HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

Date: March 2019
Medicine (INN): Chlorambucil
Medicine (ATC): L01AA02
Indication (ICD10 code): Chronic lymphocytic leukemia, low grade non-Hodgkin's lymphoma
Patient population: usually elderly population
Prevalence of condition: 624 and 1801 new cases per year respectively[1]
Level of Care: Tertiary and Quaternary
Prescriber Level: Oncologist/haemotologist (adult)
Current standard of Care: chlorambucil is standard of care in older patients.
Efficacy estimates: First introduced in 1946 as found to have an acceptable therapeutic index. [2]

Historically accepted use Criteria

	Criteria	Comment
1	The medicine is included in the WHO Model Essential Medicines List, either as a core or complementary item, for the indication requested.	YES: X / NO:
2	The medicine is currently registered by SAHPRA for the indication.	YES: X / NO:
3	There is evidence of long-established (prior to 1996*) safe and effective use of the medicine for the recognised indication in the public health sector.	YES: X / NO: Comment:
4	There are no new safety or efficacy concerns.	YES: X / NO: Comment:
5	The budget impact is not expected to be sufficiently large that a *de novo* review is justified.	YES: X / NO: Comment:
6	There is equitable access across the country, and is limited only by the availability of adequately trained staff and availability of equipment.	YES: X / NO: Comment

** The Essential Drugs Programme (EDP) of South Africa was established in terms of the National Drug Policy (NDP) which was implemented in 1996*

Recommendation

It is recommended that Chlorambucil be included as an Essential Medicine for the management of Chronic lymphocytic leukemia, low grade non-Hodgkin's lymphoma

[1] National Cancer Registry, 2014. NICD.

[2] Anslow WP, Karnofsky DA. The intravenous, subcutaneous and cutaneous toxicity of bis (beta-chloroethyl) sulfide (mustard gas) and of various derivatives. Journal of Pharmacology and Experimental Therapeutics. 1948,93(1):1-9.