

HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

<p>Date: March 2019</p> <p>Medicine (INN): Busulphan</p> <p>Medicine (ATC): L01AB01</p> <p>Indication (ICD10 code): Pre allogeneic and autologous stem cell transplant conditioning</p> <p>Patient population: Patients having allogeneic or autologous stem cell transplants</p> <p>Prevalence of condition: ~27 patients per year. ¹</p> <p>Level of Care: Tertiary and Quaternary</p> <p>Prescriber Level: Oncologist/haematologist (adult and paediatric)</p> <p>Current standard of Care: Busulphan</p> <p>Efficacy estimates: Busulfan and cyclophosphamide before transplantation provides an effective alternative to cyclophosphamide and total-body irradiation before transplantation for the treatment of acute nonlymphocytic leukaemia. ²</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: Available where bone marrow transplant is being done	

* 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 busulphan be included as an Essential Medicine for Pre allogeneic and autologous stem cell transplant conditioning.

¹ Groote Schuur Hospital, patients on busulphan 2018.

² Santos GW, Tutschka PJ, Brookmeyer R, Saral R, Beschorner WE, Bias WB, et. al. Marrow Transplantation for Acute Nonlymphocytic Leukemia after Treatment with Busulfan and Cyclophosphamide. *New England Journal of Medicine*