators will be utilized. This includes training of national master trainers, and training of trainers (TOT) at the national level who will then orient the R/CHMT who will then build the capacity of health workers and peer educators in the regions and councils implementing PrEP. This will also include a mentorship component after supportive supervision, data quality assessment and quality control visits. To increase efficiency, MOHCDGEC-approved e-learning platforms and approaches (e.g. ECHO conferencing) will be utilized as a platform for transferring knowledge and exchange of best practices.

Table 6.2: Summary of Training cascade for Capacity Building in LEN Service Delivery

Training Approach	Description
National Training Workshops	• Formal training sessions for conducted at national and regional levels to build provider capacity on LEN services.
Cascade Training Model	• Training-of-trainers approach where trained providers support training at lower levels of the health system.
On-site Mentorship and Coaching	• Continuous supportive supervision and mentorship at health facilities to strengthen practical skills.
Integration with Existing HIV Prevention Training	• Incorporation of LEN training into ongoing HIV prevention and PrEP training programs to ensure efficiency and sustainability.
Job Aids, Guidelines, and SOPs	• Use of standardized training materials including clinical guidelines, job aids, and standard operating procedures to support service delivery.

6.3 Target Groups for Training

Training will be conducted for a range of health professionals and program staff involved in the delivery, management, and monitoring of LEN services. Key cadres to be trained include:

Table 6.3: Target Health Workforce and Roles in LEN Service Delivery

Cadre	Role in LEN Service Delivery	Key Training Focus
Clinicians (Medical Officers and Clinical Officers)	• Provide clinical oversight of LEN services, assess client eligibility, conduct clinical screening, and manage adverse events.	• Eligibility assessment, clinical screening, adverse event management, clinical protocols for LEN delivery.
Nurses and Midwives	• Deliver frontline services including counselling, HIV testing, administration of LEN injections, follow-up care, and documentation.	• Client counselling, HIV testing procedures, Injection administration, follow-up care, service documentation, adverse event reporting.
Pharmacists and Pharmaceutical Technicians	• Manage LEN commodities within the supply chain and	• Storage and handling of LEN, stock monitoring,

Cadre	Role in LEN Service Delivery	Key Training Focus
	support pharmacovigilance.	dispensing procedures, and adverse event reporting.
Laboratory Technologists and Technicians	• Provide and support quality-assured HIV testing before initiation and during follow-up, ensuring adherence to the national HIV testing algorithm, collecting and referring specimens for HIV drug resistance testing among clients who seroconvert, maintaining laboratory quality standards	• knowledge and skills on Lenacapavir and its integration into the national PrEP program, HIV testing requirements for Lenacapavir users, laboratory quality assurance and biosafety, specimen collection and referral for HIV drug resistance testing
Community Health Workers and Outreach Providers	• Support community awareness, demand creation, client education, adherence support, and referral to service sites.	• Community sensitization, client education, adherence support, referral mechanisms.
Data Managers and Monitoring Officers	• Manage program data, monitoring indicators, and reporting within national health systems.	• Data collection tools, reporting systems, indicator tracking, integration into national HMIS.

Table 6.4: Key Training Topics for LEN Implementation

Training Topic	Description
Overview of Lenacapavir for HIV Prevention	• Introduction to LEN as a long-acting HIV prevention option, including mechanism of action, clinical benefits, advantages and disadvantages in comparison to other PrEP products, dosing schedule, and its role in the HIV prevention strategy.
Client Eligibility and Screening Procedures	• Clinical eligibility assessments including HIV testing using national algorithms and screening for symptoms of acute HIV infection, and identification of individuals at substantial risk of HIV acquisition, .
Clinical Protocols and Injection Administration	• Proper preparation and administration oral loading doses and subcutaneous LEN injections, safe injection practices, infection

Training Topic	Description
	prevention procedures, and accurate documentation.
Client Counselling and Informed Consent	• Communication strategies for counselling clients on HIV prevention options, explaining benefits and potential side effects, and ensuring informed decision-making.
Adverse Event Identification and Management	• Recognition and management of injection site reactions, systemic adverse events, allergic reactions, and reporting through pharmacovigilance systems.
Monitoring, Data Collection, and Reporting	• Use of program registers, electronic systems, and reporting tools to track enrolment, follow-up visits, commodity use, and program indicators.
Commodity Management and Supply Chain Procedures	• Forecasting, stock management, storage requirements, and reporting of LEN commodities to prevent stock-outs.

6.4 Supportive Supervision and Mentorship

Following initial training, **supportive supervision** will be conducted regularly to reinforce provider skills, address implementation challenges, and maintain quality service delivery. Supervisory visits will include:

- Observation of service delivery practices
- Review of clinical documentation and data reporting
- Assessment of adherence to clinical protocols and infection prevention standards
- Identification of additional training or mentorship needs

Supportive supervision will also provide an opportunity for National, Regional and Council program managers and supervisors to offer technical guidance, share best practices, and strengthen provider confidence in delivering LEN services.

Continuous capacity development will ensure that health care providers remain updated on emerging evidence, revised guidelines, and program innovations related to long-acting HIV prevention technologies.

By investing in comprehensive training and ongoing capacity building, the national program will ensure that health care providers are well-equipped to safely and effectively deliver LEN services and support the successful scale-up of long-acting HIV prevention interventions in Tanzania.

CHAPTER SEVEN: SUPPLY CHAIN MANAGEMENT

7.1 Introduction

An effective and responsive supply chain management system is critical for the successful introduction, scale-up, and sustained delivery of Long-Acting Injectable LEN within Tanzania's HIV prevention program. The supply chain system shall ensure continuous availability of quality-assured LEN commodities at all service delivery points while minimizing stock-outs, wastage, and supply interruptions. Management of LEN commodities shall be integrated into the existing national health commodity supply chain structures and systems to promote efficiency, sustainability, and accountability across all levels of the health system.

The LEN supply chain shall encompass forecasting, quantification and supply planning, procurement, distribution, storage, inventory management, logistics management information system reporting, stock monitoring, emergency redistribution, and waste management. These functions shall be implemented in accordance with national policies, guidelines, and standard operating procedures governing health commodities in Tanzania.

