

Botulinum toxin A

for treating cervical dystonia

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 cervical dystonia.

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 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 indication.

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.

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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 treating adults with cervical dystonia. 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 cervical dystonia, owing to its favourable efficacy and tolerability profile. The Committee acknowledged that the use of botulinum toxin A for this indication is supported by international clinical guidelines and that there are currently no suitable alternative treatment options.
- 2.2 Local clinical experts considered all three brands of botulinum toxin A (Botox, Dysport and Xeomin) clinically comparable for this indication.

Clinical effectiveness and safety

- 3.1 The Committee acknowledged that the dosing of botulinum toxin A is individualised based on patient need, and unit doses are not equivalent among brands. Though the dose relativity between Botox and Xeomin is generally accepted to be 1:1, there is greater uncertainty surrounding the dose relativity between Botox and Dysport. The Committee accepted a dose relativity of around 1:3 between Botox and Dysport in line with ratios used by local clinicians, results from dose conversion studies and the therapeutic relativity accepted in Australia (PBAC) for cervical dystonia.
- 3.2 The Committee considered that the pivotal trials of all three brands demonstrated that botulinum toxin A led to statistically greater disease-specific improvement compared with placebo, with no significant difference in efficacy between brands.
- 3.3 The Committee noted that botulinum toxin A was found to be well tolerated when compared with placebo based on safety results reported in the clinical trials.

Cost effectiveness

- 4.1 In the absence of local cost-effectiveness studies, the Committee considered published overseas economic analyses and agreed that botulinum toxin A was likely to be cost effective compared with best supportive care when results were generalised to the Singapore setting.
- 4.2 The Committee noted that following VBP discussions, the manufacturers for all three brands offered price discounts contingent on an MAF listing for their product. Given all three brands of botulinum toxin A were considered to be comparable in effectiveness and safety, the Committee agreed that the Botox 50 U and 100 U injection vials were the most cost effective options based on a cost-minimisation approach, due to their lowest unit cost relative to the other brands.

Estimated annual technology cost

- 5.1 The Committee estimated the annual cost impact was 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 cervical dystonia.

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 treating adults with cervical dystonia, in view of favourable clinical and cost effectiveness, and the high clinical need to subsidise this treatment to ensure appropriate patient care.
- 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

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