14.03(g) TOPOTECAN, Solution concentrate for I.V. infusion 4 mg in 4 mL (as hydrochloride), Topotecan Accord®, Accord Healthcare

1 Purpose of Application

1.1 The committee secretariat submission requested a Section 100 (Efficient Funding of Chemotherapy Program), Authority Required (STREAMLINED) listing of a new form of topotecan (referred to as Topotecan Accord® from herein) under the same conditions as the existing brand Hycamtin®.

2 Background

Registration status

2.1 Topotecan Accord was TGA registered on 4 December 2019 as a single agent for the treatment of metastatic carcinoma of the ovary after failure of first-line of subsequent therapy. It is also indicated for the treatment of small cell lung carcinoma after failure of first line chemotherapy, and in combination with cisplatin for the treatment of patients with histologically confirmed Stage IC-B, recurrent, or persistent carcinoma of the cervix, which is not amenable to curative treatment with surgery and/or radiation therapy.

2.2 The TGA also noted the new form of topotecan (as hydrochloride) concentrated injection included data that established to the TGA's satisfaction that the products can be considered bioequivalent to Hycamtin topotecan (as hydrochloride) powder for injection.

Previous PBAC consideration

2.3 The concentrated solution formulation of topotecan has not been considered by the PBAC previously.

For more detail on PBAC's view, see section 6 PBAC outcome.

3 Requested listing

3.1 The submission requested the same listing as the Hycamtin branded topotecan product as shown below:

Name, Restriction, Manner of administration and form	PBS item code	Max. amt	№.of Rpts	DPMA	Manufacturer
TOPOTECAN Injection	4617B (Public) 7260D (Private)	3500 mcg	17	$117.14 (Public) $157.35 (Private)	
Available brands					
Hycamtin (topotecan 4 mg injection, 5 vials)					Sandoz Pty Ltd
Topotecan Accord *(topotecan 4 mg/4 mL injection, 5 x 4mL vials)*					*Accord Healthcare Pty Ltd*

Category / Program: Section 100 – Efficient Funding of Chemotherapy– Public/Private
Prescriber type: ☒Medical Practitioners
Restriction Type / Method: ☒Authority Required – Streamlined (6238)
Indication: Advanced metastatic ovarian cancer
Clinical criteria:
Patient must have failed prior therapy which included a platinum compound.

3.2 The submission was referred to the PBAC as the requested form (concentrated drug solution) did not have an identical, existing form to list against through the generic brand listing process (the existing form of topotecan requires the drug powder to be dissolved in diluent).

For more details on PBAC's view, see section 6 PBAC outcome.

4 Comparator

4.1 The submission nominated the currently listed brand of the same drug, Hycamtin, as the comparator. This was appropriate.

5 Consideration of Evidence

Sponsor hearing

5.1 There was no hearing for this item as it was a committee secretariat submission.

Consumer comments

5.2 The PBAC noted and welcomed the input from organisations (2) via the Consumer Comments facility on the PBS website. Lung Foundation Australia described a range of benefits of listing a Topotecan Accord including a greater certainty of supply due to an alternative supplier as well as offering an effective alternative treatment for small cell lung cancer (SCLC) on the PBS.

5.3 The Medical Oncology Group of Australia (MOGA) also expressed its strong support for the Topotecan Accord submission, categorising it as one of the therapies of "highest priority for PBS listing" on the basis of improvements in overall survival and quality of life. The PBAC noted that the MOGA presented a European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS) for Topotecan

Accord, which was limited to 4 (out of a maximum of 5, where 5 and 4 represent the grades with substantial improvement), based on comparison with best supportive care using the O'Brien et al trial.[1]

Pricing considerations

5.4 The committee secretariat submission proposed the same price for Topotecan Accord as Hycamtin.

5.5 The committee secretariat submission did not provide financial estimates.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

6.1 The PBAC recommended the listing of a new form of topotecan, solution concentrate for I.V. infusion 4 mg in 4 mL (as hydrochloride), as an unrestricted benefit, on the basis that it should be available only under special arrangements under Section 100 (Efficient Funding of Chemotherapy).

6.2 The PBAC noted that the TGA considered the new form of topotecan to be bioequivalent to the currently listed form of topotecan, Hycamtin.

6.3 The PBAC noted that the submission requested the same listing as Hycamtin. However, the PBAC considered that expanding the current PBS listing to an unrestricted benefit would allow topotecan to be used in a number of different cancers types for a small population of patients who are intolerant to current treatment combinations. The PBAC noted that the Lung Foundation Australia and the Medical Oncology Group of Australia were supportive of extending the indication of topotecan to include small cell lung cancer.

6.4 The PBAC noted that topotecan has significantly reduced in price since it was initially listed on the PBS, and considered that changing the authority level from an Authority Required (STREAMLINED) to an unrestricted benefit would likely have only a small financial impact given that additional use would be in a small number of patients.

6.5 The PBAC considered that the change from Authority Required (STREAMLINED) to an unrestricted benefit should also be applied to topotecan (Hycamtin).

6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Topotecan Accord is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Hycamtin, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health*

[1] O'Brien MER, Ciuleanu T-E, Tsekov H, et al: Phase III Trial Comparing Supportive Care Alone With Supportive Care With Oral Topotecan in Patients With Relapsed Small-Cell Lung Cancer. Journal of Clinical Oncology 24:5441-5447, 2006

(Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009 for Pricing Pathway A were not met.

6.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

7 Recommended listing

7.1 Add new non-originator medicinal product pack to the existing listing for topotecan as shown below.

7.2 Amend restriction type from 'Authority Required (Streamlined)' to 'unrestricted benefit' for all topotecan listed products.

Name, Restriction, Manner of administration and form	PBS item code	Max. amount	№.of Rpts	Manufacturer
TOPOTECAN Injection	4617B (Public) 7260D (Private)	3500 mcg	17	
Available brands Hycamtin (topotecan 4 mg injection, 5 vials)				Sandoz Pty Ltd
Topotecan Accord *(topotecan 4 mg/4 mL injection, 5 x 4 mL vials)*				*Accord Healthcare Pty Ltd*

Amend Restriction Summary 6238 / Treatment of Concept 6238 Authority Required Streamlined as follows

Category / Program: Section 100 – Efficient Funding of Chemotherapy– Public/Private
Prescriber type: ☒Medical Practitioners
Restriction Type: ☒*Unrestricted benefit* ~~☒Authority Required – Streamlined (6238)~~
~~**Indication:**~~~~Advanced metastatic ovarian cancer~~
~~**Clinical criteria:**~~
~~Patient must have failed prior therapy which included a platinum compound.~~

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.