**Medical Services Advisory Committee****Public Summary Document**

Application No. 1800 – IncobotulinumtoxinA (XEOMIN) injection for chronic sialorrhea treatment

**Applicant: Merz Australia Pty Ltd**

**Date of MSAC consideration: 3-4 April 2025**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](http://www.msac.gov.au/)

## Purpose of application

This codependent application requested:

* Medicare Benefits Schedule (MBS) listing of injection of incobotulinumtoxinA for treatment of chronic sialorrhea; and
* Pharmaceutical Benefits Scheme (PBS) Authority Required listing of incobotulinumtoxinA (Xeomin®) for treatment of chronic sialorrhea.

## MSAC’s advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC supported the creation of a new Medicare Benefits Schedule (MBS) item for IncobotulinumtoxinA injection for the treatment of chronic sialorrhea.

MSAC noted that at its November 2024 meeting PBAC had deferred Pharmaceutical Benefits Scheme (PBS) listing but was of a mind to recommend IncobotulinumtoxinA for chronic sialorrhea pending listing of required MBS items and price reduction. MSAC acknowledged the clinical need and improved health outcomes in the defined population that would be met by funding access to chronic sialorrhea treatment. MSAC noted that PBAC had considered a price reduction incorporating a 2-year time horizon of the submitted economic model for incobotulinumtoxinA injection for chronic sialorrhea treatment and applicant had accepted the PBAC’s recommendation. MSAC supported a single MBS item that covers the treatment of chronic sialorrhea in children and adults using any PBS listed botulinum toxin product.

|  |
| --- |
| Category 3 – THERAPEUTIC PROCEDURES​ |
| MBS item \*XXXX1​Injection of IncobotulinumtoxinA (Xeomin) for the treatment of chronic sialorrhea including all such injections on any one day, if: ​​​(a)    the patient is ≥2 years of age; and ​(b)    the condition is due to a neurological or neurodevelopmental disorder.​This item cannot be claimed more than once every 16 weeks.​(Anaes) |
| Fee: $142.25 Benefit: 75% = $106.70 85% = $120.95​ |

Out of session, MSAC noted Departmental policy advice that a brand specific MBS item for IncobutlinumtoxinA (Xeomin®) may need to be implemented retain consistency with current MBS items and due to legislative and policy reasons currently preventing the implementation of generic MBS items for botulinum toxin.

Additionally, MSAC noted policy advice to include anaesthesia in the descriptor to account for patient needs, particularly in paediatric patients.

| **Consumer summary** |
| --- |
| This is an application from Merz Australia requesting Medicare Benefits Schedule (MBS) listing of the injection of incobotulinumtoxinA (Xeomin®) to treat patients with chronic sialorrhea. The Pharmaceutical Benefits Advisory Committee (PBAC) deferred their decision on listing IncobotulinumtoxinA on the Pharmaceutical Benefits Scheme (PBS) for chronic sialorrhea treatment at its November 2024 meeting, but was of a mind to support the listing pending a price reduction and an accompanying MBS listing for the injection administration service.Chronic sialorrhea is also known as hypersalivation or excessive drooling. It is common in people with neurological conditions or disorders such as Parkinson's disease, cerebral palsy and stroke. Chronic sialorrhea can result in difficulty speaking and eating, mouth irritations and lung infections. It can cause substantial loss of quality of life if not treated. This application is to treat chronic sialorrhea in adults and children aged 2 years old and older.IncobotulinumtoxinA is a purified form of botulinum toxin type A (Botox®). IncobotulinumtoxinA works when injected into the salivary glands by blocking nerve signals so that less saliva (spit) is produced, and thus less drooling.This was a streamlined application to MSAC, as it noted that the PBAC had considered recommending PBS listing incobotulinumtoxinA for treatment of chronic sialorrhea in November 2024 and suggested requirements for support including this MBS application. MSAC noted the PBAC’s conclusions that incobotulinumtoxinA is safe, effective and cost-effective (if the price is reduced).MSAC considered the injection associated with the incobotulinumtoxinA treatment is similar to other injections for botulinum toxin already listed on the MBS.MSAC noted that some people would need ultrasound imaging to precisely guide injections, and some would need a general anaesthesia for administration (especially young children). Also, depending on the care setting, a variety of extra doctors and services may also be needed, such as neurologists, rehabilitation specialists, ear-nose-throat (ENT) surgeons, plastic surgeons, geriatricians and paediatricians. MSAC considered it appropriate to have one MBS item for all patients aged 2 years and older (and not separate listings for children and adults). **MSAC’s advice to the Commonwealth Minister for Health and Aged Care**MSAC supported listing the injection of incobotulinumtoxinA to treat patients with chronic sialorrhea on the MBS. This support is dependent on PBS listing of incobotulinumtoxinA for treatment of chronic sialorrhea (as to be further considered by the PBAC). |

