

HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

Date: March 2019

Medicine (INN): Fludarabine injection

Medicine (ATC): L01BB05

Indication (ICD10 code): chronic lymphocytic leukaemia, non-Hodgkin's lymphomas, pre-conditioning regimen for allogeneic stem cell transplant, AML salvage therapy.

Patient population: Adult

Prevalence of condition: 624 and 1801 new cases per year respectively¹

Level of Care: Tertiary and Quaternary

Prescriber Level: Oncologist/haematologist (adult)

Current standard of Care: Fludarabine in combination with cyclophosphamide

Efficacy estimates: Fludarabine yielded a higher response rate with a longer duration of remission and progression-free survival than chlorambucil.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 <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
2	The medicine is currently registered by SAHPRA for the indication.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
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 <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
		Comment: Landmark study 2000, standard of care since then.	
4	There are no new safety or efficacy concerns.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
		Comment:	
5	The budget impact is not expected to be sufficiently large that a de novo review is justified.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
		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 <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
		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 Fludarabine be included as an Essential Medicine in the management of chronic lymphocytic leukaemia, non-Hodgkin's lymphomas, pre-conditioning regimen for allogeneic stem cell transplant, and AML salvage therapy.

¹ National Cancer Registry, 2014. NICD.

² Rai KR, Perterson BL, Appelbum FR, Kolitz J, Elias L, Shepherd L, Hines J, Threattle GA, Larson RA, Cheson BD, Schiffer CA. Fludarabine compared with chlorambucil as primary therapy for chronic lymphocytic leukemia. *New England Journal of Medicine*. 2000, 343 (24):1750-1757.