health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Date: 3 November 2025 Ref: 2025/11/03/EDP1

DETAILS	TOPIC	Contact
Zahiera Adam	**HIV Pre-Exposure Prophylaxis (PrEP)**	Zahiera Adam E-mail: zahiera.adam@health.gov.za

NOTICE OF REQUEST FOR COMMENT ON THE STANDARD TREATMENT GUIDELINE FOR HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) FOR PHC LEVEL OF CARE.

The ministerially appointed National Essential Medicines List Committee (NEMLC) invites comment on the draft HIV Pre-Exposure Prophylaxis guideline (STGs) for PHC level of care, as part of NEMLC's review process for prioritised topic areas. The following STG for Primary Health Care (PHC), is applicable, and comments are invited on the draft guidance. The associated evidence review, economic analysis and NEMLC report are included for additional information.

Level of care	Chapter
Primary Healthcare	PHC Chapter 11: HIV and AIDS Section 11.11 HIV PrEP

The STGs and EML are designated by level of care and are intended to guide clinicians providing care at each level; to promote access to essential medicines to manage common conditions at the respective levels of care.

Kindly circulate the invite for comment to relevant healthcare professionals at your institutions. Constructive comment regarding the identification of major errors, areas of misalignment or where updates are required, will be appreciated. Please include a short motivation to substantiate any comment made. Where an alternative medicine is recommended, this should be supported by appropriate evidence. Attached is the guideline for the Motivation of a New Medicine on the National Essential Medicines List.

It would be appreciated if comments can be received by **28 November 2025.**

Comments may be submitted *via* e-mail to:

Zahiera Adam
E-mail: zahiera.adam@health.gov.za

Your support and input in this regard is encouraged and appreciated.

Kind regards

PROF M BLOCKMAN
CO-CHAIR: NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE (NEMLC)
DATE: 3 NOVEMBER 2025

DR R DE WAAL
CO-CHAIR: NATIONAL ESSENTIAL MEDICINES LIST COMMITTEE (NEMLC)
DATE: 3 NOVEMBER 2025

GUIDELINES FOR THE MOTIVATION OF A NEW MEDICINE ON THE NATIONAL ESSENTIAL MEDICINES LIST

Section 1: Medication details

» Generic name
A fundamental principle of the Essential Drug Programme is that of generic prescribing. Most clinical trials are conducted using the generic name.

» Proposed indication
There will usually be many registered indications for the medication. However, this section should be limited to the main indication which is supported by the evidence provided in section 2.

» Prevalence of the condition in South Africa
This information is not always readily available. However, it is an important consideration in the review of a proposed essential medicine.

» Prescriber level
Here the proposed prescriber level should be included. If more than one level is proposed each relevant box should be ticked.

Section 2: Evidence and motivation

» Estimated benefit
- Effect measure: this is the clinical outcome that was reported in the clinical trial such as BP, FEV, CD_4, VL etc.
- Risk benefit: this should be reported in the clinical trial and, in most cases, includes the 95% confidence level (95% CI). Absolute risk reduction, also termed risk difference, is the difference between the absolute risk of an event in the intervention group and the absolute risk in the control group.
- Number Needed to Treat (NNT): gives the number of patients who need to be treated for a certain period of time to prevent one event. It is the reciprocal of the absolute risk or can be calculated using the formula below.

Calculations

	Bad outcome	**Good outcome**	**Total patients**
Intervention group	*a*	*c*	*a + c*
Control group	*b*	*d*	*b + d*

Measure	**Equation**
Absolute risk:	$[b/(b+d)] - [a/(a+c)]$
Number needed to treat	$\dfrac{1}{[b/(b+d)] - [a/(a+c)]}$
Relative risk	$[a/(a+c)] \div [b/(b+d)]$
Odds ratio	$\dfrac{[a/(a+c)] \div [c/(a+c)]}{[b/(b+d)] \div [d/(b+d)]} = (a/c) \div (b/d)$

Reference - Aust Prescr 2008;31:12–16

» Motivating information (GRADE approach to assess the quality of evidence)
  – The National Essential Medicine List Committee has endorsed the adoption of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach[1] for determining the certainty of evidence. Please provide information about the overall certainty of the evidence for each outcome according to that reported in the citations you use and ideally using the GRADE approach. The GRADE approach takes into account issues related to internal validity (risk of bias, inconsistency, imprecision, publication bias) but also to external validity, such as directness of results.
  – The GRADE approach – quality of evidence and definitions:

