

## Position Statement on the Therapeutic Use of Botulinum Toxin in Rehabilitation Medicine for spasticity and dystonia

### Executive Summary

Spasticity and dystonia are movement disorders that may adversely affect the lives of many people after neurological illness or injury. The effects of spasticity and dystonia are not consistent from one person to the next, in that a range of factors will influence how deficits are exhibited by an individual. However, there is good, high quality evidence to suggest that rehabilitation and pharmaceutical interventions, when utilised appropriately, can decrease the impact of spasticity and dystonia.

This document has two sections. The first presents consensus expert opinion over the utilisation of Botulinum Toxin (BoNT) as an intervention for reducing the impact of spasticity. The second section presents inconsistencies in the current Australia legislative and funding models that, while presumably unintended, actively disenfranchise people with disabilities from appropriate medical and rehabilitation intervention. A significant number of people afflicted with spasticity/dystonia can continue living in the community with the appropriate intervention.

### Section 1

#### Current practice considerations

##### Background

Upper motor neuron (UMN) syndromes result from a wide variety of conditions that damage the central nervous system (see Box 1). UMN syndromes may be seen in acute onset injuries (such as stroke or traumatic brain injury) or in progressive conditions (such as multiple sclerosis). Most causes of UMN occur later in life, but may also be present at the time of birth where the UMN syndrome is part of cerebral palsy (see box 1). The UMN syndrome presents with altered motor function in the affected limb/s, with the changes often conceptualised in terms of negative features (such as reduced voluntary muscle strength and decreased dexterity) and positive features (such as muscle over activity, dystonia and spasticity). These deficits may occur alongside a range of other associated problems that can also adversely impact on limb function, arising from cortical or subcortical dysfunction including sensory and visual neglects, motor planning deficits, attentional deficits, and increased muscle fatigue.

We will define spasticity using the definition accepted by the SPASM consortium as “disordered sensori-motor control, resulting from an upper motor neuron lesion, presenting as intermittent or sustained involuntary activation of muscles” (Pandyan et al (SPASM consortium). Disability and Rehabilitation, 2005)

Dystonia is defined as “slow, twisting, involuntary movements associated with forceful and sustained muscle contractions or spasms”.

We frequently see the combination of spasticity and dystonia as part of the UMN syndrome and call this spastic dystonia (a term first used by Denny-Brown in 1966).

### **Box 1. Common Causes of the UMN syndrome**

#### **Acute Onset**

- Stroke
- Traumatic Brain Injury
- Spinal Cord Injury
- Cerebral Hypoxia
- Encephalopathies
- Infections

#### **Chronic / Neurodegenerative/Progressive**

- Multiple Sclerosis
- Spinal Cord Injury
- Parkinson's Disease
- Multi-Infarct Dementia
- Brain Tumours

#### **Developmental/Congenital**

- Cerebral palsy

For people with such conditions, rehabilitation aims to reduce the impact of the UMN syndrome, develop compensatory strategies, reduce pain, prevent deformity, ease the burden of care, and improve function in such things as independence in activities of daily living (ADLs) and mobility. Non-pharmacological approaches for treating the positive features of the UMN syndrome include prolonged muscle stretching, muscle reinforcement, physical agents and pain management (Smania, 2010). Oral pharmacological treatments for spasticity have improved only very modestly in recent years. However, the development of injectables over the last 20-30 years (specifically botulinum toxin and intrathecal baclofen) has dramatically changed management options for some aspects of spasticity.

The intervention that has received the most attention in recent years is botulinum neurotoxin toxin type A (BoNT-A). While the above conditions are common causes of spasticity, not all of them commonly need BoNT-A. Diseases such as Hereditary Spastic Diplegia and some other neurodegenerative diseases, (e.g. Spinocerebellar Ataxia) may be seen in movement disorder clinics more frequently for BoNT-A injections.