## Summary of consideration and rationale for MSAC’s advice

MSAC noted that this co-dependent application from Merz Australia was for the MBS listing of the injection of incobotulinumtoxinA (Xeomin®) to treat patients with chronic sialorrhea. MSAC noted that it has not considered this application previously, but it has considered other injection services using the same treatment ([Application 1379](https://www.msac.gov.au/applications/1379) – Injection of incobotulinumtoxinA for blepharospasm, cervical dystonia [spasmodic torticollis] and post-stroke spasticity of the upper limb, currently listed on the MBS alongside Botox® and Dysport® [MBS items: [18353](https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18353&qt=item&criteria=xeomin), [18365](https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18365&qt=item&criteria=xeomin), [18369](https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18369&qt=item&criteria=xeomin) and [18374](https://healthgov.sharepoint.com/%3Ap%3A/r/sites/D365-HPP-Site/_layouts/15/Doc.aspx?sourcedoc=%7B27F23865-9B01-4A6D-98FF-F683BE902322%7D&file=1800%20-%201st%20discussant-%20BrienFINAL.pptx&action=edit&mobileredirect=true)]).

MSAC noted that, in November 2024, the Pharmaceutical Benefits Advisory Committee (PBAC) deferred a decision to list incobotulinumtoxinA for chronic sialorrhea on the Pharmaceutical Benefits Scheme (PBS) due to requirement of a MSAC application for an administration MBS item and a request for a price reduction to address uncertainty in the cost-effectiveness model. The PBAC considered that the claim of inferior comparative safety was reasonable and that, overall, the clinical evidence supported the claim of superior comparative effectiveness of incobotulinumtoxinA over placebo. As a result, this was a streamlined MSAC application that bypassed PASC and ESC.

MSAC noted that sialorrhea (hypersalivation or excessive drooling) is a condition characterised by the leaking of saliva from the lips and is caused by neurological conditions or disorders. Chronic sialorrhea can result in a significant reduction in quality of life through a degradation in physical and/or mental health. It can also result in difficulty speaking and eating, mouth irritations and lung infections. This application focuses on chronic sialorrhea caused by neurological conditions such as Parkinson's disease, cerebral palsy and stroke in children >2 years old and in adults.

MSAC noted the consumer input to the PBAC from healthcare professionals and Motor Neurone Disease Australia, which was supportive. Feedback noted that chronic sialorrhea can be a debilitating condition and that incobotulinumtoxinA is associated with a significant improvement to the quality of life. The feedback considered the adverse side effects, including flu-like symptoms, excessive dry mouth and swallowing difficulties, to be manageable. Feedback also included that cost was a barrier to treatment and that the PBS listing would improve accessibility.

MSAC noted that the PBAC considered the claim of inferior safety of incobotulinumtoxinA versus placebo to be reasonable ([PBAC Public Summary Document](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fm.pbs.gov.au%2Findustry%2Flisting%2Felements%2Fpbac-meetings%2Fpsd%2F2024-11%2Ffiles%2Fincobotulinumtoxina-psd-nov-2024.docx&wdOrigin=BROWSELINK), November 2024).

MSAC noted that the PBAC reviewed a cost-utility analysis, which presented a stepped economic evaluation based on the SIAXI and SIPEXI trials that compared incobtulinumtoxinA with standard care. MBS costs were included as part of the total treatment cost for both adult and paediatric patients. The incremental cost-effectiveness ratios (ICERs) were $25,000 to < $35,000 per quality-adjusted life year (QALY) gained for adults and $35,000 to < $45,000 per QALY gained for children and adolescents. The PBAC considered that the ICER values presented for the base case of the submission were acceptable but PBAC advised that for incobotulinumtoxinA to be considered cost-effective the models should (i) incorporate a 2-year time horizon, and (ii) a price reduction so that the resultant ICERs do not exceed the base case values presented in the submission.