High quality	Further research is very unlikely to change our confidence in the estimate of effect
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low quality	Any estimate of effect is very uncertain

» Cost considerations
  – Where a published reference supporting the review of cost is available comments should be made regarding its applicability to the South African public sector environment.
  – Possible unpublished information that can be included:
    o Cost per daily dose or course of therapy – for long term or chronic therapy such as hypertension the usual daily dose should be calculated (Dose x number of times a day) and converted into the number of dosing units e.g. tablets. This is then used to calculate the cost per day. For medications used in a course of therapy such as antibiotics this is then multiplied by the number of days in the course of therapy.
    o Cost minimisation is used where there is evidence to support equivalence and aims to identify the least costly treatment by identifying all the relevant costs associated with the treatment.
    o Cost-effectiveness analysis is used to compare treatment alternatives that differ in the degree of success in terms of the therapeutic or clinical outcome. By calculating a summary measurement of efficiency (a cost-effectiveness ratio), alternatives with different costs, efficacy rates, and safety rates can be fairly compared along a level playing field.

Where any of these have been performed tick the relevant block and send as an attachment with all the calculations. If possible, the spread sheet should be supplied electronically.

Section 3: Motivator's Details

The receipt of all submissions will be acknowledged. In addition, all decisions with supporting arguments will be communicated where appropriate. This section therefore forms a vital link between the motivator and the decision making process.

[1] Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, et al. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. J Clin Epidemiol. 2011;64(4):383-94

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2030 NDP

South African National Department of Health, National Essential Medicines List Committee

TITLE OF MEDICINE REVIEW[2,3]

MOTIVATOR'S DETAILS

Date submitted:	
Name:	
Registration number:	
Qualification:	
PTC motivation: Y/N	
PTC Details:	
PTC Chair:	
PTC Chair signature:	

MEDICINE DETAILS

Medicine Class	[Yes/No/NA]	*If applicable* *Please consider therapeutic interchange policy*
Medicine/s name **-INN:** **- South African name (if differs from INN)**		*http://www.whocc.no/atc_ddd_index/*
Medicine/s (ATC5):		*http://www.whocc.no/atc_ddd_index/*
Indication (ICD-10 code):		*https://www.health.gov.za/icd-10-master-industry-table/*
SAHPRA Approved	[Yes/No/Section21]	SAHPRA registered health products database *https://medapps.sahpra.org.za:6006/*
Dosage form/s	e.g., tablet, suspension	
Route of administration/s	e.g., oral, intravenous	
Patient population		
Prevalence and/or incidence of condition		*May refer to estimates or routine data (DHIS, StatsSA), not necessarily published data.*
Level of Care		
Prescriber level		

[2] The template was revised through collaboration between the South African Medical Research Council, University of Stellenbosch, NEMLC, the Essential Drugs Programme (EDP) and SA GRADE Network and approved for piloting by the NEMLC in February 2025.

[3] Please note that reviews must adhere to methodology and processes adopted by the National Essential Medicines List Committee (NEMLC). Please see the HTA Methods Guide 2022-2027 for the inclusion of medicines onto the Essential Medicines List (https://www.health.gov.za/wp-content/uploads/2024/04/HTA-Methods-Guide_FINAL_Sep-2023.pdf) and Cochrane Handbook (https://www.cochrane.org/authors/handbooks-and-manuals/handbook).

EXECUTIVE SUMMARY

- Background, including current recommendations, status quo
- We conducted a XX review of available evidence that assessed the effect of [intervention] compared to [comparator] in [population] (restrictions: XX)
- We searched [insert databases] on [date]. We identified XX clinical practice guidelines, XX systematic reviews, XX RCTs, and XX observational studies. [Brief summary of included studies]
- Effectiveness results: summary of effectiveness results
  - Stratified per comparison
  - NOTE: Reporting syntax below as example:
    - RR/OR xxx (95% CI), xxx more/less per 1000 (from XX more/less to XY more/less per 1000), NNT/NNH. (Certainty of Evidence)
- Health/contextual factors/outcomes: summary of these elements e.g. SAHPRA registration, cost, feasibility, acceptability, equity considerations
- Evidence synthesis conclusion [where needed]

Table of contents

REPORT

BACKGROUND (1 page max)

Can include disease background, disease distribution, disease risk factors, review rationale.