7.2 Forecasting

Forecasting is the process of estimating future commodity requirements based on anticipated service uptake and program implementation targets. Accurate forecasting is essential to ensure adequate commodity availability while preventing overstocking, stock-outs, and wastage.

Forecasting for LEN commodities shall be conducted using nationally approved methodologies and integrated within the broader HIV commodity forecasting processes. Forecast estimates shall be informed by program targets, projected numbers of eligible clients, service delivery expansion plans, historical consumption patterns where available, and implementation experiences from earlier phases of the rollout.

Data from the National AIDS, STIs and Hepatitis Control Program (NASHCoP), routine service delivery reports, electronic medical record systems, demographic projections, and other relevant program databases shall be utilized to estimate the number of individuals likely to initiate and continue LEN services. Forecasts shall be reviewed periodically to reflect changes in demand, implementation progress, and program performance.

7.3 Quantification and Supply Planning

Quantification is the process of determining the quantities of LEN commodities required to support program implementation over a specified period. Quantification shall follow the national Quantification and Forecasting Guidelines for Health Commodities and employ an integrated bottom-up approach involving facility, council, regional, and national levels.

The quantification process shall consider forecasted demand, stock on hand, stock in transit, expected losses and adjustments, pipeline shipments, lead times, and buffer stock requirements. Quantification outputs shall guide procurement planning and resource mobilization efforts.

Supply planning shall be undertaken following quantification exercises to determine procurement schedules, shipment timelines, and distribution requirements. Supply plans shall account for procurement lead times, minimum and maximum stock levels, available funding, and anticipated program expansion. Integrated quarterly commodity review meetings involving the Ministry of Health, Prime Minister's Office – Regional Administration and Local Government (PMO-RALG), Medical Stores Department (MSD), implementing partners, and other relevant stakeholders shall be conducted to review and adjust forecasts and supply plans as needed.

7.4 Procurement

Procurement of LEN commodities shall be conducted through approved national procurement mechanisms and in accordance with applicable laws, regulations, and quality assurance requirements. Procurement processes shall ensure that only quality-assured, registered, and approved products are acquired for use within the national HIV prevention program.

Procurement planning shall be informed by approved quantification results and available funding. Procurement decisions shall consider supplier performance, manufacturing capacity, lead times, product shelf life, and regulatory requirements. The Ministry of Health and relevant procurement agencies shall coordinate procurement activities to ensure timely acquisition and uninterrupted availability of LEN commodities.

7.5 Distribution

LEN commodities shall be distributed through the existing national health commodity distribution system coordinated by the Medical Stores Department (MSD). Distribution shall be integrated within the Integrated Logistics System (ILS) to ensure efficient movement of commodities from central warehouses to service delivery points.

Distribution planning shall be guided by facility requirements, stock status, consumption trends, and service delivery needs. Commodities shall be delivered according to established distribution schedules while ensuring product quality is maintained throughout transportation and handling processes.

Facilities receiving LEN commodities shall verify quantities received against accompanying documentation and promptly report any discrepancies through established reporting mechanisms.

7.6 Storage

Appropriate storage conditions are essential to maintain the quality, safety, and effectiveness of LEN commodities throughout the supply chain. All facilities handling

LEN shall ensure that products are stored according to manufacturer recommendations and national pharmaceutical storage standards.

LEN shall be stored at temperatures of 20°C–25°C (68°F–77°F), with permissible excursions between 15°C–30°C (59°F–86°F). Storage areas shall be secure, clean, dry, well-organized, and protected from excessive heat, direct sunlight, moisture, pests, and unauthorized access.

Routine monitoring of storage conditions shall be conducted, and appropriate records maintained to ensure product quality is preserved throughout the storage period.

7.7 Inventory Management

Effective inventory management is necessary to ensure uninterrupted commodity availability while minimizing losses, expiries, and wastage. Health facilities shall maintain accurate and up-to-date inventory records for all LEN commodities using approved inventory management tools.

LEN commodities shall be incorporated into facility stock ledgers, bin cards, and electronic inventory systems in accordance with national supply chain procedures. All stock transactions, including receipts, issues, transfers, adjustments, losses, and disposals, shall be documented accurately and promptly.

Commodity issuance shall follow the First-Expiry-First-Out (FEFO) principle to minimize product expiry and wastage. Facilities shall conduct monthly physical stock counts and reconcile physical inventory against stock records to identify and address discrepancies.

To support continuity of service delivery, facilities shall maintain a minimum buffer stock equivalent to two months of consumption, while higher levels of the supply chain shall maintain stock levels consistent with the national supply chain design.

7.8 Logistics Management Information System (LMIS) Reporting

The Electronic Logistics Management Information System (eLMIS) shall serve as the primary platform for reporting and managing LEN commodity logistics data. All facilities providing LEN services shall report commodity consumption, stock status, losses and adjustments, and requisition information through eLMIS according to national reporting schedules.

Integration between eLMIS and other electronic platforms, including Afya eHMIS, GoTHOMIS, and ePICOR 10, shall facilitate comprehensive monitoring of commodity availability and program performance. Timely and accurate reporting shall support evidence-based forecasting, quantification, procurement planning, and supply chain decision-making.

7.9 Stock Monitoring

Routine stock monitoring shall be conducted at facility, council, regional, and national levels to ensure continuous availability of LEN commodities and identify emerging supply chain challenges. Monitoring activities shall include review of stock status reports, consumption trends, stock-out rates, order fill rates, expiry tracking, and reporting performance. Data generated through eLMIS and other integrated systems shall be used to identify facilities at risk of stock shortages or overstocking and guide appropriate corrective actions.

Regular monitoring of downstream supply plans shall be undertaken to ensure continuous availability of LEN commodities at all service delivery points.

7.10 Emergency Redistribution

Emergency redistribution shall be implemented when facilities experience actual or anticipated stock imbalances resulting from stock shortages, excess stock, impending expiries, or unexpected changes in commodity demand.

Redistribution decisions shall be guided by stock status reports, consumption patterns, expiry monitoring information, and service delivery needs. All redistribution activities shall be coordinated through established supply chain structures and documented appropriately to ensure accountability and traceability of commodities.

