

HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

Date: March 2019
Medicine (INN): Cytarabine injection
Medicine (ATC): L01BC01
Indication (ICD10 code): acute myeloid leukaemia (AML) and acute lymphoid leukaemia (ALL)
Patient population: adults and children
Prevalence of condition: 624 new leukaemia cases per year¹
Level of Care: Tertiary and Quaternary
Prescriber Level: Oncologist/haematologist (adult and paediatric)
Current standard of Care: cytarabine in conjunction with an anthracycline
Efficacy estimates: 82% of AML patients achieved complete remission with high dose sequential chemotherapeutic remission-induction regimen consisting of 7-day courses of cytarabine, thioguanine and daunorubicin.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:	
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 cytarabine be included as an Essential Medicine for the treatment of acute myeloid and acute lymphoid leukaemia.

¹ National Cancer Registry, 2014. NICD.

² Gale RP, Cline MJ. High remission-induction rate in acute myeloid leukaemia. *The Lancet*. 1977, 390(8010): 497-499.