MSAC noted that the proposed MBS fee was $142.25 for the injection administration for both the paediatric and adult populations. This fee is equivalent to MBS items [18372](https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18372&qt=item) (paediatric) and [18374](https://www9.health.gov.au/mbs/search.cfm?q=18374&Submit=&sopt=S) (adult), which are for the injection of Botox® (18372), Dysport® and IncobotulinumtoxinA (18374) to treat bilateral blepharospasm. Clinical opinion was that the administration costs for those existing items and proposed incobotulinumtoxinA treatments should be identical, to which MSAC agreed. The proposed incobotulinumtoxinA treatment would also require access to a specialist consultation (MBS item 116, fee of $87.30), with some patients also requiring an ultrasound- (US-) assisted injection (MBS item 55848, fee of $153.20). According to the SIAXI and SIPEXI trials, 55% of adult patients and 100% of paediatric patients will require a US-guided injection.

MSAC queried the rationale for 2 MBS listings (one for adults and one for paediatric patients) with the same fee, and advised that a single MBS listing for patients ≥2 years old would be appropriate.

MSAC noted that the revised financial impact, including to the MBS, that on balance the utilisation estimates were reasonable to the PBAC. The applicant provided additional further calculations in their pre-MSAC response showing net cost to the MBS (assuming half of all patients require general anaesthesia (GA), and basing US use on the SIAXI and SIPEXI trials) was $0 to < $10 million in year 1 and $0 to < $10 million in year 6 at the 85% rebate. MSAC considered it appropriate to use existing GA MBS items and that no new items would be required.

MSAC considered that the MBS impact varies depending on the:

* setting, such as in hospital, a ‘day centre’ or clinic room (that is, if it is an A-, B- or C-type procedure)
* use of US
* use of GA, and therefore the need for an anaesthetist (and pre-anaesthesia consultation and anaesthetic management).

MSAC considered the proportion of patients requiring US and GA to be uncertain among paediatric and adult patients. MSAC noted from the pre-MSAC response that in the paediatric SIPEXI trial, 90% of participants received some form of anaesthetic intervention throughout, and about 15% required concomitant GA. MSAC also noted that incobotulinumtoxinA would likely be administered in different settings and may receive different level of MBS reimbursement.

MSAC noted the Department’s query whether the MBS listing should be agnostic, based on the MBS Review Taskforce [Final report on the review of neurosurgery and neurology MBS items](https://www.health.gov.au/resources/publications/taskforce-final-report-neurosurgery-and-neurology-mbs-items?language=en) (2018) that stated that Botox® and Dysport® could be used to treat chronic sialorrhea, not just incobotulinumtoxinA. However, MSAC considered that different botulinum toxin products are not biosimilar may require separate PBAC submissions for PBS listing. However, MSAC considered it appropriate make the MBS item for administration agnostic to the type of PBS-listed botulinum toxin product administered. MSAC noted that the PBAC advised restricting the service to patients with severe chronic sialorrhea, which would be determined by using the Drooling Severity and Frequency Scale (DSFS) score of at least six and one point improvement is required to continue treatment on the PBS.

MSAC supported creation of a new MBS item for the injection of incobotulinumtoxinA for patients with chronic sialorrhea, based on the codependent PBS listing of incobotulinumtoxinA for treatment of chronic sialorrhea.

## Background

In November 2024, the PBAC deferred making a recommendation for the listing of incobotulinumtoxinA for the treatment of chronic sialorrhea due to neurological disorders. While the PBAC was of a mind to recommend incobotulinumtoxinA, the PBAC noted that an MSAC application for the administration of incobotulinumtoxinA for chronic sialorrhea was also required to ensure there would be access to the required MBS items.

The PBAC considered that the evidence presented demonstrated an improvement in both the severity and frequency of sialorrhea compared with placebo. The PBAC considered that, on balance, the incobotulinumtoxinA utilisation estimates provided in the submission were reasonable.