BoNT-A is one of eight potent neurotoxins made by the *Clostridium botulinum* bacteria that produces "botulism" food poisoning. In botulism, BoNT-A impairs the generation of muscle force by effectively disconnecting the nerve stimulus from the muscle response. In this capacity it produces widespread weakness, initially of the swallowing and respiratory muscles, and often resulting in death. In medical usage, however, extremely small and localised doses of BoNT-A can be selectively injected into the specific muscles that are producing limitations in passive or active function.

### **Box 2. Positive UMN features treatable by BoNT-A**

- Spasticity – Focal, Segmental, Multifocal.
- Dystonias – Focal, Segmental, Multifocal.
- Spastic dystonia
- Bruxism
- Associated reactions
- Pain

BoNT has developed a central role in the treatment of many elements of positive UMN features (see Box 2). There is strong, Level One evidence of its efficacy in decreasing muscle over activity in both spasticity (for example Elia AE et al; Rosales RL et al) and dystonia (Jankovic J). This evidence is mostly limited to so-called ‘impairment’ level research, coinciding with the Body Function and Structure domain of the World Health Organisation’s International Classification of Disease (ICF). At this stage, the evidence for improvements in function (within the ICF Activity domain) or for cost-benefit have lagged behind that for impairment level improvement, in large part due to limitations of the research tools. (Barden 2014)

Ref:

Elia AE et al. Botulinum Neurotoxins for Post-Stroke Spasticity in Adults: A Systematic Review. *Movement Disorders*. 2009;24(6):801-812.

Rosales RL et al. Evidence-based Systematic Review on the Efficacy and Safety of Botulinum Toxin-A therapy in post-stroke spasticity. *Journal of Neural Transmission*. 2008;115(4):617-623.

Jankovic J. Treatment of dystonia. *Lancet Neurol*. 2006;5:864-872.

**The Australasian Faculty of Rehabilitation Medicine (AFRM) and the Rehabilitation Medicine Society of Australia and New Zealand (RMSANZ) are committed to best practice with regard to spasticity management.**

BoNT can be of benefit in reducing muscle over activity and improving function, participation and quality of life for individual patients, and has also been shown to reduce the overall costs for ongoing care of some patients. There is evidence that the use of BoNT-A in spasticity is cost-effective. {Ref 1,2,3}

***In those circumstances where treatment of muscle over activity is required, the AFRM and RMSANZ concur with international consensus that appropriate use of BoNT should be seen as part of a broad based, coordinated multidisciplinary approach in the management of focal spasticity due to UMN syndrome, where it impedes function. BoNT should only rarely be used as an isolated intervention in the management of this condition.***

## Legislative Considerations

At the present time, a number of BoNTs are commercially available in the Australian and New Zealand market (detailed in Table 1). Three of these products are botulinum neurotoxin type A (BoNT-A) and one is a Botulinum toxin type B (BoNT-B). BoNT-A and B show markedly different properties and BoNT-B is considered less useful in a rehabilitation context. For this reason, the remainder of the article will focus on BoNT-A unless otherwise specified. The three BoNT-A products are not entirely bio-equivalent in terms of dosing regimes, a point recognised by the US Food and Drug Administration (FDA) with each product having a separate designation for scientific literature.

Table 1. Available Botulinum Toxins

| Toxin type | Trade Name | FDA name                   | Recommended maximum dosage | Effect duration  |
|------------|------------|----------------------------|----------------------------|--|
| A          | Botox      | <i>onabotulinumtoxinA</i>  | 400 units                  | 6-9 months (autonomic)<br>3-4 months (skeletal muscle) |
|            | Dysport    | <i>abobotulinumtoxinA</i>  | 1000 Ipsen units           |  |
|            | Xeomin     | <i>incobotulinumtoxinA</i> | 400 units                  |  |
| B          | Myobloc    |                            |                            | 2-3 months (skeletal muscle)                           |
|            | Neurobloc  | <i>rimabotulinumtoxinB</i> | 10000 units                |  |

Ref: Walker TJ, Dayan SH. Comparison and Overview of Currently Available Neurotoxins. *The Journal of Clinical and Aesthetic Dermatology*. 2014;7(2):31-39.

