

**6.08 BOTULINUM TOXIN TYPE A,
Lyophilised powder for injection 100 units,
Botox[®], Allergan Australia Pty Limited.**

1 Purpose of Application

- 1.1 The minor submission requested amendments to the current Section 100 Botulinum Toxin Program listing to add gynaecologists to the treating practitioners for the treatment of patients with urinary incontinence due to idiopathic overactive bladder (IOAB).

2 Requested listing

- 2.1 The submission did not provide a requested listing. The secretariat suggested wording for the restriction is provided below with additions to the current restriction indicated in italics.

Public Summary Document – March 2017 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
BOTULINUM TOXIN TYPE A botulinum toxin type A 100 units injection, 1 vial	4	0	\$1625.94	Botox®	Allergan Australia Pty Limited

Category / Program	Section 100 – Botulinum toxin program
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Urinary incontinence
PBS Indication:	Urinary incontinence
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:	Must be treated by a urologist; OR Must be treated by a urogynaecologist; OR Must be treated by a gynaecologist.
Clinical criteria:	The condition must be due to idiopathic overactive bladder, AND The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, AND Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, AND Patient must be willing and able to self-catheterise, AND The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.
Population criteria:	Patient must be aged 18 years or older.
Administrative Advice	Special Pricing Arrangements apply. The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.
Cautions	Contraindications to treatment include known sensitivity to botulinum toxin.

For more detail on PBAC's view, see section 5 "PBAC outcome"

3 Background

- 3.1 Botulinum toxin type A was TGA registered for “the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adult patients who have an inadequate response to or are intolerant of an anticholinergic medication” on 14 August 2013.
- 3.2 The PBAC recommended botulinum toxin type A for the treatment of urinary incontinence due to idiopathic overactive bladder at the November 2013 meeting.
- 3.3 Botulinum toxin type A is currently PBS-listed for the following indications:
- Urinary incontinence
 - Blepharospasm or hemifacial spasm
 - Dynamic equinus foot deformity
 - Moderate to severe spasticity of the upper limb
 - Moderate to severe spasticity of the upper limb following a stroke
 - Chronic migraine
 - Severe primary axillary hyperhidrosis
 - Spasmodic torticollis

4 Current situation

- 4.1 The submission stated that gynaecologists are currently involved in the diagnosis and management of urinary incontinence due to IOAB. Due to the inability to prescribe botulinum toxin type A through the PBS or Medicare Benefits Schedule (MBS), gynaecologists use sacral neuromodulation, or sacral nerve stimulation (SNS).
- 4.2 The submission indicated that gynaecologists currently receive training for, and regularly perform, the procedure to deliver botulinum toxin type A to the affected site of patients with IOAB.
- 4.3 The Medical Services Advisory Committee (MSAC) noted that SNS is a more expensive and invasive second-line treatment for IOAB compared to botulinum toxin type A¹. The submission argued that allowing gynaecologists to provide this treatment would enable patients to access this less invasive treatment option with their current treatment provider.
- 4.4 The PBAC noted that botulinum toxin type a was a co-dependent technology, with the procedure for delivery of the drug reimbursed under the MBS. The PBAC noted that medical practitioners can only claim the relevant MBS item (18379) if the botulinum toxin type A is PBS-subsidised, and therefore if gynaecologists are

¹ Medical Services Advisory Committee, 2013, *Application 1272 – Intravesical injection of botulinum toxin type A (BOTOX®) into the bladder wall for urinary incontinence due to idiopathic overactive bladder*, viewed 12 January 2017, [http://www.msac.gov.au/internet/msac/publishing.nsf/Content/82E8A67E05088D3ACA25801000123BB7/\\$File/1272-PSD-Botox%20for%20iOAB-accessible%20\(D14-1954004\).pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/82E8A67E05088D3ACA25801000123BB7/$File/1272-PSD-Botox%20for%20iOAB-accessible%20(D14-1954004).pdf)

included in the PBS listing, they will also be able to claim an MBS item for the delivery of the drug.

For more detail on PBAC's view, see section 5 "PBAC outcome"

Sponsor hearing

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

Consumer comments

4.6 The PBAC noted that no consumer comments were received for this item. The PBAC noted that the submission provided a letter from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists in support of the request.

Estimated PBS usage & financial implications

4.7 The minor submission did not provide financial estimates, but claimed that there would be a small number of gynaecologists that choose to provide this treatment, and therefore that the financial implications would be minimal.

4.8 The PBAC noted that the proposed change to the restriction did not affect the eligible patient population, and did not increase the risk of leakage.

4.9 The PBAC also noted that there may be a reduction in MBS costs associated with referrals reducing referrals to specialists who can provide this treatment, and a reduction in the use of SNS. Although the magnitude of this difference was likely to be small, there was no evidence provided in the submission to support an estimate of this potential saving.

4.10 The PBAC noted that botulinum toxin type A for IOAB is subject to a Risk Share Arrangement (RSA), and that the RSA would not be amended as a result of this change.

For more detail on PBAC's view, see section 5 "PBAC outcome"

5 PBAC Outcome

5.1 The PBAC recommended the amendment to the current Section 100 Botulinum Toxin Program listing of botulinum toxin type a, for the treatment of patients with urinary incontinence due to idiopathic overactive bladder (IOAB) to add gynaecologists to the treating practitioners who are able to provide PBS-subsidised treatment.

5.2 The PBAC noted that gynaecologists are currently involved in the diagnosis and management of urinary incontinence due to IOAB, and currently receive training for, and regularly perform, the necessary procedure to deliver botulinum toxin type A to the affected site of patients with IOAB.

- 5.3 The PBAC noted that extending the restriction to gynaecologists as treatment providers for IOAB through the PBS or MBS may decrease the use of a more expensive and invasive second-line treatment, sacral neuromodulation (or sacral nerve stimulation) and would allow patients to be managed by their current treatment provider. The PBAC recommended removing urogynaecologists as approved prescribers from the treatment criteria as they will be included in the general gynaecologist classification.
- 5.4 The PBAC considered that the number of eligible patients will not be affected by a change in restriction, and it is anticipated that only a small number of gynaecologists would choose to provide this treatment. The PBAC also considered that allowing gynaecologists to provide this treatment is unlikely to lead to inappropriate use outside the restriction. The PBAC noted that botulinum toxin type a for IOAB is subject to a Risk Share Arrangement (RSA), and considered that the RSA would not need to be amended as a result of this change. Therefore, the PBAC was of the view that there would be no financial implications to the PBS of allowing gynaecologists to provide botulinum toxin type a treatment for IOAB.
- 5.5 The PBAC advised that botulinum toxin type A is not suitable for prescribing by nurse practitioners.
- 5.6 The PBAC noted that this submission is not eligible for an Independent Review. Independent Review is not available in response to a request to modify or extend an existing listing.

Outcome:

Recommended

6 Recommended listing

6.1 Amend existing listing as follows:

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Population criteria:	Patient must be aged 18 years or older.
Administrative Advice	Special Pricing Arrangements apply. The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.
Cautions	Contraindications to treatment include known sensitivity to botulinum toxin.

7 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.

8 Sponsor's Comment

The sponsor had no comment.