

# Botulinum toxin A

## *for treating blepharospasm and hemifacial spasm*

Technology Guidance from the MOH Drug Advisory Committee

### Guidance recommendations

The Ministry of Health's Drug Advisory Committee has recommended:

- ✓ *Clostridium botulinum* toxin type A neurotoxin complex (Botox) 50 U and 100 U injection vials for treating adults with blepharospasm or hemifacial spasm.

Botulinum toxin A must be administered by a neurologist trained in movement disorder or a specialist physician who has undergone training to administer botulinum toxin type A to patients with movement disorders.

#### **Subsidy status**

*Clostridium botulinum* toxin type A neurotoxin complex (Botox) 50 U and 100 U injection vials are recommended for inclusion on the Medication Assistance Fund (MAF) for the abovementioned indications.

MAF **does not** apply to Botox 200 U injection vial, Dysport 300 U and 500 U injection vials and Xeomin 50 U and 100 U injection vials.

*Published on 2 September 2019*

## Factors considered to inform the recommendations for subsidy

### Technology evaluation

- 1.1 The MOH Drug Advisory Committee (“the Committee”) considered the evidence presented for the technology evaluation of botulinum toxin A for the management of blepharospasm and hemifacial spasm in adults. The Agency for Care Effectiveness conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for all three brands of botulinum toxin A (Botox, Dysport and Xeomin) was considered in line with the registered indications.
- 1.2 The evidence was used to inform the Committee’s deliberations around four core decision-making criteria:
  - Clinical need of patients and nature of the condition;
  - Clinical effectiveness and safety of the technology;
  - Cost-effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives; and
  - Estimated annual technology cost and the number of patients likely to benefit from the technology.
- 1.3 Additional factors, including social and value judgments, may also inform the Committee’s subsidy considerations.

### Clinical need

- 2.1 The Committee noted that botulinum toxin A is routinely used as a first-line therapeutic option for treating blepharospasm and hemifacial spasm in adults in Singapore, in line with international clinical guidelines, owing to its favourable efficacy and tolerability profile and the lack of suitable alternative treatment options.

### Clinical effectiveness and safety

- 3.1 The Committee acknowledged that published studies demonstrated that botulinum toxin type A was clinically effective in improving clinical symptoms and functional impairment compared with placebo in patients with blepharospasm.
- 3.2 The Committee noted that while evidence supporting the use of botulinum toxin A in patients with hemifacial spasm was limited to a few small and poor-quality trials, the drug was shown to be effective in improving symptoms and clinical status compared with placebo.

- 3.3 The Committee noted that botulinum toxin A was generally well-tolerated by patients with either condition in the studies.
- 3.4 The Committee considered that all three registered brands of botulinum toxin type A (Botox, Dysport and Xeomin) were clinically comparable in terms of their efficacy and safety profile for treating blepharospasm at a dose equivalence ratio of 1:4:1, according to published evidence. Similarly, the efficacy and safety of Botox and Dysport were considered comparable for treating hemifacial spasm at a dose equivalence ratio of 1:4.

## Cost effectiveness

- 4.1 The Committee noted that no local economic evaluations on the use of botulinum toxin A for treating blepharospasm were available. It acknowledged that a published economic evaluation in UK showed that botulinum toxin A was cost-effective compared with placebo in patients with blepharospasm at an ICER of £3,734/QALY and agreed that the results were generalisable to the Singapore setting.
- 4.2 The Committee noted that no published local or overseas cost-effectiveness studies on the use of botulinum toxin type A for treating hemifacial spasm were available. However, based on the good clinical efficacy of botulinum toxin type A in patients with hemifacial spasm and the lower total dose and associated treatment cost required for this condition compared with blepharospasm, the Committee considered that botulinum toxin type A was likely to be cost-effective for hemifacial spasm in the Singapore context.
- 4.3 In view of comparable effectiveness and safety among the three available brands of botulinum toxin A, the Committee agreed a cost-minimisation approach was appropriate to select the lowest priced drug brand for subsidy. A dose relativity ratio of 1:4:1 (Botox:Dysport:Xeomin) was used in the cost minimisation analysis, in line with data from randomised controlled trials and the therapeutic relativity accepted in Australia (PBAC). The manufacturers of all three brands of botulinum toxin A offered price discounts as part of value-based pricing (VBP) discussions. The Committee agreed that Botox was the most cost-effective treatment option given its lowest unit price.

## Estimated annual technology cost

- 5.1 The Committee estimated the annual cost impact to be less than SG\$500,000 in the first year of listing Botox 50 U and 100 U injection vials on the MAF for patients with blepharospasm or hemifacial spasm.

## Recommendation

- 6.1 Based on available evidence, the Committee recommended botulinum toxin type A (Botox) 50 U and 100 U injection vials be listed on the MAF for the management of blepharospasm and hemifacial spasm, given its acceptable clinical and cost-effectiveness, and the high clinical need for this treatment in the absence of alternative treatment options.
- 6.2 Botox 200 U injection vial, Dysport 300 U and 500 U injection vials and Xeomin 50 U and 100 U injection vials were not recommended due to their higher costs compared with Botox 50 U and 100 U injection vials that were not justified by the clinical outcomes they provide over Botox 50 U and 100 U injection vials.

### About the Agency

The Agency for Care Effectiveness (ACE) is the national health technology assessment agency in Singapore residing within the Ministry of Health. It conducts evaluations to inform the subsidy of treatments, and produces guidance on the appropriate use of treatments for public hospitals and institutions in Singapore. When using the guidance, the responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

Find out more about ACE at [www.ace-hta.gov.sg/about](http://www.ace-hta.gov.sg/about)

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