The MSAC has not previously considered incobotulinumtoxinA injection for chronic sialorrhea. However, injection services for incobotulinumtoxinA in other clinical indications had been considered, recommended by MSAC (Application 1379 – IncobotulinumtoxinA, injection of, for blepharospasm, cervical dystonia (spasmodic torticollis) and post-stroke spasticity of the upper limb) and are currently listed on the MBS alongside comparators Botox® and Dysport® (MBS Items: [18353](https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18353&qt=item&criteria=xeomin), [18365](https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18365&qt=item&criteria=xeomin), [18369](https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18369&qt=item&criteria=xeomin), and [18374](https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=18374&qt=item&criteria=xeomin)).

IncobotulinumtoxinA is the only botulinum toxin preparation that is TGA-indicated for the treatment of chronic sialorrhea.

Injections in this indication are recommended to be delivered less frequent than once every 16 weeks.

Neurologists, rehabilitation specialists, ENT surgeons, and plastic surgeons can provide the service to both adult and paediatric populations, in addition to geriatricians for the adult population, and paediatricians for the paediatric population.

## Prerequisites to implementation of any funding advice

IncobotulinumtoxinA was first registered on the Australian Register of Therapeutic Goods (ARTG) on the 21st of March 2014. In October 2022 a request to extend the indication to include sialorrhea was submitted and was approved in November 2023. It was approved for use in chronic sialorrhea in adults and children and adolescents (aged 2 years to 17 years) and has the ARTG ID 205508.

## Proposal for public funding

The listing of two new MBS items is requested in order to provide injection services to adults (Table 1) and paediatric patients (Table 2) with chronic sialorrhea.

The proposed fee/s are equivalent to the fee/s for injection services of incobotulinumtoxinA for bilateral blepharospasm (MBS Items 18372/4), which according to clinician response similarly involve multiple injections to both sides of the patient’s face.

The Department considered proposed MBS item needs ‘anaes.’ added to the descriptor to indicate to providers that this is a service for which anaesthesia may be required. The SIPXI trial (2-17 years) offered general anaesthesia, medication for analgesia, and analgosedation unless contraindicated and in line with international guidelines on sedation in children. However the trial did not report the exact proportion of patients who required anaesthesia or sedation for the injection procedure. In the incobotulinumtoxinA arms of the SIPXI trial 38/248 (25.7%) of patients aged 6-17 years and 4/35 (11.4%) of patients aged 2-5 years were administered concomitant general anaesthetics. The clinical trial report also reported the proportion of patients who used concomitant hypnotics and sedatives (Anatomical Therapeutic Chemical class level 3). However, the department considered that it is not known whether these were used for procedural sedation or other indications. The Royal Children’s Hospital Melbourne information guide [on Saliva Control in Children](https://www.rch.org.au/uploadedfiles/main/content/plastic/salivabook.pdf) state that the procedure is done under a brief general anaesthetic as a ‘day stay’ procedure.

Table 1 Presentation of newly proposed MBS items for injection services for Xeomin for sialorrhea.

| Category 3 – THERAPEUTIC PROCEDURES |
| --- |
| MBS item \*XXXX1IncobotulinumtoxinA (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 condition is due to a neurological disorder.This item cannot be claimed more than once every 16 weeks.*(Anaes.)* |
| Fee: $142.25 Benefit: 75% = $106.70 85% = $120.95 |

Table 2 Presentation of newly proposed MBS items for injection services for Xeomin for sialorrhea.

| Category 3 – THERAPEUTIC PROCEDURES |
| --- |
| MBS item \*XXXX2IncobotulinumtoxinA (Xeomin), injection of, for the treatment of chronic sialorrhea including all such injections on any one day, if: (a)    the patient is at 2-17 years of age; and (b)    the condition is due to a neurological or neurodevelopmental disorder.This item cannot be claimed more than once every 16 weeks.*(Anaes.)* |
| Fee: $142.25 Benefit: 75% = $106.70 85% = $120.95 |

It was assumed that all services will also attract a specialist consultation fee of $87.30 (MBS item 116).

Additionally, per the key trials, 55% of adults and 100% of patients aged 2-17 years required ultrasound imaging to guide injections. In the paediatric trial (SIPXI) injection of both salivary glands at each side was performed at each injection visit using mandatory ultrasound guidance. The ADAR incorporated an ultrasound fee of $153.20 (MBS item 55848) for musculoskeletal ultrasound, in conjunction with a surgical procedure using interventional techniques. The use of this item may not be appropriate as the item is for use with a surgical procedure.