7.11 Waste Management

Expired, damaged, obsolete, or otherwise unusable LEN commodities shall be managed in accordance with national pharmaceutical waste management guidelines and environmental protection regulations. Facilities shall establish procedures for identifying, segregating, documenting, and securely storing unusable commodities pending disposal. Disposal activities shall be conducted using approved methods and under the supervision of authorized personnel. Records of all disposals shall be maintained for accountability, regulatory compliance, and audit purposes. Routine expiry monitoring and adherence to FEFO principles shall be implemented to minimize wastage and optimize utilization of available commodities.

7.12 Strengthening Supply Chain Systems for LEN Scale-Up

The successful scale-up of LEN will depend on continued strengthening of national commodity management systems and integration of LEN into existing electronic and logistics platforms. Integration of LEN commodities within eLMIS, Afya eHMIS, GoTHOMIS, ePICOR 10, and other national systems will improve visibility of commodity data, strengthen forecasting and inventory management, support timely decision-making, and enhance accountability across the supply chain. A well-functioning supply chain system will ensure reliable access to long-acting injectable HIV prevention services, minimize supply disruptions, improve program efficiency, and support the successful national scale-up of LEN as part of Tanzania's comprehensive HIV prevention program.

CHAPTER EIGHT: GOVERNANCE, COORDINATION AND PROGRAM MANAGEMENT

8.1 Governance and Coordination

Strong governance and effective coordination mechanisms will be essential for the successful introduction and scale-up of long-acting injectable LEN for HIV prevention. The introduction of LEN involves multiple stakeholders across the health system, including government institutions, implementing partners, civil society, and development partners. Clear leadership, defined roles, and coordinated planning will ensure that implementation is efficient, aligned with national priorities, and responsive to emerging challenges.

The Ministry of Health (MOH) will provide overall leadership and strategic direction for the introduction of LEN through NASHCoP. The Ministry will be responsible for policy guidance, national coordination, resource mobilization, and oversight of program implementation. LEN introduction will be aligned with the broader national HIV prevention strategy and integrated within existing national HIV and PrEP programs.

8.2 National Leadership and Oversight

NASHCoP will coordinate the development and implementation of policies, guidelines, and operational frameworks required for LEN introduction. Key responsibilities of the national program will include:

- Development and dissemination of national operational guidelines for LEN implementation
- Coordination of training and capacity-building initiatives
- Oversight of supply chain management and commodity distribution
- Integration of LEN monitoring indicators into national HIV program reporting systems
- Ensuring alignment with national HIV prevention policies and strategies
- Coordinating Demand creation and Promotion of LEN

NASHCoP will also ensure that LEN implementation is consistent with national regulatory requirements and ethical standards for the introduction of new health technologies.

8.3 Engagement of Government Stakeholders

Multiple government institutions will play a role in supporting the introduction of LEN. These may include:

- Tanzania Medicines and Medical Devices Authority responsible for product registration and pharmacovigilance
- Prime Ministers officer, Regional Administrative and Local Government.
- Public health programs involved in HIV prevention, sexual and reproductive health, and community health services
- National supply chain and medical stores departments responsible for procurement and distribution of commodities

- Training and Researching institutions supporting the development of health workforce capacity

Engaging these stakeholders will help ensure that LEN is integrated effectively within the broader health system and that implementation is supported by appropriate policies and regulatory frameworks.

8.4 Collaboration with Implementing Partners

Implementing partners, including national and international organizations supporting HIV programs, will play a key role in operationalizing LEN services. These partners may contribute to:

- Technical assistance for program design and implementation
- Training and mentorship of health care providers
- Support for community engagement and demand creation activities
- Strengthening monitoring and evaluation systems
- Supporting supply chain and commodity management systems

Collaboration with implementing partners will help accelerate program rollout and strengthen service delivery capacity at national and sub-national levels**.**

8.5 Engagement with Civil Society Organizations

Civil society organizations (CSOs) are important partners in ensuring that HIV prevention programs are inclusive, equitable, and responsive to community needs. CSOs will support LEN introduction by:

- Promoting community awareness and demand creation
- Reaching underserved and priority populations
- Providing community-based support services
- Facilitating community feedback on service delivery

Their involvement will help ensure that the introduction of LEN is guided by community perspectives and promotes equitable access to HIV prevention services.

8.6 Collaboration with Development Partners

Development partners will provide strategic, technical, and financial support for the introduction and scale-up of LEN. These partners may support:

- Program planning and policy development
- Funding for procurement of commodities and program implementation
- Technical expertise for training, monitoring, and evaluation
- Operational research and learning activities

Close collaboration with development partners will help mobilize resources and ensure alignment with global HIV prevention initiatives and evidence-based practices.

8.7 Coordination Mechanisms

To ensure effective collaboration among stakeholders, regular coordination mechanisms will be established at national and sub-national levels. These may include:

- National HIV program coordination meetings
- Technical working group meetings focused on HIV prevention and PrEP
- Health Sector Prevention Committee
- Multisectoral Prevention Committee
- Stakeholder consultation forums
- Joint program review meetings

These platforms will allow stakeholders to share updates, review program progress, coordinate activities, and address operational challenges.

8.8 Program Review and Problem Solving

Regular coordination meetings will provide an opportunity to:

- Review implementation progress and performance indicators
- Identify operational challenges and bottlenecks
- Share lessons learned and best practices
- Strengthen alignment of partner activities with national priorities

Strong coordination and collaboration among stakeholders will enable timely identification and resolution of implementation challenges, supporting the effective and sustainable rollout of LEN services nationwide. Establishing robust governance structures and coordination mechanisms will ensure that LEN introduction is well-managed, aligned with national HIV prevention priorities, and implemented efficiently through a collaborative approach.

8.9 Ethical Considerations

The introduction and implementation of long-acting injectable LEN for HIV prevention must be guided by strong ethical principles to ensure that services are delivered in a manner that respects the rights, dignity, and well-being of all individuals. Ethical considerations are particularly important in HIV prevention programs, where issues such as stigma, discrimination, confidentiality, and access to services can significantly influence individuals' willingness and ability to seek care.

All LEN services should be implemented in accordance with national health policies, professional ethical standards, and internationally recognized principles for public health practice. The Ministry of Health and implementing partners must ensure that service delivery promotes **equity, respect for autonomy, and protection of client rights**, while prioritizing populations at substantial risk of HIV infection.

