HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

Date: March 2019
Medicine (INN): Daunorubicin injection
Medicine (ATC): L01DB02
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 year[1]
Level of Care: Tertiary and Quaternary
Prescriber Level: Oncologist/haemotologist (adult and paediatric)
Current standard of Care: Daunorubicin in combination
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: 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 daunorubicin be included as an Essential Medicine in the management of acute myeloid leukaemia (AML) and acute lymphoid leukaemia (ALL).

[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.