

## 6.23 VARENICLINE

### Tablet 1 mg (as tartrate)

### Champix<sup>®</sup>, Pfizer Australia Pty Ltd

#### 1 Purpose of Item

- 1.1 The minor submission requested a change to the existing listing of varenicline (PBS item codes 5469W and 9129L) to enable continuing PBS subsidised treatment to be available to patients should they commence treatment with a non-PBS subsidised initiation pack provided to them as an inpatient in a public hospital.

#### 2 Requested changes to the existing listing

- 2.1 The submission requested the following restrictions with suggested deletions crossed out with strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
VARENICLINE Tablet 1 mg (as tartrate), 56	2	0	\$208.61	Champix Pfizer Australia Pty Ltd

PBS Item 9129L

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
PBS Indication:	Nicotine dependence
Treatment phase:	Continuation of a short-term (12 weeks or 24 weeks) course of treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Treatment criteria:	Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

<b>Clinical criteria:</b>	<p>The treatment must be as an aid to achieving abstinence from smoking,</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition,</p> <p>AND</p> <p>Patient must have previously received <del>PBS-subsidised</del> treatment with this drug during this current course of treatment,</p>
<b>Administrative Advice</b>	<p>Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.</p> <p>Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.</p> <p>Note No increase in the maximum quantity or number of units may be authorised.</p> <p>Note No increase in the maximum number of repeats may be authorised.</p>

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
VARENICLINE Tablet 1 mg (as tartrate), 56	1	2	\$109.55	Champix Pfizer Australia Pty Ltd

PBS Item 5469W

Category / Program	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
<b>PBS Indication:</b>	Nicotine dependence
<b>Treatment phase:</b>	Completion of a short-term (24 weeks) course of treatment
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined

<b>Treatment criteria:</b>	Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.
<b>Clinical criteria:</b>	<p>The treatment must be as an aid to achieving abstinence from smoking,</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition,</p> <p>AND</p> <p>Patient must have previously received <del>PBS-subsidised</del> treatment with this drug during this current course of treatment,</p> <p>AND</p> <p>Patient must have ceased smoking in the process of completing an initial 12-weeks or ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment.</p>
<b>Administrative Advice</b>	<p>Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.</p> <p>Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.</p> <p>Note No increase in the maximum quantity or number of units may be authorised.</p> <p>Note No increase in the maximum number of repeats may be authorised.</p>

### 3 Current Situation

- 3.1 The minor submission requested a change to the clinical criteria that would broaden the patient population to include patients who received an initiation pack of varenicline therapy as an inpatient in a public hospital.
- 3.2 The PBAC noted that DUSC reviewed a report analysing the impact of nicotine replacement therapy (NRT) products changing from Authority Required to Authority Required (STREAMLINED) on 1 December 2013. The review showed that the change in restriction level did not significantly impact the utilisation trends on the R/PBS smoking cessation therapies.

#### ***Sponsor hearing***

- 3.3 There was no hearing for this item as it was a minor submission.

### Consumer comments

3.4 The PBAC noted that no consumer comments were received for this resubmission.

## 4 PBAC Outcome

4.1 The PBAC recommended the removal of the requirement for the initiation of treatment to be PBS subsidised for the continuing treatment (item 9129L) listing. The PBAC considered it unlikely that this amendment would result in any issues or potential leakage for varenicline.

4.2 The PBAC proposed no changes to item 5469W which completes the course of varenicline.

### Outcome:

Recommended

## 5 Recommended listing

Amend item.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name	Manufacturer
VARENICLINE Tablet 1 mg (as tartrate), 56	2	0	Champix	Pfizer Australia Pty Ltd

PBS Item 9129L

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
PBS Indication:	Nicotine dependence
Treatment phase:	Continuation of a short-term (12 weeks or 24 weeks) course of treatment
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
Treatment criteria:	Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program.

<p><b>Clinical criteria:</b></p>	<p>The treatment must be as an aid to achieving abstinence from smoking,</p> <p>AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition,</p> <p>AND</p> <p>Patient must have previously received <del>PBS-subsidised</del> treatment with this drug during this current course of treatment,</p>
<p><b>Administrative Advice</b></p>	<p>Note A course of treatment with this drug is 12 weeks or up to 24 weeks, if initial treatment of 12 weeks has been successful.</p> <p>Note A patient may only qualify for PBS-subsidised treatment under this treatment phase restriction once during a short-term course of treatment.</p> <p>Note No increase in the maximum quantity or number of units may be authorised.</p> <p>Note No increase in the maximum number of repeats may be authorised.</p>

## 6 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

## 7 Sponsor's Comment

The sponsor had no comment.