## The Australian Legislative Environment

In Australia, the Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Scheme (PBS) have established a confusing range of approved indications and decisions regarding funding for BoNT-A. A similar situation exists for New Zealand. The similarities and differences in these schemes as they refer to Rehabilitation Medicine are detailed in Appendix X. It is not the purpose of this section of the document to discuss these issues in detail. However, by way of example, the three commercial preparations have different accepted indications: Botox has TGA approval for the treatment of focal spasticity of any aetiology, whereas Dysport and Xeomin are only approved for upper limb spasticity following stroke. In the situation of a person having upper limb spasticity, the Australian PBS only approves funding for a maximum 4 treatments per limb per lifetime (although Medicare will fund the procedure without limitation), whereas in New Zealand this decision is devolved to each of the 20 District Health Boards. The inconsistencies and inequities that these decisions cause at the personal level for patients, and a review of published evidence to support these restrictions, forms the second part of this review.

## Adherence to government requirements

Australian and New Zealand Governments have a set of regulations regarding the appropriate use and monitoring of BoNT-A injections.

***AFRM / RMSANZ support full compliance with these regulations but we note there are sound clinical indications for BoNT-A injection that do not fall within current funding guidelines and restrictions.***

## Best Practice Recommendations

### Patient Selection:

- a) That accredited practitioners/team selecting patients for potential BoNT-A injections do so with the clear understanding that there are a range of treatment options for the management of spasticity and dystonia, and that all of these other options have been carefully considered for that patient.
- b) That accredited practitioners selecting patients for BoNT-A have appropriate experience in patient assessment, spasticity assessment, functional assessment, as well as having a clear understanding of the potential outcomes of BoNT-A injections.
- c) That accredited practitioners offering BoNT-A injections to patients have an appropriate level of expertise in patient selection, muscle selection, indications, precautions, exclusions and dosage of various forms of BoNT-A.

### Patient Preparation:

- a) Indications, and patient and treating team goals should be identified and recorded prior to the procedure. Injection planning should be undertaken in accordance with the patient's self-selected goals, with appropriate guidance from the injector and/or multidisciplinary team. Goals should be agreed upon by both the patient (and/or parent/guardian) and the accredited practitioner before injections commence and informed consent should be obtained.
- b) Once BoNT-A injection is offered, the patient must be informed of the potential benefits and risks of the procedure and side effects of the drug. The person and/or their carers should be given every opportunity to ask questions and to be provided answers in a way that encourages open communication.

- c) Outcomes of the BoNT-A injection should be measured via patient interview and/or examination at an appropriate time, by an appropriately trained accredited practitioner. The outcome measures should be recorded pre and post injection.
- d) It should be determined that the patient will be available to undergo therapy (e.g. physiotherapy or occupational therapy) during the time of peak BoNT-A activity in order to maximise the likelihood of functional gains.

#### **The Injector:**

BoNT-A injections should be carried out or supervised by an appropriately trained medical practitioner. The injector should also disclose the experience of the injector/s, particularly where training is being undertaken.

Previously, practitioners were required to be accredited under the S100 scheme for Medicare funding to be available for prescribing and injecting BoNT-A. This scheme was devolved to the Authority prescription system in 2016, and the need for injectors to have training at any level was withdrawn. The RMSANZ recommends that new injectors should continue to be required to have training in such skills as assessment, muscle selection, muscle localisation techniques, dosages risks and complications and so on to protect the public and avoid waste of resources through poorly performed or naïve injection strategies. The RMSANZ is currently developing a voluntary accreditation system covering these and other facets of management of patients with BoNT-A.

