

HISTORICALLY ACCEPTED USE

Tertiary and Quaternary Committee

Executive Summary

Date: April 2019

Medicine (INN): Cisplatin - Radiosensitiser

Medicine (ATC): L01XA01

Indication/s (ICD10 code): Various malignancies including: C00-C15, C34, C44, C51-C53, C60, C67.

Patient population: Various malignancies including: Head and neck, oesophagus, lung, cervical, vulvovaginal, anal, bladder, penile, squamous cell carcinoma of the skin.

Prevalence of condition:¹

Cancer site	New cases in 2014	Cases/100 000/year
Cervical	5735	20.73
Vagina	164	0.59
Head and neck	2097	7.83
Oesophagus	1498	5.55
Lung	2727	10.14
Vulva	343	1.24
Anus	220	0.81
Bladder	1279	4.78
Penile	172	0.65
Squamous cell carcinoma of skin	6678	24.8

Level of Care: Tertiary and Quaternary

Prescriber Level: Oncologist

Current standard of Care: Cisplatin

Efficacy estimates: Cervical Cancer:²

Relative risk of progression of disease or death was 0.57 (95 percent confidence interval, 0.42 to 0.78) in the group given radiotherapy combined with cisplatin therapy, versus group given radiotherapy combined with hydroxyurea therapy.

AND

Relative risk of progression of disease or death was 0.55 (95 percent confidence interval, 0.40 to 0.75) in the group given radiotherapy combined with cisplatin, fluorouracil, and hydroxyurea, versus the group given radiotherapy combined with hydroxyurea therapy.

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"/>
		Included as a radiosensitiser for the following: cervical cancer, head and neck cancer, nasopharyngeal cancer	

¹ National Cancer Registry. 2014.

² Rose PG¹, Bundy BN, Watkins EB, Thigpen JT, Deppe G, Maiman MA, Clarke-Pearson DL, Insalaco S. Concurrent cisplatin-based radiotherapy and chemotherapy for locally advanced cervical cancer. N Engl J Med. 1999 Apr 15;340(15):1144-53.

2	The medicine is currently registered by SAHPRA for the indication.	<p style="text-align: center;">YES NO</p> <p style="text-align: center;"><input checked="" type="checkbox"/> <input type="checkbox"/></p> <p>Registered for treatment of cancer since late 1970's</p>
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.	<p style="text-align: center;">YES NO</p> <p style="text-align: center;"><input checked="" type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>
4	No new safety or efficacy concerns.	<p style="text-align: center;">YES NO</p> <p style="text-align: center;"><input checked="" type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>
5	Budget impact is not expected to have an incremental increase, that a de novo review is justified.	<p style="text-align: center;">YES NO</p> <p style="text-align: center;"><input checked="" type="checkbox"/> <input type="checkbox"/></p> <p>Comment: dose 30 - 40mg/m² weekly for 6 weeks</p>
6	Equitable access across the country is essential, and is limited only by the availability of adequately trained staff and availability of equipment.	<p style="text-align: center;">YES NO</p> <p style="text-align: center;"><input checked="" type="checkbox"/> <input type="checkbox"/></p> <p>Comment</p>

** 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 cisplatin be included on the Essential Medicines List as a radiosensitising agent