## Population

As this is part of a streamlined-codependent submission, there was no PICO developed via PASC. The population that are eligible for incobotulinumtoxinA injection for chronic sialorrhea treatment are as per the TGA approved Product Information:

“Children and adolescents aged 2-17 years with chronic sialorrhea due to neurological or neurodevelopmental disorders, and adults (≥18 years) with chronic sialorrhea due to neurological disorders.”

Sialorrhea (excessive drooling) is an excess spillage of saliva over the lip margin. Sialorrhea is generally diagnosed by clinical assessment based on the experience of the patients and parents/caregivers as well as the observations by healthcare professionals. However, the most used quantitative measure to describe the severity of sialorrhea is the Drooling Severity and Frequency Scale (DSFS). Patients with severe chronic sialorrhea can suffer from quality-of-life issues (such as social isolation) and unintelligible speech to facial skin maceration and even increased morbidity and mortality due to dehydration, choking, aspiration, and pneumonia.[[1]](#footnote-2)

The proposed PBS restriction requires the individual to reach a combined DSFS score of 6 or more – indicated severe chronic sialorrhea – to initiate treatment with incobotulinumtoxinA and maintain an at least a one-point improvement compared to baseline to maintain treatment. Paediatric patients who initiate treatment for cerebral palsy or developmental disorders will be eligible for continued treatment as an adult. The PBAC considered that these criteria were appropriate. The PBAC also noted that the submission suggested that it may be reasonable to extend the PBS listing criteria to include patients with other neurological conditions known to cause chronic sialorrhea. However, the PBAC advised that the proposed extension to the PBS listing was not appropriate due to the lack of clinical trial evidence. (6.04 incobotulinumtoxinA, ratified minutes, Nov 2024, paragraphs 7.4 to 7.5).

## Comparator

The comparator in the PBAC submission was supportive care via current clinical management.

The comparator was considered by PBAC. The PBAC noted that other botulinum toxin type A injections are not TGA-approved for sialorrhea treatment and while several anticholinergics are used off-label to treat sialorrhea, they are associated with toxicity and poor tolerance. Considering this the PBAC accepted the nominated comparator of supportive care via current clinical management (6.04 incobotulinumtoxinA, ratified minutes, Nov 2024, paragraph 7.6).

## Characteristics of the evidence base

The PBAC considered the results of two phase III trials – SIAXI[[2]](#footnote-3) and SIPEXI[[3]](#footnote-4) - form the evidence base for incobotulinumtoxinA treatment of chronic sialorrhea (Table 3). These trials consist of a randomised, double-blind, placebo-controlled period evaluating efficacy and safety, and a randomised open-label non-controlled extension period evaluating safety. The PBAC considered that the evidence presented demonstrated an improvement in both the severity and frequency of sialorrhea compared with placebo. However, due to short trial durations and the lack established MCIDs, the magnitude of this benefit was uncertain (6.04 incobotulinumtoxinA, ratified minutes, Nov 2024, paragraph 7.7). The PBAC considered that the claim of inferior safety of incobotulinumtoxinA versus placebo was reasonable (6.04 incobotulinumtoxinA, ratified minutes, Nov 2024, paragraph 7.8).

Table 3 Key features of the clinical evidence for incobotulinumtoxinA (Xeomin®) for chronic sialorrhea treatment (considered by PBAC)

| References | N | Design/duration | Risk of bias | Patient population | Outcome(s) | Use in modelled evaluation |
| --- | --- | --- | --- | --- | --- | --- |
| IncobotulinumtoxinA vs placebo (standard care) |
| Jost 2019 | 184 | DB RCT = 16 weeksOL = 48 weeks  | Low | Adults with chronic sialorrhea due to Parkinson’s disease, stroke, and traumatic brain injury randomised to Xeomin or placebo treatment arms.  | Efficacy: uSFR, DSFS, GICS, EQ-5D-3LSafety | uSFRDSFSEQ-5D-3L |
| Berweck 2021 | 220 | DB RCT = 16 weeksOL = 48 weeks | Low | Children and adolescents with chronic sialorrhea due to cerebral palsy, traumatic brain injury, or other congenital neurodevelopmental disorders, randomised to Xeomin or placebo treatment arms. | Efficacy: uSFR, mTDS, GICS.Safety | uSFRmTDS |

DB = double blind; DSFS = drooling severity and frequency scale; EQ-5D-3L = EuroQol-5 Dimensions-3 Level; GICS: global impression of change scale; mTDS = modified teacher’s drooling scale; OL = open label; OS = overall survival; RCT = randomised controlled trial; uSFR = unstimulated salivary flow rate

## Comparative safety and efficacy

The ADAR presented the key results from the clinical. These have not been re-presented as PBAC has assessed the clinical evidence.