8.10 Informed Client Choice

A fundamental ethical principle in HIV prevention is ensuring that individuals have the **right to make informed decisions about their health care**. Clients must be provided with clear, accurate, and comprehensive information about LEN and other available HIV prevention options before initiating services.

Health care providers should ensure that clients understand:

- What LEN is and how it works to prevent HIV infection
- The dosing schedule and the need for repeat injections every six months
- Potential side effects and risks associated with the medication
- The importance of regular HIV testing and follow-up visits
- Alternative HIV prevention methods such as oral PrEP and condoms
- The use of other prevention methods for STI prevention and unplanned pregnancies

Clients should be encouraged to ask questions and should never feel pressured to choose LEN. Instead, providers should promote **voluntary, client-centered decision-making**, allowing individuals to select the HIV prevention method that best suits their needs, preferences, and circumstances.

8.11 Confidentiality and Privacy

Maintaining client confidentiality is essential for building trust and encouraging individuals to access HIV prevention services. Health facilities and service providers must ensure that all client information related to LEN services is handled with strict confidentiality.

Measures to protect confidentiality should include:

- Conducting consultations and counselling in private settings
- Safeguarding client medical records and data systems
- Limiting access to client information to authorized health care personnel only
- Ensuring that community outreach and follow-up activities respect client privacy

Protecting confidentiality is particularly important for individuals who may face stigma or discrimination related to HIV prevention or sexual health services.

8.12 Equitable Access for Priority Populations

Ensuring equitable access to LEN is a key ethical consideration, particularly for populations that face higher risk of HIV infection and may experience barriers to accessing health services. Implementation strategies should prioritize access for populations that are disproportionately affected by HIV, including:

- Men and women at high risk
- People who inject drugs
- Vulnerable adolescent girls (15-19 years)

- Young women (20-24 years)
- High-risk pregnant and breastfeeding women
- HIV-negative partners of sero-discordant couples
- Mobile populations (e.g., long-distance truck drivers, fisherfolk and fishing communities, miners and mining communities, construction and plantation workers)
- Other Individuals who are at substantial risk of HIV infection

Efforts should be made to address structural and social barriers that may prevent these populations from accessing HIV prevention services. This may include expanding services to community-based settings, providing youth-friendly services, and engaging community organizations that support priority populations.

8.12.1 Respect for Community Values and Cultural Sensitivity

Program implementation should also consider local cultural contexts and community values. Community engagement efforts should ensure that LEN services are introduced in ways that are culturally appropriate and respectful of community perspectives while maintaining adherence to ethical principles and human rights.

8.12.2 Ethical Oversight and Accountability

The Ministry of Health and implementing partners should ensure that mechanisms are in place to monitor adherence to ethical standards during program implementation. This may include:

- Clear policies and guidelines on ethical service delivery
- Training for health care providers on ethical principles and client rights
- Mechanisms for clients to provide feedback or report concerns related to service delivery

By integrating strong ethical safeguards into program design and implementation, the introduction of LEN for HIV prevention can promote trust in health services, protect client rights, and ensure equitable access to this important HIV prevention intervention.

CHAPTER NINE: DEMAND CREATION, SOCIAL AND BEHAVIOR CHANGE COMMUNICATION (SBCC) AND COMMUNITY ENGAGEMENT

9.1 Demand Creation and Community Awareness

The successful introduction and scale-up of long-acting injectable LEN for HIV prevention will depend not only on the availability of services but also on strong community awareness, acceptance, and demand. Demand creation and community engagement efforts are therefore critical to ensure that individuals at substantial risk of HIV infection are informed about this new prevention option and are able to access services without stigma or barriers.

Demand creation activities should be implemented as part of broader HIV prevention communication strategies and aligned with national HIV prevention programs. The Ministry of Health, in collaboration with implementing partners, civil society organizations, community leaders, and affected communities, will coordinate comprehensive outreach and communication efforts to promote awareness and uptake of LEN.

9.1.1 Community Sensitization and Awareness Campaigns

Community sensitization campaigns should aim to provide accurate information about LEN, address misconceptions, and encourage individuals at risk of HIV to seek prevention services.

Community awareness activities may include:

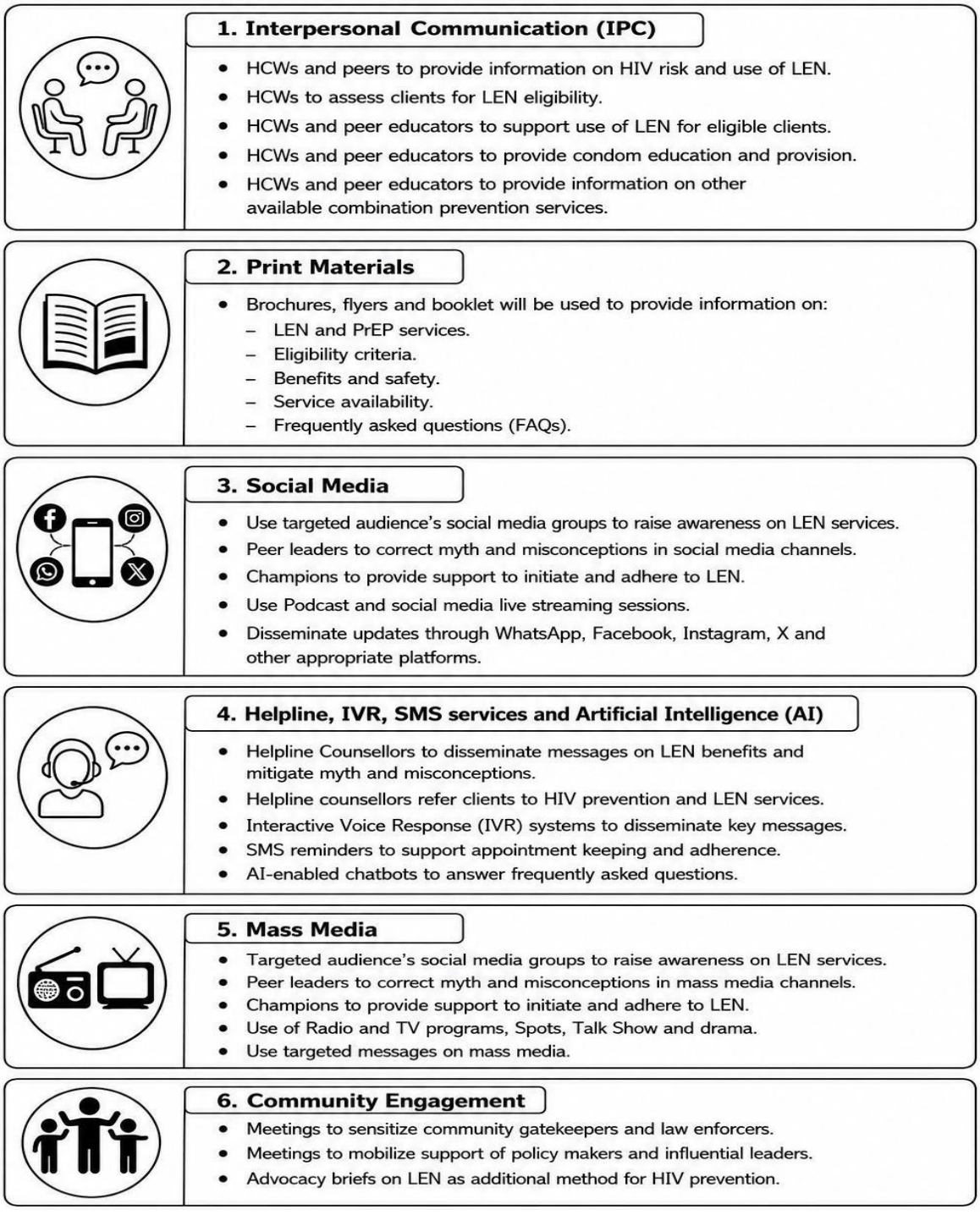
- Public health education sessions in communities
- Community dialogue forums and advocacy to local leaders and law enforcers
- Use of mass media such as radio, television, and social media
- Advocacy and awareness creation to politicians and Parliamentarians
- Orientation to Media professionals and Content Creators
- Distribution of information, education, and communication (IEC) materials
- Engagement of community influencers and local champions