#### **The Procedure:**

- a) The environment should be appropriate for a number of considerations, including (but not limited to) privacy, confidentiality, comfort, and cleanliness.
- b) There should be appropriate lighting, and adequate space and equipment for effective patient transfers, and patient positioning for purposes of the procedure. There should be adequate staffing.
- c) In certain circumstances (e.g. children, patients with intellectual disability) it may be appropriate to use some form of analgesia/sedation/anaesthetic for safe and effective injection of BoNT-A. In these cases, it is recommended that there may need to be appropriate preparation space (e.g. theatre space or anaesthetic bay) as well as appropriately trained staff, and support equipment.
- d) In addition to anatomical surface landmarks, the injector should use guidance (e.g. electrical stimulation/EMG or ultrasound) for muscle localisation when appropriate.
- e) Care must be taken with dosage and dilution, taking into account factors such as body weight and co-morbidities.
- f) A record should be kept for each muscle injected, the dose, dilution, the type of BoNT-A and the pre and post injection outcome measures.
- g) Any unexpected events or complications should be recorded.
- h) After the injection, appropriate follow-up plans should be provided clearly to the patient, including instructions for the patient for ongoing rehabilitation management, and contacts in case of questions or concerns.
- i) After the procedure, the patient/carer should be given the opportunity to ask further questions.

#### **Other Considerations:**

##### **Multidisciplinary Team Management**

**The AFRM / RMSANZ strongly recommends the involvement of a multidisciplinary team (rehabilitation physician, nurse, physiotherapist, occupational therapist and the orthotist) as part of the therapeutic process.**

Whilst it is feasible for individual accredited practitioners to take on all of the roles of assessor, patient selector, proceduralist, and follow-up practitioner, the evidence suggests that better patient outcomes are achieved through the use of a multidisciplinary team.

### **Measures**

The AFRM / RMSANZ recommends that pre and post injection measures may include (but not be limited to):

#### **I. Objective measures of change, e.g.:**

- a. Range of movement
- b. Degree of spasticity (e.g. Modified Ashworth Score, Tardieu)
- c. Degree of dystonia (Fahn Marsden Dystonia Scale)
- d. Speed of movement
- e. Quality of movement

#### **II. Measures of function/goal attainment, e.g.:**

- a. Goal Attainment Scale
- b. Canadian Occupational Performance Measure
- c. Timed Up and Go
- d. Balance (Berg Balance Score)- *Ref. Singer JC et al. Neurorehab and Neural Repair 2016;30(7):626-634.*
- e. Walking Speed or Gait Velocity- *Ref. Eng JJ. Expert Rev Neurothera 2007;7(10):1417-1436.*
- f. Walking distance/tolerance

#### **III. Measures of patient /carer satisfaction, e.g.;**

- a. Patient subjective satisfaction
- b. Visual Analog Scale for spasticity/Dystonia associated pain
- c. Examples of improved participation
- d. Carer burden scales (e.g. Caregiver Burden Inventory CBI)

#### **IV. Duration of effectiveness of injection(s)**

### **Research, Education and Training**

More research continues to expand our knowledge about the indications, potential benefits, and complications of BoNT-A in the management of spasticity. The AFRM / RMSANZ believes that accredited practitioners who take on the responsibility for injecting BoNT-A or establishing BoNT-A injection clinics should participate in their own personal professional development in this arena, in particular with regard to pharmacotherapy, identifying suitable indications, optimising delivery and minimising potential complications associated with BoNT-A.

Further it is expected that RMSANZ accredited injectors will also accept responsibility for training other practitioners, both new and other accredited injectors, and participate in research activities wherever possible.

There continue to be changes in product availability, recommendations for procedures, and indications. As the uses for BoNT-A expand, so too does the need for more workforce supervised by accredited medical practitioners expert in the treatment of spasticity and dystonia and in the use of BoNT-A.

## Section 2

### A comparison of current TGA/PBS guidelines and best practice: RMSANZ Recommendations

An expert working party has undertaken a preliminary review of the literature and polled RMSANZ members, to assess what evidence supports the current restrictions surrounding the use of BoNT-A. There is encouraging research evidence as well as extensive clinical experience supporting more widespread use of BoNT-A in different indications.

There is strong opinion that many of the current funding restrictions are not reflective of modern best practice. BoNT-A is used more widely for a larger number of conditions than the PBS approved indications. Indeed, the TGA (Therapeutic Goods Administration) accepts the use of BoNT-A as appropriate in circumstances that the PBS does not cover. In certain circumstances Workcover insurers subsidise treatment.

