MSAC application 1817

MSAC Application for Xeomin (incobotulinumtoxinA) for treatment of lower limb spasticity following an acute event

Application for MBS eligible service or health technology

HPP Application number:

HPP200364

Application title:

MSAC Application for Xeomin (incobotulinumtoxinA) for treatment of lower limb spasticity following an acute event

Submitting organisation:

MERZ AUSTRALIA PTY LTD

Submitting organisation ABN:

62151073559

Application description

Succinct description of the medical condition/s:

Spasticity of the lower limb is a disabling complication of stroke that leads to pain, abnormal gait, functional disability, and reduced quality of life. It also increases caregiver burden, health resource utilisation, and long-term healthcare costs due to falls, contractures, and institutionalisation.

Lower limb spasticity following stroke is a debilitating condition affecting approximately 40% of stroke survivors. This condition most commonly manifests within the first month following stroke, predominantly affecting ankle plantar flexors and causing equinovarus deformities that significantly impair mobility and quality of life.

Succinct description of the service or health technology:

IncobotulinumtoxinA (Xeomin) is a purified formulation of botulinum neurotoxin that can be used to treat a range of neurological conditions. The safety and efficacy of Xeomin has been established in clinical trials in lower limb spasticity following an acute event.

The goal of treatment with Xeomin is to reduce muscle spasms, facilitating mobility and dexterity, improving patient ease of care as well as hygiene/selfcare, facilitating brace use, improving posture, minimizing contractures and deformity as well as

reducing pain. Xeomin is also indicated for other neuromuscular conditions such as cervical dystonia, blepharospasm, and chronic sialorrhea, as well spasticity of the upper limb following an acute event, and lower/upper limb spasticity as a result of cerebral palsy.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Consultant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name:

MERZ AUSTRALIA PTY LTD

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

Yes

Which list/schedule will the other health technologies be listed on?

Pharmaceutical Benefits Scheme

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

Amendment

What is the nature of the amendment?

Minor amendment to the item descriptor that does not affect how the service is delivered

Justification for amendment:

The molecule (incobotulinumtoxinA) and brand name (XEOMIN) are required to be specified in the MBS listings in order for the specific pharmaceutical treatment to be administered.

The method of administration is identical to the already listed molecules in the MBS items.

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Selected reason type
18360	Expansion or amendment to existing item

What is the type of service or health technology?

Therapeutic

PICO sets

Application PICO sets:

PICO set number	PICO set name
1	IncobotulinumtoxinA (XEOMIN) for lower limb spasticity in adults

Population

Describe the population in which the proposed health technology is intended to be used:

Adults with moderate to severe spasticity of the lower-limb following an acute event.

This event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

Intervention

Name of the proposed health technology:

incobotulinumtoxinA (XEOMIN)

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Botulinum toxin type A (BOTOX®). Botox is the nominated comparator as it is the market leading injectable toxin for the indication/s sought and has a 1:1 dose equivalence with incobotulinumtoxinA (XEOMIN®).

Botox is administered using the MBS Item 18360 that this submission proposes to amend.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

Treatment with incobotulinumtoxinA (Xeomin) results in non-inferior health outcomes when compared to Botox.

Health benefits evaluated in the clinical trial evidence include:

- Quantitative measures of spasticity using the Modified Ashworth Scale

Health harms evaluated include:

- Incidence of treatment emergent AEs (TEAEs), TEAEs of special interest, (TEAESIs) and serious TEAEs.