Messaging should be culturally appropriate, linguistically accessible, and tailored to the needs of specific populations and geographic contexts.

9.2 Communication Approaches and Channels

Social and Behaviour Change Communication (SBCC) interventions will be implemented at both facility and community level using the existing structures to create awareness, sustained demand, and facilitate access to LEN services amongst key target audiences. Due to the nature of PrEP interventions for key and vulnerable populations, the interpersonal approach will be the key approach for effectiveness. Figure 9.1 below illustrates examples of key approaches for PrEP SBCC.

Figure 9.1: Examples of LEN SBCC Approaches



9.2.1 Engagement with Civil Society Organizations

Civil society organizations (CSOs) and community-based organizations play an important role in reaching populations that may have limited access to health facilities or face stigma and discrimination when seeking HIV services. These organizations often have established trust within communities and can support the introduction of LEN through:

- Community outreach and education
- Mobilization of priority populations
- Advocacy for equitable access to HIV prevention services
- Support for community feedback and accountability mechanisms

Partnerships with CSOs will help ensure that demand creation efforts are inclusive and responsive to the needs of most at risk populations.

9.2.2 Role of Peer Educators and Community Mobilizers

Peer educators and community mobilizers are essential for increasing awareness and encouraging uptake of HIV prevention services among populations at higher risk of HIV infection. Individuals are often more receptive to information provided by peers who share similar experiences or backgrounds.

Peer educators and mobilizers can support LEN introduction by:

- Providing community-level education on HIV prevention options
- Sharing information on how LEN works and who may benefit from it
- Addressing myths and misconceptions about injectable HIV prevention
- Referring eligible individuals to health facilities offering LEN services
- Supporting adherence and follow-up by reminding clients of scheduled injection visits

These peer-led approaches can be particularly effective among young people, key populations, and other communities with higher HIV vulnerability.

9.3 Adolescent and Youth-Friendly Communication Approaches

Young people represent an important target group for HIV prevention services. Communication strategies targeting youth should use **youth-friendly approaches** that resonate with their communication preferences and information needs.

Effective Adolescent and youth engagement strategies may include:

- Social media and digital communication platforms
- Interactive youth dialogues and school-based outreach
- Adolescent and Youth ambassadors and peer-led education programs
- Use of relatable messaging, storytelling, and multimedia content
- Use of Youth led Social Media Content Creators

Communication materials should be designed to be engaging, non-judgmental, and empowering, encouraging young people to make informed choices about their sexual and reproductive health.

Table 9.1: Key Messaging for LEN Demand Creation

Key Message Area	Description
Safe and Approved	• WHO recommends LEN as an additional HIV prevention (PrEP) option and Tanzania Medicines and Medical Devices Authority granted regulatory approval in December 2025. • Side effect are mild and temporary
High Effectiveness	• LEN has demonstrated high levels of protection against HIV infection when used correctly, making it a powerful addition to the existing HIV prevention options.
Long-Acting Protection	• LEN provides long-lasting protection with only two injections per year. This reduces the need for daily medication and minimizes frequent clinic visits, making it a convenient prevention option for many individuals.
Client Choice in HIV Prevention	• LEN expands the range of HIV prevention options available, allowing individuals to choose the method that best fits their needs, lifestyles, and preferences. This reinforces a client-centred approach where individuals can select from oral PrEP, long-acting injectable PrEP, condoms, and other prevention strategies.
Lenacapavir Is Not an HIV Vaccine	• Clear communication should emphasize that LEN is not an HIV vaccine but a form of pre-exposure prophylaxis (PrEP). LEN works by maintaining protective levels of antiretroviral medicine in the body to prevent HIV infection if exposure occurs. Unlike vaccines, which stimulate the immune system to develop long-term immunity, LEN requires regular injections every six months to maintain protection. Clients should also be encouraged to continue other prevention practices such as condom use and regular HIV testing.
Risk compensation	• LEN is part of HIV prevention options. However, LEN does not protect against other STIs and unplanned pregnancies
Addressing Stigma and Promoting Community Support	• Demand creation strategies should address stigma and misinformation that may discourage individuals from seeking HIV prevention services. Community engagement should help normalize the use of LEN for HIV prevention and strengthening community understanding that choosing HIV prevention is an act of self-care/responsibility and empowerment.

Key Message Area	Description
Service readiness	• Ensure reliable commodity availability, trained healthcare service providers, and accessible services to promote safe, equitable, and high-quality LEN services for HIV prevention.