There is evidence that the use of BoNT-A in spasticity is cost-effective. {Ref 1,2,3}

Furthermore, the expert working party feels that the conditions treated by rehabilitation physicians (severe focal spasticity, dystonia and severe pain and the resultant disability) are at least as important as some other indications that allow subsidised treatment.

As noted in Section 1 of this Position Statement, the legislative environment for the use of BoNT-A and its funding is inconsistent and variable in different countries and across the range of available products.

***RMSAMZ feels compelled to draw the attention of governments and legislative authorities and other relevant professional bodies to a more consistent and appropriate definition of the indications for use, administration, research and education of professionals in the usage of BoNT-A.***

***The following points constitute some (but not necessarily all) of the considerations relevant for 'appropriate use' of BoNT-A in the treatment of spasticity, dystonia and pain. The decision to treat should be based on the potential to reduce impairments (e.g. spasticity/dystonia, pain) limitations in activity and participation. The treatment should also be aimed at improving passive function (e.g. personal hygiene), improving the quality of lives of the patients, reducing the carer burden, and to use scarce healthcare resources most efficiently.***

The following conditions are often treated when toxin is available from non-PBS sources:

*Upper limb spasticity post stroke more than four times in a life.*

*Lower limb spasticity post stroke (often combined with UL treatment) {4}*

*Shoulder pain post CVA {5,6}*

*Painful muscle dystonia beyond just the cervical spine {7,8}*

*Adult Cerebral palsy treatment for those who did not receive treatment prior to age 18*

*Focal spasticity/dystonia in non-stroke upper motor neuron conditions such as Traumatic Brain Injury, Spinal Cord Injury/illness, Multiple Sclerosis, and Neurodegenerative conditions such as Parkinson's Disease.*

This leads to equity issues. Only the well-resourced or those who are lucky enough to live near well-funded public services have access to the toxin. The current access rules are arbitrary and unfair.

Many examples are evident; however, the following examples stand out:



- A child injured prior to birth would have CP and therefore be eligible for lifetime treatment. A child with spasticity from a fall or MVA after the age of 2 would not.
- A young adult who lived in a rural area and so did not have access to a BoNT-A injection service prior to age 18 would never receive subsidised treatment but those near a major children's hospital (capital city) would.
- An adult with a history of CVA whose spasticity is optimally managed is unable to access BoNT-A after 4 treatments, significantly impacting on their long-term ability to work and function independently.
- Post-stroke spasticity involves both upper and lower limb. Under the current guidelines focal post-stroke lower limb spasticity interfering with standing and walking is not covered by PBS.
- A patient who has a brain haemorrhage from a faulty blood vessel or due to high blood pressure receives subsidised treatment for upper limb treatment whereas someone having a brain haemorrhage due to a fall or assault does not.

**The expert working party recommends that serious consideration should be given to the following:**

- 1. A lifetime subsidy for UL spasticity post stroke when there has been a clinically significant improvement.**
- 2. A subsidy for focal spasticity treatment for any of the proprietary brands.**
- 3. A subsidy for appropriately trained specialists to treat focal spasticity of the upper and lower limbs regardless of aetiology.**
- 4. A subsidy for treatment of painful dystonias by appropriately trained specialists including rehabilitation physicians.**
- 5. An immediate end to the requirements for CP patients to have treatment initiated prior to 18 years old.**

The expert working party recognises that BoNT-A is an expensive medication. We also recognise that government has a role in ensuring that medicines that are subsidised in patient's best interest and cost effectively. We argue that the current restrictions are illogical and not backed by the latest scientific research, nor do they meet patient need.

