**South African National Essential Medicines List**

**Technology Assessment Scope**

**Component: STG chapter and section**

**Generic name of health technology and relevant indication (e.g. x for treating x)**

**Date**

*Scope for health technology assessment by Essential Drugs Programme*

# Summary of the scope

|  |
| --- |
| **Medicine:**  **Indication under review:**  **Review question:**  **Patient population:**  **Level/s of Care:**  **Current standard of care/ comparators:**  **Outcomes to be assessed:**  **Assessment output required:** |

## Scope developed by: Name

**Evidence Review Committee appraising the topic:**

* PHC/Adult Hospital, Paediatric Hospital, Tertiary & Quaternary

# Introduction/ Background

* Information about the condition (prevalence/ incidence/ burden of the disease)
* Context on how the health technology can be used in South Africa and why it might be beneficial (e.g. current gap in care in treatment pathway)
* Any relevant policy considerations or related clinical guidelines that should be considered
* Clear statement about why the analysis is required

# Purpose/Objective

Adapt the following statement:

To assess the [effectiveness/ safety/ cost/ other] of the use of [technology x] compared to [technology b] for [patient population and disease/condition] in [health care setting]

# Description of the technology

* Anatomical Therapeutic Classification
* Formulation/s available in South Africa (if more than one, indicate which formulation under review)
* Route of administration (if more than one, indicate which route of administration is under review)

# Indication to be assessed

State indication relevant to this review (use SAHPRA approved indication if available: <https://www.sahpra.org.za/pi-pil-repository/>)

Complete PICOS table:

|  |  |
| --- | --- |
| Criteria | Details |
| Population | * Patient population who will be eligible to receive the health technology being assessed. Include specifics on condition/disease, age, sex, comorbidities, and subgroups. |
| Intervention | * Technology being assessed and its place in the current care pathway * Will it replace current treatment or be an add-on therapy? * Include specifics of dose, duration, delivery mode, co-intervention/s, setting (e.g. inpatient/ outpatient) |
| Comparison | * Current standard of care and currently available for use in South African public health sector * Should be the treatment most clinicians will replace with the technology being assessed, or the treatment most prescribed currently for the management of the disease/condition. * Can be active treatment or placebo * Include specifics of dose, duration, mode of delivery |
| Outcomes | * Identify principal measures for clinical effectiveness for population of interest and with consideration of place in care pathway/stage of disease. * Include both clinical and safety outcomes * Specify primary and secondary outcomes (including survival, disease progression and health-related quality of life) * Define time horizon - time it takes to demonstrate the identified outcomes (may vary for clinical and economic outcomes). * If applicable, identify feasibility, acceptability, and cost-effectiveness outcome data |
| Likely study designs or data sources to be included | * Systematic reviews * Primary studies (order of preference: RCTs, observational studies, case series) * Clinical practice guidelines (CPGs) and health technology assessments (HTAs) |

# Other considerations

* Equity in health for marginalized groups
* Social value (includes relative importance and acceptability of the intervention to stakeholders)
* Feasibility / ease of implementation

# List of stakeholders to be consulted

# REferences

Vancouver style format

# Assessment output required

Select all relevant analysis required to address the decision problem.

|  |  |  |  |
| --- | --- | --- | --- |
| Type | Notes to the reviewer | | Indicate when appropriate |
| STAGE 1: Technical Report | | | |
| Brief Technical Review Report |  | |  |
| Standard Technical Review Report |  | |  |
| STAGE 2: Additional Analysis | | | |
| Rapid Systematic Review | |  |  |
| Systematic Review | |  |  |
| Cost-Comparison Analysis | |  |  |
| Budget Impact Analysis | |  |  |
| Rapid Review of Economic Evaluations | |  |  |
| Basic Cost-Effectiveness Analysis | |  |  |
| Comprehensive Cost-Effectiveness Analysis | |  |  |
| Pricing Analysis | |  |  |
| Other | |  |  |