9.4 Community Feedback and Participation

Community engagement should include mechanisms for communities to provide feedback on service delivery and program implementation. This can be achieved through:

- Community advisory groups;
  - Council/Ward/Village multisectoral AIDS Committee CMAC, WMAC, VMAC
  - Community umbrella organizations
- Feedback sessions with community representatives
- Monitoring of community perceptions and concerns
- Community Dialogues
- Client satisfactory survey, toll free, hotline, social media feedback, suggestion box, help desk
- Community led Monitoring

Integrating community perspectives will ensure that LEN services remain responsive to community needs and that demand creation strategies continue to be effective. Through comprehensive community engagement and demand creation efforts, the national program will increase awareness and acceptance of LEN, promote uptake of long-acting HIV prevention options, and support equitable access to HIV prevention services across Tanzania.

CHAPTER TEN: MONITORING, EVALUATION AND LEARNING

10.1 Introduction

The introduction of Long-Acting Injectable LEN will be implemented as an enhancement to the existing National PrEP Program. LEN will be integrated as an additional PrEP option within the national HIV prevention package and will utilize existing national systems for monitoring, reporting, quality improvement and data use.

10.2 Indicator Matrix Revision

The National HIV Prevention Indicator Matrix will be updated to incorporate LEN-related indicators. Most updates will involve disaggregation of existing PrEP indicators by product type, while a limited number of new indicators will be introduced for LEN safety, effectiveness and continuation monitoring.

Table 10.1: Indicators for LEN Implementation

Indicator Name	Definition	Disaggregation	Frequency
Number of individuals screened for PrEP eligibility	Clients assessed for HIV risk and eligibility for PrEP, including LEN	Age, sex, population group	Monthly
Number of individuals initiated on LEN	Clients receiving first dose of LEN for HIV prevention	Age, sex, population group	Monthly
Number of clients returning for repeat injection	Clients receiving subsequent scheduled doses	Age, sex	Monthly
Continuation rate at 6 months	Proportion of clients who remain on LEN at 6 months after initiation, Calculated as monthly cohort	Age, sex	Monthly
Number of clients discontinuing LEN	Clients who stop treatment, with reasons	Reason for discontinuation, age, sex	Monthly
Number of health facilities providing LEN	Number of health facilities offering LEN services during the reporting period.	Facility level, region, council, facility type	Monthly
Product switching (LEN to Oral and Oral to LEN)	Number of clients who transitioned from LEN to oral PrEP or from oral PrEP to LEN during the reporting period.	Direction of switch (LEN→Oral, Oral→LEN), age, sex, population group, reason for switching	Monthly

10.3 Integration into National Recording and Reporting Systems

All LEN-related service data shall be captured through the existing national HIV Prevention recording and reporting system to ensure sustainability, standardization, and integration within the national monitoring framework. Data collection for LEN services will utilize both the Unified Community System (UCS) and standardized national facility-based recording and reporting tools to ensure comprehensive capture of service delivery data across community and facility platforms.

Existing PrEP tools, registers, reporting forms, and electronic information systems will be updated to incorporate LEN-specific variables and indicators, while maintaining a unified reporting framework for all PrEP products. Data collected through community and facility platforms will be harmonized, consolidated, and integrated into the national Health Management Information System (HMIS).

The integrated data system will support routine program monitoring, enhanced surveillance, commodity forecasting and supply planning, quality improvement initiatives, strategic planning, performance management, and evidence-based decision-making at facility, council, regional, and national levels.

10.4 Enhanced Surveillance among LEN Clients

Given that LEN is a new long-acting HIV prevention product, enhanced surveillance will be conducted among all clients initiated on LEN. Surveillance activities will be integrated into the national Health Management Information System (HMIS).

The surveillance system will monitor:

Safety Outcomes

- Injection site reactions (e.g., pain, swelling, erythema, induration, nodules)
- Systemic adverse events (adverse events affecting the whole body or organ systems rather than being limited to the injection site, such as fever, headache, fatigue, nausea, myalgia, arthralgia, dizziness, or malaise)
- Serious adverse events (SAEs) (events resulting in death, life-threatening illness, hospitalization or prolongation of hospitalization, persistent or significant disability/incapacity, congenital anomaly, or other medically important events)
- Allergic and hypersensitivity reactions (e.g., rash, urticaria, angioedema, anaphylaxis)

Pregnancy outcomes among women using LEN (including pregnancy status, maternal outcomes, birth outcomes, and infant outcomes where applicable)

Program Effectiveness Outcomes

- HIV seroconversion among current LEN users
- Missed injection appointments

Continuation Outcomes

- Retention at 6 months
- Product switching patterns
- Reasons for discontinuation

Surveillance Reporting

Enhanced surveillance findings will be reviewed through routine facility, district, regional, and national review meetings and will inform program improvements, policy updates, pharmacovigilance actions, commodity forecasting, and future scale-up decisions.

10.5 Quality Improvement and Data Quality Assurance

Quality Improvement (QI) and Data Quality Assessments (DQA) for LEN will follow existing national HIV program guidelines, tools and procedures. Routine supportive supervision, RDQA, data verification, validation, mentorship and performance reviews will be conducted.

10.6 Program Evaluation and Learning

LEN evaluation will be conducted as part of the overall prevention program evaluation which is tied to MTR and terminal evaluation of the NASHCoP strategic plan.

Implementation science, operational research, routine program reviews and evaluations will be used to assess acceptability, uptake, continuation, operational feasibility, safety and effectiveness of LEN.

10.7 Defined Benchmarks for Success

To ensure effective implementation and accountability in the introduction of long-acting injectable LEN, a set of clear, measurable benchmarks will be used to monitor program performance during early rollout and scale-up phases. These benchmarks provide targets against which progress can be assessed and guide timely corrective actions where needed.