#### **References:**

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## Appendix 1

### Background to Consensus Process

This position statement is the result of consideration of an Expert Working Group appointed by the Board of the RMSANZ and draws upon earlier work by the NeuroRehabilitation Special Interest Group and Policy and Advocacy Committee of the AFRM in 2013. Modifications to the 2013 document are based on the experience of this committee, with reference to:

- The international consensus statement for the use of botulinum toxin treatment in adults and children with neurological impairments (European Journal of Neurology 2010, 17 (suppl.2))
- Spasticity in adults: management using botulinum toxin. National Guidelines. Royal College of Physicians, January 2009
- Botulinum toxin assessment, intervention and after-care for lower limb disorders of movement and muscle tone in adults: international consensus statement (European Journal of Neurology 2010, 17(suppl.2))

#### **Participating members of the RMSANZ Botulinum Toxin Expert Working Group included:**

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## Appendix 2

### Current regulatory framework for each commercially available BoNT-A product

#### Botox: Allergan

The following information has been supplied by Allergan:

##### Australian Approved Product Information Indications:

- 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;
- Urinary incontinence due to neurogenic detrusor over activity resulting from a defined neurological illness (such as spinal cord injury or multiple sclerosis) and not controlled adequately by anticholinergic agents;
- Prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month of which at least 8 days are with migraine);
- Strabismus;
- Blepharospasm associated with dystonia, including benign blepharospasm & VIIth nerve disorders (hemifacial spasm) in patients 12 years & over;
- Cervical dystonia (spasmodic torticollis);
- Focal spasticity of the upper & lower limbs, including dynamic equinus foot deformity due to spasticity in juvenile cerebral palsy patients 2 years & older;
- Severe primary hyperhidrosis of the axillae;
- Focal spasticity in adults;
- Spasmodic dysphonia;
- Upper facial rhytides (glabellar lines, crow's feet and forehead lines) in adults.

##### All of the following are PBS reimbursed (with criteria):

- Severe Primary Axillary Hyperhidrosis (patients 12 years of age and older)
- Upper Limb Post Stroke (patients 18 years of age and older)
- Upper Limb Cerebral Palsy (patients 2 -17 years of age)
- Upper Limb Cerebral Palsy (patients 18 years of age of older) - Patient must have commenced PBS-subsidised treatment with Botulinum Toxin Type A Purified Neurotoxin Complex as a paediatric patient.
- Cervical Dystonia (Spasmodic Torticollis)
- Dynamic Equinus Foot (patients 2 -17 years of age)
- Dynamic Equinus Foot (patients 18 years of age of older) - Patient must have commenced PBS-subsidised treatment with Botulinum Toxin Type A Purified Neurotoxin Complex as a paediatric patient.
- Blepharospasm in patients  $\geq 12$  years of age
- Hemifacial Spasm in patients  $\geq 12$  years of age
- Chronic Migraine (patients 18 years of age of older)
- Neurogenic Detrusor Over activity (NDO) (patients 18 years of age of older)
- Overactive Bladder (OAB) (patients 18 years of age of older)

##### New Zealand Approved Indications:

- For the treatment of overactive bladder with symptoms of urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication

- For the treatment of urinary incontinence due to neurogenic detrusor over activity (e.g. spinal cord injury or multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication
- For the prophylaxis of headaches in adults with chronic migraine (headaches on at least 15 days per month with headache lasting 4 hours a day or longer, of which at least 8 days are with migraine)
- For the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VIIth nerve disorders in patients 12 years of age and above
- To reduce the subjective symptoms and objective signs of spasmodic torticollis (cervical dystonia) in adults
- Treatment of focal spasticity in children two years and older
- For the treatment of primary hyperhidrosis of the axillae
- For the treatment of focal spasticity in adults.
- For the treatment of upper facial rhytides, including forehead, crow's feet and glabellar lines

**Funding:** Decisions regarding reimbursement are undertaken on a District Health Board (DHB) basis, of which there are 20. Most DHB's will cover the cost of Botox for approved indications (excluding treatment of upper facial rhytides, including forehead, crow's feet and glabellar lines).

## Dysport: Ipsen

The following information has been supplied by Ipsen:

Australia

### **Indications:**

For the treatment of

- spasticity of the upper limb in adults following a stroke
- spasmodic torticollis in adults
- dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, two years of age or older
- blepharospasm in adults
- hemifacial spasm in adults
- moderate to severe glabellar lines in adults

### **Funding:**

Note: only the 300U and 500U vials are reimbursed through the PBS

For the treatment of

#### Moderate to severe spasticity of the upper limb following a stroke

(the date of the stroke must be documented in the patient's medical records when treatment is initiated, standard management includes physiotherapy and/or oral spasticity agents).

