

HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

<p>Date: March 2019</p> <p>Medicine (INN): Mercaptopurine</p> <p>Medicine (ATC): L01BB02</p> <p>Indication (ICD10 code): acute leukaemia</p> <p>Patient population: adults and children</p> <p>Prevalence of condition: ~135 cases per year (age 0-19)¹</p> <p>Level of Care: Tertiary and Quaternary</p> <p>Prescriber Level: oncologist/haematologist</p> <p>Current standard of Care: Mercaptopurine as maintenance</p> <p>Efficacy estimates: Of the 45 children with acute leukaemia treated with 6-mercaptopurine, 15 developed haematologic and clinical remission after 2 to 9 weeks of therapy. Remissions lasted 2 to 23 weeks.²</p>
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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"/>
4	There are no new safety or efficacy concerns.	YES <input checked="" type="checkbox"/>	NO <input type="checkbox"/>
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"/>
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"/>

* 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 mercaptopurine be included as an Essential Medicine in the management of acute leukaemia.

¹ National Cancer Registry, 2014. NICD.

² Burchenal JH, Murphy ML, Ellison RR, Sykes MP, Tan TC, Leone LA, Karnofsky DA, Craver LF, Dargeon HW, Rhoads CP. Clinical Evaluation of a New Antimetabolite 6-Mercaptopurine, in the Treatment of Leukemia and Allied Diseases. *Blood*. 1953, 8:965-999.