

# **MSAC application 1800**

**IncobotulinumtoxinA (XEOMIN)  
injection code for chronic sialorrhea  
treatment**

## Application for MBS eligible service or health technology

**HPP Application number:**

HPP200237

**Application title:**

IncobotulinumtoxinA (XEOMIN) injection code for chronic sialorrhea treatment

**Submitting organisation:**

MERZ AUSTRALIA PTY LTD

**Submitting organisation ABN:**

62151073559

### Application description

**Succinct description of the medical condition/s:**

Sialorrhea, also known as hypersalivation or excessive drooling, is a condition characterised by spillage of saliva from the lips. It is considered abnormal after the age of 4. Chronic sialorrhea, where salival control cannot be maintained either through excessive salival production or saliva pooling, can be the result of hypersecretion, anatomic abnormalities, or neurological conditions. This submission focuses on chronic sialorrhea as a result of neurological conditions or disorders such as Parkinson's disease, cerebral palsy, stroke, etc.

Chronic sialorrhea can result in a significant reduction in quality of life for the patient and/or their families and carers, as well as a risk of dehydration, choking, aspiration, and pneumonia.

**Succinct description of the service or health technology:**

IncobotulinumtoxinA (Xeomin) is a purified formulation of botulinum neurotoxin. Xeomin can be injected into salivary glands to decrease saliva production to control chronic sialorrhea. The safety and efficacy of Xeomin for the treatment of chronic sialorrhea has been proven in randomised controlled trials of adult and paediatric patients with neurological and/or neurodevelopmental disorders.

Xeomin is also indicated for a range of neuromuscular conditions such as cervical dystonia, blepharospasm, and spasticity of the lower and upper limbs.

## 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? (if 'Yes' above)**

Pharmaceutical Benefits Scheme

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

New

## Relevant MBS items

**Please select any relevant MBS items.**

**What is the type of service or health technology?**

Therapeutic

## PICO set

IncobotulinumtoxinA for chronic sialorrhoea due to neurological/neurodevelopmental disorders

## Population

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

Children and adolescents aged 2-17 years with chronic sialorrhea due to neurological or neurodevelopmental disorders, and adults ( $\geq 18$  years) with chronic sialorrhea due to neurological disorders.

## 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:**

In both adults and paediatric patients, there is no standard comparator for a proposed incobotulinumtoxinA (Xeomin) listing. There are currently no PBS listed items for chronic sialorrhea, nor specific MBS services. The comparator then is supportive care.

## Outcomes

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

Treatment of chronic sialorrhea with incobotulinumtoxinA (Xeomin) results in superior health outcomes to standard care, with a tolerable safety profile.

The health benefits evaluated in the clinical trial evidence for sialorrhea include:

- Quantitative measurement of salivary control via uSFR (unstimulated salivary flow rate).
- Qualitative measurement of salivary control using scales such as DSFS.
- Global impression of change scale.

- Quality of life improvements via EQ-5D-3L.

Health harms are evaluated via incidence of adverse events, evidence of toxin spread, dental/oral examination, and monitoring of suicidality.

## Proposed MBS items

**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:**

AAAAA

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

18,372

**Category number:**

THERAPEUTIC PROCEDURES

**Category description:**

BOTULINUM TOXIN INJECTIONS

**Proposed item descriptor:**

IncobotulinumtoxinA (Xeomin), injection of, for the treatment of chronic sialorrhea including all such injections on any one day, if:

- a) The patient is at least 18 years of age; and
- b) The chronic sialorrhea is due to a neurological disorder

**Proposed MBS fee:**

\$142.25

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

\$498.50

**Please specify any anticipated out of pocket expenses:**

\$0.00

**Provide any further details and explain:**

Fee presented is identical to fee for MBS Item 18374 – for treatment of bilateral blepharospasm with incobotulinumtoxinA. Reasoning is that the injection process is similar, consisting of multiple injections into both sides of the face.

**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):**

18,372

**Category number:**

THERAPEUTIC PROCEDURES

**Category description:**

BOTULINUM TOXIN INJECTIONS

**Proposed item descriptor:**

IncobotulinumtoxinA (Xeomin), injection of, for the treatment of chronic sialorrhea including all such injections on any one day. if:

- a) The patient is between 2 and 17 years of age; and
- b) The chronic sialorrhea is due to a neurological or neurodevelopmental disorder.

**Proposed MBS fee:**

\$142.25

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

\$651.70

**Please specify any anticipated out of pocket expenses:**

\$0.00

**Provide any further details and explain:**

Injection service fee is described as above.

Inclusion of MBS ultrasound service fee (item number 55848) as it is necessary to locate salivary glands in a paediatric population, whereas anatomical markers can be used in an adult population.

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

No funding.

## 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)?**

Superior

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

Treatment of chronic sialorrhea with incobotulinumtoxinA (Xeomin) is superior to standard care with regards to efficacy, and non-inferior with regards to safety, in both adult and children/adolescent populations. This was demonstrated in two randomised controlled trials – SIAXI and SIPEXI.

## Estimated utilisation

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

Sialorrhea is a symptom of several neurological and neurodevelopmental disorders. As such, the prevalence of sialorrhea was estimated via the different neurological conditions.

- Prevalence rate of Parkinson’s Disease in Australia - 315 per 100,000
- Incidence of stroke cases in adult population of Australia - 140 per 100,000
- Prevalent population of adult stroke victims in Australia - 442,600
- Incidence rate of traumatic brain injury in adults in Australia - 790 per 1000,000

- Prevalence rate of Atypical Parkinson's Disease in Australia - 416 per 100,000
- Total number of children with cerebral palsy in Australia - 14,332
- Incidence rate of traumatic brain injury in paediatric population of Australia - 2.8 per 100
- Percentage of children with disability/developmental disorder - 4.5%

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

**Year 1 estimated uptake (%):**

Redacted

**Year 2 estimated uptake (%):**

Redacted

**Year 3 estimated uptake (%):**

Redacted

**Year 4 estimated uptake (%):**

Redacted

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

Redacted

**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.

**Optionally, provide details:**

As the treatment is used chronically, the stopping rule is based on the treatment's effectiveness and tolerability.

**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



**Optionally, provide details:**

Treatment is recommended once every 16 weeks.

## **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:**

Australian and New Zealand Association of Neurologists

Australian and New Zealand Society for Geriatric Medicine

Rehabilitation Medicine Society of Australia and New Zealand

Australasian Society for Developmental Paediatrics

Australian Society of Otolaryngology Head and Neck Surgery

Australian Society of Plastic Surgeons

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

Cerebral Palsy Australia

Parkinson's Australia

MND Australia

Stroke Foundation

Neurodevelopment Australia

**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

## 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:**

Treating chronic sialorrhea with incobotulinumtoxinA (Xeomin) required injections into salivary glands. A PBAC submission was considered at the November 2024 meeting, and the PBAC deferred a decision. Reasons for the deferral will not be shared with the sponsor until the 13th of December.

The PBS listings requires an MBS injecting code as all other botulinum toxin therapies for other indications do.