**South African National Essential Medicines List**

**Basic or Comprehensive Cost-Effectiveness Analysis**

**Name of STG ERC**

**Component: STG chapter and section**

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

**Date**

# EXECUTIVE SUMMARY

|  |
| --- |
| **Medicine:** **Indication:** **Research question:****Patient population:** **Level of Care:** **Prescriber level:** **Current Standard of Care/ Comparator(s):** **Methods:****Findings:**  **Recommendations:****Reviewers:** **PTC affiliation:** **Disclosures:** **Funding support:**  |

**NAMES OF REVIEWERS**

**AFFILIATION AND CONFLICT OF INTEREST**

Potential conflict of interest statement included here.

Official form should be completed and sent to EDP prior to undertaking the review.

*Some information can be sourced from Technical Report or other Stage 2 analyses (e.g. Cost-Comparison Analysis)*

# Background

Brief description of the following:

* Rationale for why this type of analysis has been selected
* Brief description of the condition, the current care pathway and treatment alternatives already available in the South African public health sector (reference Standard Treatment Guidelines and other Department of Health clinical guidelines, if relevant).

# Patient population

Provide a detailed description of the target population, including age, gender, risk factors, prevalence, incidence, ethnicity, geographical distribution, income distribution.

# Disease and indication

Description of proposed use of medicine in South African setting

* Clinical indications
* Stage of disease
* Disease progression
* Prognosis

Description of current management of the indication in the South African setting (clinical care pathway)

# Medicine

Include detail table from Technical Review Report showing indications, formulation, dose and dosing requirements, length of treatment etc.

# Comparators

Clearly describe the alternatives compared in the analysis

# Clinical evidence

Report clinical evidence that will be used in the model (informed by clinical section of Technical Review Report plus additional literature if needed)

List of clinical parameter values, including high and low values and/or confidence intervals

**Clinical effectiveness evidence**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Study name (year published) | Study name (year published) | Add more columns if needed |
| Study design | e.g. systematic review, RCT |  |  |
| Population |  |  |  |
| Intervention(s) |  |  |  |
| Comparator(s) |  |  |  |
| Outcomes  | Indicate which outcomes are incorporated into base-case analysis |  |  |

Present narrative summary of each study, presenting each outcome under a separate subheading.

Provide key clinical assumptions and limitations that should be considered when interpreting the results.

# Outcome measures

Description of outcome measures included in the analysis

* Natural units reported
* Adverse events
* Life-years saved

Summarise key clinical parameters and variables to be included in the CEA.

List of assumptions regarding the structure and approach to the analysis and the likely significance of the assumption made

# Health related quality of life

Description of how HRQoL was measured (location and context)

Description of how HRQoL was valued i.e. value set used

# Costs

Description of costs

* Main cost drivers in analysis
* Important cost considerations in the analysis

List of cost parameter values and sources

* Drug acquisition costs
* Medicine administration and monitoring costs
* Hospital costs
* Primary care costs
* Adverse events costs
* Other relevant health system costs

# Time horizon

Clearly state and justify the time horizon selected

# Model

Description of modelling approach taken

* Model type
* Markov states
* Transition

List of model assumptions (including the model structure and approach to the analysis) and the likely significance of the assumptions made.

**Key model assumptions**

|  |  |  |  |
| --- | --- | --- | --- |
| Model input | Assumption | Justification | Reference |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# Results

**Results derived from the model**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Cost | Health Outcome  | Incremental cost | Incremental outcome | Incremental cost-effectiveness ratio |
| Comparator intervention  |  |  |  |  |  |
| New intervention  |  |  |  |  |  |

Cost effectiveness plane (graph)

Description of the results and likely implications for pharmaceutical budget and health system

# Sensitivity analysis

Results of sensitivity analysis (including tornado diagram)

Discussion of uncertainty in the analysis

# Discussion and conclusion

Include discussion of equity implications of the analysis

# Research recommendations

List of research recommendations (to inform this or other similar decisions)

# References

Vancouver style format.