

HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

Date: March 2019

Medicine (INN): Melphalan (injection and tablets)

Medicine (ATC): L01AA03

Indication (ICD10 code): Multiple myeloma (oral-remission induction combined with steroids in older) (IV –pre-autologous stem cell transplant in multiple myeloma and lymphomas)

Patient population: adults

Prevalence of condition: 310 new cases/year¹

Level of Care: Tertiary and Quaternary

Prescriber Level: Oncologist or haematologist

Current standard of Care: Oral melphalan plus prednisone (multiple myeloma transplant ineligible). Intravenous melphalan high dose prior to autologous stem cell transplant.

Efficacy estimates: Objective response in 49% of patients with multiple myeloma treated with melphalan.² Shown to be an effective conditioning agent.³

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 <i>de novo</i> 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 melphalan be include as an Essential Medicine in the management of multiple myeloma.

¹ National Cancer Registry, 2014. NICD.

² Alexanian R, Bergsagel DE, Migliore PJ, et.al. Melphalan Therapy for plasma cell myeloma. *Blood*. 1968, 31 (1).

³ Moreau P, Facon R, Attal M, et.al. Comparison of 200mg/m² melphalan and 8Gy total body irradiation plus 140 mg/m² melphalan as conditioning regimens for peripherhal blood stem cell transplantation in patients with newly diagnosed multiple myeloma: final analysis of the Intergroupe Francophone du Myelome 9505 randomized trial. *Blood*. 2002, 99 (3): 731-735.