Table 10.2: Defined Benchmarks for Success for LEN Introduction

Domain	Indicator	Definition / Description	Target
Service Uptake and Coverage	Clients initiated on LEN	Proportion of planned clients initiated on LEN within the first 12 months of implementation	≥90%
	Geographic coverage	Proportion of planned service delivery sites activated and providing LEN services	≥80%
	Equity in access	Proportion of LEN initiations among priority populations (e.g., AGYW, PWID, sero-different couples, MARPs)	≥70%

Domain	Indicator	Definition / Description	Target
Adherence and Continuation	On-time injection rate	Proportion of clients receiving injections within the allowable window (±2 weeks)	≥85%
	6-month continuation rate	Proportion of clients remaining on LEN at 6 months after initiation	≥70%
	12-month continuation rate	Proportion of clients remaining on LEN at 12 months after initiation	≥60%
Safety and Quality of Care	HIV testing compliance	Proportion of clients tested for HIV prior to each injection	100%
	Adverse event reporting	Proportion of adverse events properly documented and reported according to national pharmacovigilance guidelines	≥95%
	Seroconversion management	Proportion of clients who seroconvert and are promptly linked to ART services and investigated	100%
Supply Chain Performance	Stock-out rate	Proportion of facilities reporting stock-outs of LEN within a reporting period	≤5%
	Stock reporting completeness	Proportion of facilities submitting complete and timely stock reports	≥95%
	Stock adequacy	Facilities maintaining at least three (3) months of LEN stock on hand	100%
Data Quality and Reporting	Reporting completeness	Proportion of facilities submitting complete monthly LEN reports through DHIS2	≥95%
	Reporting timeliness	Proportion of reports submitted within the required timeframe	≥90%
	Data accuracy	Concordance between source documents and reported data during data quality assessments	≥90%
Client Experience and Acceptability	Client satisfaction	Proportion of clients reporting satisfaction with LEN services	≥85%
	Retention support	Proportion of clients receiving appointment reminders or follow-up support	≥80%
	Product preference	Increasing proportion of clients opting for LEN within the overall PrEP method mix over time	Increasing trend
Program Management and Supervision	Site readiness	Proportion of activated sites meeting minimum readiness criteria prior to initiation	100%
	Supportive supervision	Proportion of sites receiving at least one supervisory visit per quarter	≥90%

Domain	Indicator	Definition / Description	Target
	Provider competency	Proportion of trained providers demonstrating competency in LEN service delivery	≥95%
Continuous Improvement and Learning	Review meetings	Regular quarterly review meetings conducted at national and sub-national levels	100%
	Documentation of lessons learned	Availability and dissemination of best practices and lessons learned	Ongoing
	SOP updates	Timely revision of SOPs and strategies based on data and emerging evidence	As needed

CHAPTER ELEVEN: RISK MANAGEMENT

11.1 Risk Mitigation and Safety Management for LEN Introduction

The introduction of long-acting injectable LEN requires a proactive and structured approach to identify, monitor, and mitigate potential risks associated with its clinical use, program implementation, and community acceptance. Given its novel mechanism of action and extended dosing interval, robust safety and risk management systems are essential to ensure client safety, maintain public trust, and support effective program scale-up.

11.2 Clinical Risk Mitigation

To minimize clinical risks associated with LEN use, strict adherence to national clinical protocols will be ensured:

HIV Testing Prior to Administration: All clients must have a confirmed HIV-negative status before each injection to prevent inadvertent use in individuals with undiagnosed HIV infection.

Management of Seroconversion and Resistance: Any client diagnosed with HIV while on LEN will be promptly linked to ART services, with appropriate HIV drug resistance (HIVDR) testing conducted in line with national guidelines.

Adverse Event Monitoring: All adverse drug reactions (ADRs), including injection-site reactions and systemic events, will be documented and reported through the national pharmacovigilance system. Serious adverse events (SAEs) will be reported immediately.

Clinical Follow-up: Routine follow-up visits will include assessment of side effects, adherence to injection schedules, and ongoing eligibility.

11.3 Programmatic Risk Mitigation

Operational risks that may affect service continuity and quality will be addressed through the following measures:

Missed or Delayed Injections: Clear protocols will be established for managing delayed doses, including allowable dosing windows (e.g., ±2 weeks) and re-engagement strategies for clients who miss appointments.

Supply Chain Continuity: Strengthened forecasting, procurement, and distribution systems will ensure consistent availability of LEN, with defined buffer stock levels and real-time stock monitoring to prevent stock-outs.

Service Delivery Readiness: Standardized site readiness assessments, provider training, and supportive supervision will ensure that facilities are adequately prepared to deliver high-quality LEN services.

Data Quality and Reporting: Integration of LEN indicators into the national HMIS (DHIS2) will support accurate and timely data reporting, enabling early identification of programmatic gaps.

11.4 Community and Behavioral Risk Mitigation

Community perceptions and client-level factors will be actively managed to ensure acceptability and uptake:

Addressing Misinformation and Stigma: Targeted social and behavior change communication (SBCC) strategies will be implemented to provide accurate information about LEN, address myths, and reduce stigma associated with PrEP use.

Informed Choice and Consent: Clients will receive comprehensive counselling on available PrEP options, including benefits, risks, and dosing schedules, to support informed decision-making.

Client Retention and Support: Peer navigators and community health workers will support adherence, appointment reminders, and follow-up, particularly for high-risk and mobile populations.

11.5 System-Level Risk Mitigation

Health system constraints that could impact implementation will be addressed through coordinated efforts:

Table 11.1 LEN Implementation Risk Matrix

Risk	Potential Impact	Mitigation Measures	Responsible Person/Level	Monitoring Indicator
HIV infection not detected before LEN administration	Risk of HIV drug resistance and delayed ART initiation	Conduct HIV testing and assess for symptoms of acute HIV infection before every LEN injection in accordance with national guidelines	Healthcare provider; Facility In-charge	% of clients tested for HIV before each LEN injection
Missed or delayed LEN injections	Reduced HIV prevention effectiveness	Implement appointment reminders, active client follow-up, and manage delayed injections according to	Healthcare provider; Peer navigator; Community health worker	Proportion of clients receiving injections within the recommended dosing window