PURPOSE/OBJECTIVE i.e., PICO question:

Population Subgroups	*Are there any important subgroups that need to be considered?*
Intervention(s)	*Class level intervention, avoid trade names. Consider grouping of interventions (e.g. SSRI vs an individual drug)*
Comparator(s)	*Standard of Care, or placebo. Is more there more than one comparator?*
Outcome(s)	*Focus on patient important outcomes, avoid composite outcomes, try keep max 7 outcomes, only those that are critical for decision making. Check if there are core outcomes sets for the condition – link to COMET)*
Study types	*CPGs, SRs of RCTs or other, RCTs, avoid observational studies, where possible*

METHODS

1. **Data Sources**
   General description of where the team has searched for evidence

2. **Search Strategy**
   Description of the electronic search strategy for evidence, including terms and Boolean operators. Detail in appendix.

3. **Study selection and eligibility criteria, data extraction and analysis, and evidence synthesis**
   Describe who did study screening and how, who and what data was extracted and how, how analysis was handled and/or synthesised

4. **Assessment of methodological quality**
   Which tools were used per eligible study design/s. Consult with methodologist if needed.

5. **GRADE assessment**

RESULTS

1. Result of the search
   This can be a narrative description. Results can be presented using a study flow diagram

2. Description of included studies (clinical practice guidelines, systematic reviews and RCTs)
   - 2.1. Clinical Practice Guidelines
   - 2.2. Systematic reviews
   - 2.3. RCTs
   - 2.4. Etc

3. Methodological quality of included studies

EFFECTIVENESS OF THE INTERVENTION

Where feasible/possible present Summary of Findings Tables.

Comparison	Number of included studies

Comparison 1
1. Outcome 1
2. Outcome 2
3. Outcome 3
4. Outcome 4 etc

Comparison 2
1. Outcome 1
2. Outcome 2
3. Outcome 3
4. Outcome 4 etc

Comparison 3
1. Outcome 1
2. Outcome 2
3. Outcome 3
4. Outcome 4 etc

DISCUSSION (1 to 2 pages)

Summary of results

Other reviews on this topic

Limitations in the review

CONCLUSION

REVIEW TEAM

The following people were involved in this review:

Name	Affiliation(s)	Role and Contribution	Interest declaration

EXPERT REVIEW COMMITTEE MEMBERS

Name	Affiliation(s)	Role and Contribution	Interest declaration

ACKNOWLEDGEMENTS

REFERENCES

Vancouver Style Referencing

APPENDICES (EXAMPLE)

1. Figures and Tables
   - Figure 1: Study flow diagram
   - Table 1: Characteristics of included studies
   - Table 2: List of excluded studies (if applicable)
   - Figure 2. Risk of bias summary (where applicable)
   - Figure 3. Forest plot of [intervention] vs [comparison] for [outcome]
   - Figure 4. Forest plot of [intervention] vs [comparison] for [outcome]
   - Figure 5. Forest plot of [intervention] vs [comparison] for [outcome]
   - Figure 6. Forest plot of [intervention] vs [comparison] for [outcome]
   - Figure 7. Other graphics/funnel plots (where applicable)
2. GRADE Evidence Profiles
   - GRADE Table 1
   - GRADE Table 2, etc

FIGURE 1. STUDY FLOW DIAGRAM

Table 1. Characteristics of included studies

See TiDierR checklist as reference/example

Table 2. List of excluded studies (if applicable)

Studies excluded after full text screening, - reference and reason for exclusion

Figure 2. Risk of bias summary (where applicable)
Figure 3. Forest plot of [intervention] vs [comparison] for [outcome]
Figure 4. Forest plot of [intervention] vs [comparison] for [outcome]
Figure 5. Forest plot of [intervention] vs [comparison] for [outcome]
Figure 6. Forest plot of [intervention] vs [comparison] for [outcome]
Figure 7. Other graphics/funnel plots (where applicable)

Table 2. Other tables (e.g. description of interventions)

Appendix 1: Search Strategies

Search strategy for Pubmed
Date:

Search strategy for [database]
Date: