

## HISTORICALLY ACCEPTED USE

### Tertiary and Quaternary Committee

#### Executive Summary

**Date:** March 2019

**Medicine (INN):** Calcium folinate

**Medicine (ATC):** V03AF03

**Indication/s (ICD10 code):** 1. Potentiating agent with 5-Fluorouracil (5-FU); 2. Rescue following high dose methotrexate.

**Patient population/s:** Various malignancies

**Prevalence of condition:** Varied

**Level of Care:** Tertiary and Quaternary

**Prescriber Level:** Oncologist and haematologist (adult and paediatrics)

**Current standard of Care:** Calcium folinate together with 5-FU and other agents

**Efficacy estimates:** Calcium folinate shown to modulate 5-FU in patients with advanced adenocarcinoma of the colon.<sup>1</sup> Tetrahydrofolate rescue in patients receiving high dose dihydrofolate reductase inhibition.

#### 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 calcium folinate be included as an Essential Medicine for various malignancies.

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<sup>1</sup> Rustum YM. Biochemical rationale for the 5-fluorouracil leucovorin combination and update of clinical experience. *Journal of Chemotherapy*. 1990 2(1):5-11.