Risk	Potential Impact	Mitigation Measures	Responsible Person/Level	Monitoring Indicator
		national guidance		
Adverse drug reactions or serious adverse events	Client harm and reduced confidence in LEN	Prompt clinical management, documentation, and reporting through the national pharmacovigilance system in accordance with TMDA guidelines	Healthcare provider; Pharmacovigilance focal person	Number of adverse events reported
Drug–drug interactions (e.g., rifamycin-based TB treatment)	Reduced LEN effectiveness	Review concomitant medications at every visit and transition eligible clients to oral TDF-based PrEP when indicated	Healthcare provider	Number of clients appropriately managed for drug interactions
Stock-out of LEN commodities	Interrupted service delivery	Strengthen forecasting, procurement, inventory management, and maintain buffer stock	Pharmacist; Facility In-charge; Council/Regional Pharmacist	Number of facilities experiencing LEN stock-outs
Inadequately trained healthcare providers	Poor quality of service delivery	Conduct training, mentorship, and supportive supervision	Ministry of Health; Regional/Council Health Management Teams; Implementing Partners	Proportion of providers trained on LEN service delivery
Poor data quality and incomplete reporting	Inaccurate program monitoring	Integrate LEN indicators into routine HMIS, conduct regular data quality assessments,	M&E Officer; Facility In-charge	Reporting completeness and timeliness

Risk	Potential Impact	Mitigation Measures	Responsible Person/Level	Monitoring Indicator
		and provide feedback		
Misinformation, stigma, and low community acceptance	Low uptake and poor continuation	Implement SBCC activities, community engagement, and client-centred counselling	Healthcare providers; Community health workers; Implementing Partners	Number of SBCC/community engagement activities conducted
Poor client retention	Reduced continuation on LEN	Appointment reminders, peer support, differentiated service delivery, and active follow-up of missed appointments	Healthcare provider; Peer navigator	Six-month LEN continuation rate

Annex 1(a): Taskforce for the Introduction of Lenacapavir in Tanzania

S. No	Participants Name	Affiliation
1	Dr. Zeye Nkomela	NASHCoP
2	Dr. Seraphine Charles	NASHCoP
3	Dr. Subira Hemedi Shoko	NASHCoP
4	Mr. Ambwene Mwakalobo	NASHCoP
5	Dr. Hollo Sondo	NASHCoP
6	Mr. Jeremiah Mushi	NASHCoP
7	Felchism Apolinary	TMDA
8	Dr. Catherine Muwonge	WHO
9	Dr. Johnson Lyimo	WHO
10	Dr. Bonaventura Mpondo	UNAIDS
11	Dr. Collin Sendeu	UNAIDS
12	Dr. Nyagonde Nyagonde	USG
13	Dr. Janet Mwambona	USG
14	Dr. Alick Kayange	USG
15	Dr. George Mgomella	USG
16	Dr. Oscar Rwabiyago	USG

Annex 1(b): List of Contributors to the Development of the Lenacapavir Introduction Operational Guide

S. No	Participants Name	Affiliation
1	Dr.Prosper Njau	NASHCoP
2	Dr. Jerome Kamwela	NASHCoP
3	Dr. Michael Msangi	NASHCoP
4	Dr. Upendo Mabongo	NASHCoP
5	Mr. Amani Kiondo	NASHCoP
6	Ms. Neema Shabalenga	NASHCoP
7	Mr. Veryeh Sambu	NASHCoP
8	Mr. Sylvester Kwilasa	NASHCoP
9	Dr. Mgaya Matthew	PMOLARG
10	Dr. Malya Immanuel	PMOLARG
11	Dr. Charles Shija	PMOLARG
12	Eriko Kawanga	TACAIDS
13	Mr. Mohamed Turay	UNAIDS
14	Dr. Nathaniel Kalengo	USG
15	Dr. Seleman Mfaume	USG
16	Dr. Diana Nicholaus	USG
17	Dr. Carolyn Mbelwa	USG
18	Dr. Evangelina Chihoma	USG
19	Mr. Cherif Cisse	USG
20	Mr. Jonathan Grund	USG
21	Dr. Bhavin Jani	USG

S. No	Participants Name	Affiliation
22	Ms. Jane Kitalile	USG
23	Dr. Makune Makune	USG
24	Dr. Hiltruda Temba	USG
25	Ms. Emma John	AMREF
26	Dr. Neema Makyao	AMREF
27	Dr. Barbara Manzi	FHI 360
28	Dr. Elizabeth Herman	FHI 360
29	Dr. George Matasha	HJFMRI
30	Dr. Chaita Chai	HJFMRI
31	Dr. Raymond Bandio	ICAP
32	Mr. Arnold Nicholaus	KVP FORUM
33	Dr. Appolinary Bukuku	THPS
34	Dr. Mayega Samson	Consultant
35	Dr. Nyambuli Jigabha	Consultant

Annex 2: Geographical Rollout Plan for LEN

Rollout Methodology

The implementation of LEN will follow a phased, tiered health system approach to ensure systematic, equitable, and sustainable scale-up of services across Tanzania. The rollout will begin at national and specialized hospitals with advanced clinical capacity and well-established HIV prevention and treatment services. These facilities will serve as centers of excellence for the initial introduction of LEN, providing opportunities to strengthen provider competencies, establish robust service delivery and supply chain systems, and generate implementation lessons to inform subsequent phases of the rollout.

The phased expansion is guided by the level and capacity of health facilities to ensure equitable access to LEN services, reduce disparities in service availability, and enable all eligible clients to benefit from this HIV prevention intervention. All parastatal hospitals will commence implementation during **Phase I** of the rollout.

Phased Rollout Plan

Phase	Implementation Period	Facilities
Phase I	April – June 2027	All National Hospitals, Specialized Hospitals, and Parastatal Hospitals
Phase II	July – September 2027	All Zonal Referral Hospitals and 17 Regional Referral Hospitals
Phase III	October – December 2027	Remaining 13 Regional Referral Hospitals, all 92 Council Hospitals, and all Designated District Hospitals

Phase	Implementation Period	Facilities
Phase IV	January – March 2028	High-volume Health Facilities, Selected Faith-Based Organization (FBO) and Private Health Facilities, and Stand-alone Pharmacies

Expected Outcome

The phased implementation approach is expected to strengthen health system readiness, ensure high-quality service delivery, facilitate continuous learning and quality improvement, and progressively expand access to Lenacapavir services nationwide while maintaining equity, efficiency, and sustainability


UHURU
NA
UMOJA


NATIONAL AIDS, STIs & HEPATITIS CONTROL PROGRAM
NASHCOP
MPANGO WA TAIFA WA KUDHIBITI UKIMWI,
MAGONJWA YA NGONO NA HOMA YA INI