The PBAC considered that the evidence presented demonstrated an improvement in both the severity and frequency of sialorrhea compared with placebo. However, due to short trial durations and the lack established minimal clinically important differences (MCID), the magnitude of this benefit was uncertain (6.04 incobotulinumtoxinA, ratified minutes, Nov 2024, paragraph 7.7). The PBAC considered that the claim of inferior safety of incobotulinumtoxinA versus placebo was reasonable (6.04 incobotulinumtoxinA, ratified minutes, Nov 2024, paragraph 7.8).

## Economic evaluation

The PBAC considered a cost-utility analysis to support the cost-effectiveness of incobotulinumtoxinA versus placebo, with the economic model reporting incremental cost-effectiveness ratios (ICERs) of $25,000 to < $35,000 per quality adjusted life year (QALY) gained for adults and $35,000 to < $45,000 per QALY gained for children and adolescents. The PBAC considered that the ICER values presented for the base case of the submission were acceptable. The PBAC advised that for incobotulinumtoxinA to be considered cost-effective the models should (i) incorporate a 2-year time horizon (base case 5 years), and (ii) a price reduction so that the resultant ICERs do not exceed the base case values presented in the submission. The key results considered by the PBAC are presented in Table 4.

**Table 4: Key sensitivity analyses for adult and children and adolescent models**

| **Analyses** | **Incremental cost** | **Incremental QALY** | **ICER** |
| --- | --- | --- | --- |
| **Adults**  |
| **Base case** | **$**| | **0.27** | **$**| 1 |
| 2-year time horizon (base case 5 years) | $| | 0.11 | **$**| 2 |
| **Children and adolescents** |
| **Base case** | **$**| | **0.25** | **$**| 2 |
| 2-year time horizon (base case 5 years) | $| | 0.11 | $| 2 |
| Including anaesthesia costs for children and adolescents **a** | $| | 0.25 | $| 2 |

Source: Table 16, p45 of the November 2024 PBAC commentary, 6.04 incobotulinumtoxinA ratified PBAC minutes

a Total anaesthesia costs: $162.50, including anaesthesia brief consultation: MBS 17610= $49.75; anaesthesia fees: 1:01 HOURS to 1:15 HOURS, MBS 23055=$112.75

The redacted values correspond to the following ranges:

1 $25,000 to < $35,000

2 $35,000 to < $45,000

The ADAR stated that since the PBAC has accepted the cost effectiveness of Xeomin at a 2-year time horizon with an injection administration fee of $142.25, the proposed MBS item at an equivalent value will ensure that the total cost of treatment will remain cost-effective.

## Financial/budgetary impacts

The ADAR presented utilisation and financial based on the those presented in their submission to PBAC, rather than the revised estimates considered by PBAC. The revised estimates considered by the PBAC corrected calculation errors and double counting (refer to paragraph 6.116, November 2024 PBAC minutes). A comparison of these prescription numbers is presented in Table 5. The Departmental Overview has calculated revised financial estimates using the revised estimates in the PBAC minutes.

Table 5: Estimation of the number of incobotulinumtoxinA prescriptions

|  | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Year 6 |
| --- | --- | --- | --- | --- | --- | --- |
| **Total scripts number**  |
| Adults | | 1 | | 1 | | 1 | | 2 | | 3 | | 3 |
| Children and adolescents  | | 4 | | 1 | | 1 | | 1 | | 2 | | 2 |
| Total  | | 1 | | 1 | | 2 | | 3 | | 3 | | 3 |
| **Revised estimated total scripts number (as per PBAC minutes)** |
| Adults | | 1 | | 1 | | 3 | | 5 | | 6 | | 6 |
| Children and adolescents  | | 1  | | 1 | | 1 | | 2 | | 2 | | 2 |
| Total  | | 1 | | 2 | | 3 | | 5 | | 7 | | 7 |

Source: Table 4.2.2, p40 of the November 2024 incobotulinumtoxinA PBAC commentary.

