MSAC application 1808

IncobotulinumtoxinA (XEOMIN) injection for cerebral palsy spasticity of the lower and/or upper limbs

Application for MBS eligible service or health technology

HPP Application number:

HPP200276

Application title:

IncobotulinumtoxinA (XEOMIN) injection for cerebral palsy spasticity of the lower and/or upper limbs

Submitting organisation:

MERZ AUSTRALIA PTY LTD

Submitting organisation ABN:

62151073559

Application description

Succinct description of the medical condition/s:

Cerebral palsy refers to a group of neurological disorders that appear in infancy or early childhood and permanently affect body movement and muscle coordination. Up to 90% of individuals with cerebral palsy experience spasticity in one or more muscle groups, where muscles spasm or tighten and result in a limited range of passive and active motion. Spasticity can affect the upper and lower limbs reducing function and mobility and ultimately result in contractures which render the limb functionless and may require surgery.

Succinct description of the service or health technology:

IncobotulinumtoxinA (Xeomin) is a purified formulation of botulnium neurotoxin that can be used to treat spasitcity in individuals 2 years and older with cerebral palsy. The safety and efficacy of Xeomin has been established in clinical trials in upper and lower limbs of patients with cerebral palsy.

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 and blepharospasm, as well spasticity of the upper limb following an acute event.

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?

No

Which list/schedule will the other health technologies be listed on? *(if 'Yes' above)*

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? *(if an amendment)*

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

Justification for amendment: *(if an 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
18354	Expansion or amendment to existing item
18361	Expansion or amendment to existing item

What is the type of service or health technology?

Therapeutic

PICO set

IncobotulinumtoxinA (XEOMIN) for cerebral palsy spasticity of the lower and/or upper limbs

Population

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

Patients with cerebral palsy aged 2 years and older with:

- Moderate to severe spasticity of the upper limb.
- Dynamic equinus foot deformity due to spasticity.

Select the most applicable Medical condition terminology (SNOMED CT):

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®).

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 for upper and lower limb spasticity include:

- Qualitative measure of spasticity using the Ashworth scale
- Global impression of change scale (GICS)
- Other measures of motor function including modified Tardieu Scale (MTS) and Gross Motor Function Measure (GMFM)
- Questionnaire on pain caused by spasticity (QPS)

Health harms evaluated include:

- Incidence of adverse events
- Evidence of toxin spread

Proposed MBS items

Proposed item:

AAAAA

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

18354

Category number:

THERAPEUTIC PROCEDURES

Category description:

BOTULINUM TOXIN INJECTIONS

Proposed item descriptor:

Botulinum Toxin Type A Purified Neurotixin Complex (Botox), Clostridium Botulinum Type A Toxin-Haemagglutinin Complex (Dysport), or incobotulinumtoxinA (Xeomin) injection of, for the treatment of dynamic equinus foot deformity (including equinovarus and equinovalgus) due to spasticity in an ambulant cerebral palsy

patient, if:(a) the patient is at least 2 years of age; and (b) 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 lower limb), including all injections per set (Anaes.)

Proposed MBS fee:

$142.25

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

$142.25

Please specify any anticipated out of pocket expenses:

$0.00

Provide any further details and explain:

N/A

Please provide at least one proposed item with their descriptor and associated costs, for each population / intervention: (repeat the fields highlighted below for each proposed item provided)

Proposed item:

BBBBB

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

18361

Category number:

THERAPEUTIC PROCEDURES

Category description:

BOTULINUM TOXIN INJECTIONS

Proposed item descriptor:

Clostridium Botulinum Type A Toxin-Haemagglutinin Complex (Dysport), Botulinum Toxin Type A Purified Neurotoxin Complex (Botox), or incobotulinumtoxinA (Xeomin), injection of, for the treatment of moderate to severe upper limb spasticity due to

cerebral palsy if: (a) the patient is at least 2 years of age; and (b) 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 upper limb), including all injections per set (Anaes.)

Proposed MBS fee:

$142.25

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

$142.25

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):

Service is currently funded through the MBS.

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 upper or lower limb spasticity with incobotulinumtoxinA (Xeomin) is non-inferior to Botox with regards to efficacy and safety, in patients with cerebral palsy aged 2 years or older. This was demonstrated in two randomised controlled trials – TIM and XARA, with supporting evidence from two other randomised studies – TIMO and Study R-201212.

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:

There are currently approximately 34,000 Australians living with cerebral palsy and using NDIS figures presented in the Australian Cerebral Palsy Register Report (2023), it was calculated that approximately 14,000 of this group are between the ages of 2-17. It was also reported that the cerebral palsy birth rate in Australia is currently 1.5 per 1000 live births.

The prevalence and incidence of cerebral palsy is well defined and the listing of Xeomin for the treatment of upper and lower limb spasticity is not expected to increase diagnosis and impact the growth of the market.

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:

113

Optionally, provide details:

It is estimated that 113 PBS services for Xeomin will be dispensed for the treatment of 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 113 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

Optionally, provide details:

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

3 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.

Entity who provides the health technology/service

- Australasian Society for Developmental Paediatrics
- Australian and New Zealand Association of Neurologists
- Australian Society of Plastic Surgeons
- Rehabilitation Medicine Society of Australia and New Zealand

Entity who may be impacted by the health technology/service

- Australasian Academy of Cerebral Palsy and Developmental Medicine
- Movement Disorders Society of Australia and New Zealand

Entities relevant to the proposed service/health technology

- Cerebral Palsy Australia

Entity who produces similar products

- AbbVie Pty Ltd
- Ipsen Pty Ltd

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