

HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

<p>Date: March 2019</p> <p>Medicine (INN): <u>Asparaginase</u></p> <p>Medicine (ATC): L01XX02</p> <p>Indication (ICD10 code): Acute lymphoblastic leukemia (ALL)</p> <p>Patient population: children and adults</p> <p>Prevalence of condition: Children aged 2 to 3 years (>90 cases per 1 million per year), with rates decreasing to fewer than 30 cases per 1 million by age 8 years. ¹</p> <p>Level of Care: Tertiary and Quaternary</p> <p>Prescriber Level: Oncologist and haematologist (adult and paediatric)</p> <p>Current standard of Care: Asparaginase in combination with other agents</p> <p>Efficacy estimates: Lymphoma inhibition described with L-asparaginase in 1963. ² Shown to be valuable in combination chemotherapy for ALL. ³</p>

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 asparaginase be included as an Essential Medicine for the management of ALL.

¹ Herbst MC. Fact Sheet on Childhood Acute Lymphoblastic Leukaemia (ALL). Cancer Association of South Africa. November 2017.

² Broome JD. Evidence that the L-asparaginase of guinea pig serum is responsible for its antilyphoma effects. *Journal of experimental medicine*. 1963: 99-120

³ Müller HJ, Boos J. Use of L-asparaginase in childhood ALL. *Critical Reviews in Oncology/hematology*. 1998, 28(2):97-113.