Technology Guidance

Botulinum toxin A

for treating focal spasticity of the upper or lower limbs in children with cerebral palsy

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, and
- ✓ *Clostridium botulinum* type A toxin-haemagglutinin complex (Dysport) 300 U and 500 U injection vials

for treating children, aged 2 years or older, with focal spasticity of the upper or lower limbs (including dynamic equinus foot deformity) due to cerebral palsy, and who:

- do not have significant joint contractures, i.e. the affected joint is not permanently fixed in position due to shortening of the target muscle; and
- are concurrently receiving ongoing supportive therapy, e.g. physiotherapy or occupational therapy.

Botulinum toxin A must be administered by either a neurologist trained in movement disorder or a rehabilitation physician who has undergone training to administer botulinum toxin A.

Funding 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 from 2 September 2019.

Clostridium botulinum type A toxin-haemagglutinin complex (Dysport) 300 U and 500 U injection vials are recommended for inclusion on the MAF for the abovementioned indication from 1 November 2025.

MAF assistance **does not** apply to Botox 200 U injection vial or other brands of botulinum toxin A.

Updated: 16 September 2025

Technology evaluation

1.1. The MOH Drug Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of botulinum toxin type A for treating focal spasticity of the upper or lower limbs in children with cerebral palsy in April 2019. The Agency for Care Effectiveness conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for two brands of botulinum toxin type A (Botox and Dysport) was considered. As the use of Xeomin in children has not been approved by the Health Sciences Authority (HSA), this brand of botulinum toxin type A was not considered in the evaluation.

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 funding considerations.

1.4. The Committee considered a revised price proposal for Dysport in July 2025.

Clinical need

2.1. In children with cerebral palsy, there is high clinical need for effective treatments for focal spasticity of the upper and lower limbs (including dynamic equinus foot deformity). The Committee acknowledged that use of botulinum toxin type A for these conditions currently constitutes standard of care in local practice, in line with international clinical guidelines.

2.2. Local clinical experts considered Botox and Dysport to be clinically comparable for treating focal spasticity in children with cerebral palsy.

Clinical effectiveness and safety

3.1. The Committee acknowledged that the dosing of botulinum toxin type A is individualised based on patient need, and unit doses are not equivalent among brands. Given the 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 focal spasticity in children.

3.2. The Committee considered published clinical studies which showed that the concurrent use of botulinum toxin type A with supportive therapy (e.g. physiotherapy or occupational therapy) was clinically effective in reducing muscle spasticity and allowing achievement of functional goals in children with upper limb focal spasticity and dynamic equinus foot deformity. Although clinical data were limited for lower limb focal spasticity, there was some evidence showing benefit of botulinum toxin type A in reducing spasticity in calf muscles and hip adductors in children with cerebral palsy. The Committee acknowledged that there was a high clinical need for effective treatment for patients with lower limb spasticity and considered that the benefit of botulinum toxin type A in these patients outweighed the risks.

3.3. The Committee noted that botulinum toxin type A was generally well-tolerated in all studies.

3.4. The Committee considered that the clinical outcomes for each brand of botulinum toxin type A (Botox or Dysport) were consistent across the studies, and concluded that they were clinically comparable in terms of their efficacy and safety profiles for treating focal spasticity in children with cerebral palsy.

Cost effectiveness

4.1. The Committee noted that there were no local cost-effectiveness studies of botulinum toxin type A in children with focal spasticity due to cerebral palsy. However, the Committee concluded that it was likely to be cost-effective for this population, given they had previously determined that it was cost-effective for a related indication (focal spasticity of the upper limbs due to stroke) in adults.

4.2. The companies of both brands of botulinum toxin A offered price reductions as part of value-based pricing (VBP) discussions. The Committee agreed that Botox was the most cost-effective treatment option based on appropriate dose conversion ratios.

4.3. In July 2025, following a revised price proposal for Dysport, the Committee agreed that the cost of Dysport was reasonable and could be considered an acceptable use of healthcare resources.

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 botulinum toxin A on the MAF for children with focal spasticity.

Recommendations

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 focal spasticity of the upper or lower limbs (including dynamic equinus foot deformity) in children with cerebral palsy, 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 and Dysport 300 U and 500 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.

6.3. Xeomin 50 U and 100 U injection vials are not approved for use in children with focal spasticity and are not recommended for subsidy.

6.4. In July 2025, the Committee also recommended Dysport 300 U and 500 U injection vials for listing on the MAF in line with the same clinical criteria as Botox 50 U and 100 U injection vials, following an acceptable price reduction offered by the company.

VERSION HISTORY

Guidance on botulinum toxin A
for treating focal spasticity of the upper or lower limbs in children with cerebral palsy

This Version History is provided to track any updates or changes to the guidance following the first publication date. It is not part of the guidance.

1. **Publication of guidance**
   Date of Publication 2 Sep 2019

2. **Guidance updated to extend MAF listing to Dysport 300 U and 500 U injection vials**
   Date of Publication 16 Sep 2025

Agency for Care Effectiveness - ACE Agency for Care Effectiveness (ACE)

About the Agency

The Agency for Care Effectiveness (ACE) was established by the Ministry of Health (Singapore) to drive better decision-making in healthcare through health technology assessment (HTA), clinical guidance, and education.

As the national HTA agency, ACE conducts evaluations to inform government funding decisions for treatments, diagnostic tests and vaccines, and produces guidance for public hospitals and institutions in Singapore.

The guidance is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition. 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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