The condition must be moderate to severe spasticity of the upper limb/s following a stroke, defined as a Modified Ashworth Scale rating of 3 or more AND the treatment must not be initiated until three months post-stroke AND the treatment must only be used as second line therapy when standard management has failed OR the treatment must only be used as an adjunct to physical therapy AND the treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (total of Botox, Dysport, Xeomin) AND the treatment must not exceed 4 treatment periods (total Botox, Dysport, and Xeomin) per upper limb per lifetime AND patient must not have established severe contracture in the limb to be treated.

The patient must be 18 years or older.

The patient must be treated by a neurologist, OR an orthopaedic surgeon, OR a rehabilitation specialist, OR a plastic surgeon, OR a geriatrician.

#### Spasmodic torticollis

(The patient must have spasmodic torticollis AND the treatment must be as a monotherapy OR the treatment must be as adjunctive therapy to current standard of care).

The patient must be treated by a neurologist OR a plastic surgeon OR a rehabilitation specialist.

#### Dynamic equinus foot deformity

The condition must be due to spasticity AND the patient must have cerebral palsy AND patient must be ambulant).

Patient must be aged from 2 to 17 years inclusive or if the patient is 18 years or older they must have commenced on PBS-subsidised treatment with clostridium botulinum type A toxin haemagglutinin complex as a paediatric patient.

Patient must be treated by a neurologist, OR an orthopaedic surgeon, OR a paediatrician OR a rehabilitation specialist.

#### Blepharospasm or hemifacial spasm

(The patient must have blepharospasm OR hemifacial spasm)

Patient must be aged 18 years or older

The patient must be treated by a neurologist OR an ophthalmologist OR an otolaryngology head and neck surgeon OR a plastic surgeon.

New Zealand

**Indications:**

For the treatment of:

Glabellar lines

Spasticity of the arm in patients following a stroke

Dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients, two years of age or older, only in hospital specialist centres with appropriately trained personnel

Spasmodic torticollis in adults. Blepharospasm in adults

Hemifacial spasm in adults

Dysport is also indicated for the symptomatic treatment of axillary hyperhidrosis (excessive sweating).

**Funding:**

For the treatment of:

Glabellar lines

Spasticity of the arm in patients following a stroke

Dynamic equinus foot deformity due to spasticity in paediatric cerebral palsy patients, two years of age or older, only in hospital specialist centres with appropriately trained personnel

Spasmodic torticollis in adults. Blepharospasm in adults

Hemifacial spasm in adults

Dysport is also indicated for the symptomatic treatment of axillary hyperhidrosis (excessive sweating).

## **Xeomin: Merz**

The following information has been supplied by Merz:

### **AUSTRALIA**

#### **Indications:**

Xeomin® is indicated for the treatment of:

- Cervical Dystonia in adults
- Blepharospasm in adults
- Post-Stroke Spasticity of the upper limb in adults
- Glabellar frown lines in adults

Merz Australia have applied to the TGA for the inclusion of the adult indication “treatment of spasticity of the upper limb”

#### **Funding:**

- Xeomin (100 units) is PBS listed for Cervical Dystonia, Blepharospasm and Post Stroke Spasticity of the Upper Limb
- Please find below link pertaining to funding definitions.
- <http://www.pbs.gov.au/medicine/item/10983C-10994P-11005F>

### **NEW ZEALAND**

#### **Indications:**

Xeomin® is indicated for the treatment of:

- Cervical Dystonia in adults
- Blepharospasm in adults
- Post-Stroke Spasticity of the upper limb in adults
- Glabellar frown lines in adults

#### **Funding:**

- Xeomin is not available in New Zealand on the Hospital Medicines List (HML) Part II of Section H of the Pharmaceutical Schedule.