



PB 87 of 2014

National Health (Botulinum Toxin Program) Special Arrangement Amendment Instrument 2014 (No. 2)

National Health Act 1953

I, KIM BESSELL, Assistant Secretary, Pharmaceutical Access Branch, Department of Health, delegate of the Minister for Health, make this Amendment Instrument under subsections 100(1) and 100(2) of the *National Health Act 1953*.

Dated 24 October 2014

KIM BESSELL
Assistant Secretary
Pharmaceutical Access Branch
Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Botulinum Toxin Program) Special Arrangement Amendment Instrument 2014 (No.2)*.

(2) This Instrument may also be cited as PB 87 of 2014.

2 Commencement

(1) This instrument commences on 1 November 2014.

3 Amendment of PB 89 of 2011

Schedule 1 amends the *National Health (Botulinum Toxin Program) Special Arrangement 2011* (PB 89 of 2011).

Schedule 1 Amendments

[1] Subsection 10(1)

omit:

and 12B

insert:

, 12B and 12C

[2] After section 12B

insert:

12C Entitlement to botulinum toxin pharmaceutical benefits for treatment of urinary incontinence due to idiopathic overactive bladder

- (1) This section applies to eligible patients receiving treatment of urinary incontinence due to idiopathic overactive bladder who:
 - (a) are aged 18 years or more; and
 - (b) are willing and able to self-catheterise; and
 - (c) have experienced at least 14 episodes of urinary incontinence per week prior to commencement of treatment with a botulinum toxin pharmaceutical benefit; and
 - (d) have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents.
- (2) A person mentioned in subsection (1) is not eligible to receive a botulinum toxin pharmaceutical benefit under this Special Arrangement if the person does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

[3] After section 17A

insert:

17B Eligible medical practitioner in relation to urinary incontinence due to idiopathic overactive bladder

A medical practitioner who has the specialist qualification of urology or urogynaecology and is an eligible medical practitioner in relation to any condition mentioned in Schedule 3 other than urinary incontinence due to idiopathic overactive bladder, is taken to be an eligible medical practitioner in relation to urinary incontinence due to idiopathic overactive bladder.

[4] Subsection 18(3)

omit:

or (7)

insert:

, (7) or (8)

[5] Subsection 18(6)

omit:

- (6) If an applicant practitioner is a specialist in urology or urogynaecology and seeks authorisation to administer a botulinum toxin pharmaceutical benefit, under this Special Arrangement, for the treatment of urinary incontinence due to neurogenic detrusor overactivity, as demonstrated by urodynamic study for patients with multiple sclerosis, spinal cord injury or who are 18 years or older and have spina bifida, the applicant practitioner must:
- (a) have been trained by a specialist in the same speciality as the applicant practitioner in the administration of botulinum toxin pharmaceutical benefits to treat urinary incontinence due to neurogenic detrusor overactivity; and
 - (b) provide evidence of the applicant practitioner's training in the form of a letter from a person who is an eligible medical practitioner for this Special Arrangement, stating that the applicant practitioner has been involved in at least 10 procedures, having been the primary operator, under supervision, in at least 5 procedures administering a botulinum toxin pharmaceutical benefit.

insert:

- (6) If an applicant practitioner is a specialist in urology or urogynaecology and seeks authorisation to administer a botulinum toxin pharmaceutical benefit, under this Special Arrangement, for the treatment of urinary incontinence due to neurogenic detrusor overactivity, as demonstrated by urodynamic study for patients with multiple sclerosis, spinal cord injury or who are 18 years or older and have spina bifida, the applicant practitioner must provide evidence of successful training in the form of:
- (a) a Statutory Declaration outlining their involvement in at least 10 procedures administering botulinum toxin for the treatment of urinary incontinence, including the number performed under supervision; or
 - (b) a written statement from the provider of a course of training relating to the administration of botulinum toxin for the treatment of urinary incontinence, noting that this may have been completed overseas.

[6] After subsection 18(7)

insert:

- (8) If an applicant practitioner is a specialist in urology or urogynaecology and seeks authorisation to administer a botulinum toxin pharmaceutical benefit, under this Special Arrangement, for the treatment of urinary incontinence due to idiopathic overactive bladder, the applicant practitioner must provide evidence of successful training in the form of:
- (a) a Statutory Declaration outlining their involvement in at least 10 procedures administering botulinum toxin for the treatment of urinary incontinence, including the number performed under supervision; or
 - (b) a written statement from the provider of a course of training relating to the administration of botulinum toxin for the treatment of urinary incontinence, noting that this may have been completed overseas.

[7] Schedule 3

after:

10	Treatment of chronic migraine in patients who are 18 years or older.	Botulinum Toxin Type A Purified Neurotoxin Complex	Neurology
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insert:

11	Treatment of urinary incontinence due to idiopathic overactive bladder in patients who are 18 years or older.	Botulinum Toxin Type A Purified Neurotoxin Complex	Urology Urogynaecology
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