Proposed MBS item

Please provide at least one proposed item with their descriptor and associated costs, for each population / intervention:

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

18360

Category number:

THERAPEUTIC PROCEDURES

Category description:

BOTULINUM TOXIN INJECTIONS

Proposed item descriptor:

Botulinum Toxin Type A Purified Neurotoxin Complex (Botox), or Clostridium Botulinum Type A Toxin Haemagglutinin Complex (Dysport), or incobotulinumtoxinA (Xeomin), injection of, for the treatment of moderate to severe focal spasticity, if: (a)the patient is at least 18 years of age; and (b)the spasticity is associated with a previously diagnosed neurological disorder; and (c)treatment is provided as: (i)second line therapy when standard treatment for the conditions has failed; or (ii)an adjunct to physical therapy; and (d)the treatment is for all or any of the muscles subserving one functional activity and supplied by one motor nerve, with a maximum of 4 sets of injections for the patient on any one day (with a maximum of 2 sets of injections for each limb), including all injections per set; and (e)the treatment is not provided on the same occasion as a service mentioned in item 18365

Proposed MBS fee:

$145.65

Indicate the overall cost per patient of providing the proposed health technology:

$145.65

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

N/A

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

Self-funded by patients.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Non-inferior

Please state what the overall claim is, and provide a rationale:

Treatment of lower limb spasticity with incobotulinumtoxinA (Xeomin) following an acute event is non-inferior to Botox with regards to efficacy and safety. This was demonstrated in a randomised controlled trial, J-PLUS, details of which are tabulated in the Summary of Evidence. Results of J-PLUS were compared to Botox study results via an indirect analysis which was provided to the PBAC for review at its March 2026 meeting.

The non-inferiority of Xeomin and Botox has been well-established and accepted by the PBAC, with the products considered equivalent and interchangeable on a patient-level basis. In the public summary document for the most recent consideration of Xeomin in 2019, the PBAC declared that "…BOTOX®, Dysport® and Xeomin®, should be treated as interchangeable on an individual patient basis under Section 101(3BA) of the National Health Act 1953." (6.12 INCOBOTULINUMTOXINA, Public Summary Document, Paragraph 6.16, November 2019 PBAC Meeting). The PBS therapeutic relativity sheets list Xeomin and Botox as having a 1:1 dose equivalence.

Estimated Utilisation

Estimate the prevalence and/or incidence of the proposed population:

According to the Australian Stroke Foundation 2023 data, there are over 445,000 stroke survivors living in Australia. In 2024, a total of 45,785 strokes were recorded, comprising 34,793 first-ever strokes and 10,992 recurrent strokes, effectively one stroke every 11 minutes. The crude incidence rate is estimated at 159 per 100,000 population, with an age-standardized rate of 124 events per 100,000 in 2021.

The amendment to the MBS item will not increase the patient pool as it is a well-established condition with established items that have been listed for many years - Xeomin will only displace patients from other items rather than expand the population.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

2.5

Year 2 estimated uptake (%):

5

Year 3 estimated uptake (%):

10

Year 4 estimated uptake (%):

10

Estimate the number of patients who will utilise the proposed technology for the first full year:

108

Optionally, provide details:

It is estimated that 108 PBS services for Xeomin will be dispensed for the treatment of lower limb spasticity in the first full year of listing, as patients switch from either Botox or Dysport. With each PBS service requiring an injection administration MBS item code, there will also be 108 MBS services claimed in the first year of listing.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Treatment is used chronically until efficacy stops

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Maximum of 4 times per year.

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entities who provide the health technology/service:

Australian and New Zealand Association of Neurologists

Australian Society of Plastic Surgeons

Rehabilitation Medicine Society of Australia and New Zealand

Australian and New Zealand Society for Geriatric Medicine

Entity who may be impacted by the health technology/service:

Movement Disorders Society of Australia and New Zealand

Entities who produce similar products:

AbbVie Pty Ltd

Ipsen Pty Ltd

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

Stroke Foundation

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

No

Codependent details

Will a submission be made to the Pharmaceutical Benefits Advisory Committee (PBAC)?

Yes

Please provide a rationale for the codependency and indicate how the proposed PBS restriction would reference the intervention(s) proposed for MSAC consideration:

The PBS listing for incobotulinumtoxinA (Xeomin) will be for the indication of moderate to severe spasticity of the lower limb following an acute event and requires an injection code on the MBS to be administered.

The amendment to MBS item 18360 requires incotulinumtoxinA (Xeomin) to be included in the descriptor by name.