The redacted values correspond to the following ranges

1 500 to < 5,000

2 5.000 to < 10,000

3 10,000 to < 20,000

4 0 to < 500

5 20,000 to < 30,000

6 30,000 to < 40,000

7 40,000 to < 50,000

As stated earlier, the PBS listing of IncobotulinumtoxinA for the treatment of sialorrhea will increase MBS utilisation and cost, as all patients will require injection fees and specialist consultations, as well as ultrasound for most.

Table 6 details the MBS items that will likely be affected per the applicant by the PBS listing of Xeomin for the treatment of sialorrhea. All patients are expected to use the proposed MBS item for injection (fee of $142.25) and a specialist consultation fee of $87.30 (MBS item number 116). In the SIAXI clinical trial (adult patients), 55% of patients additionally required ultrasound imaging to guide the identification of injection sites. The ultrasound fee of $153.20 (MBS item number 55848) was therefore applied to only 55% of all adult patients. In the SIPEXI clinical trial all paediatric patients required ultrasound imaging to guide the identification of injection sites. Therefore, the ultrasound fee was applied to all paediatric patients. The Department noted that clinicians may not be able to claim the MBS item number 55848 as it for use conjunction with a surgical procedure.

Table 6. MBS items affected by listing of Xeomin

|  |  |  |
| --- | --- | --- |
| **Description** | **Fee/Value** | **Source** |
| Specialist Consultation | $87.30  | MBS item 116 |
| Injection Administration | $142.25 | Proposed MBS item |
| Ultrasound  | $153.20 | MBS item 55848 |
| Proportion of adult patients requiring ultrasound | 55% | SIAXI |
| Proportion of paediatric patients requiring ultrasound | 100% | SIPEXI |

Source: Table 17, p16 of the ADAR

The financial estimates in the ADAR did not include anaesthesia costs. The PBAC Pre-sub-committee response (PSCR) stated that as anaesthesia was not a requirement of the SIPEXI (paediatric) trial and that as expert opinion did not consider it necessary, it was not included. However, the department does note that in the SIPEXI trial these interventions were offered to all children. General anaesthetics were administered for 23.6% of the placebo group (6−17 years old), and for 11.4% and 25.7% of the incobotulinumtoxinA groups (2−5 years old, 6−17 years old, respectively). The Royal Children’s Hospital Melbourne information guide [on Saliva Control in Children](https://www.rch.org.au/uploadedfiles/main/content/plastic/salivabook.pdf) state that the procedure is done under a brief general anaesthetic as a ‘day stay’ procedure. Therefore, the department have considered MBS fees that could represent general anaesthesia costs in Table 7. Anaesthesia costs may be underestimated because MBS costs for anaesthesia also include modifying units to recognise added anaesthesia complexities. For example, patients aged less than 4 years or 75 years and older maybe eligible for additional MBS items due to age (item 25013 or 25014).

Table 7. MBS items that could represent general anaesthesia costs

|  |  |  |
| --- | --- | --- |
| **Description** | **Fee/Value** | **Source** |
| Pre-anaesthesia consult <15min | $49.75 | MBS item 17610 |
| Initiate anaesthesia management | $112.75 | MBS item 20100 |
| Anaesthesia 16-30mins | $45.10 | MBS item 23025 |

Source: Compiled by the Department

The Department compiled Table 8 which shows the changes in use of MBS item using the revised patient and prescription numbers shown earlier in Table 5. The use of specialist consultation items was corrected by the Department to be the same as the number of injections administered. General anaesthesia costs are also incorporated into Table 8 using assumptions of 100% utilisation in children and adolescents.

Table 8. Net changes to the MBS

| **MBS Item Description**  | **FY 2025-26** | **FY 2026-27** | **FY 2027-28** | **FY 2028-29** | **FY 2029-30** | **FY 2030-31** |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated volume increases to the MBS (ADAR)** |
| Injection Administration | | 1 | | 1  | | 2 | | 3 | | 3 | | 3 |
| Consultation | | 4 | | 1 | | 1 | | 1 | | 2 | | 2 |
| Ultrasound - Adult | | 4 | | 1 | | 1 | | 1 | | 2 | | 2 |
| Ultrasound - Paediatric | | 4 | | 1 | | 1 | | 1 | | 1 | | 1 |
| **Total MBS services** | | 1 | | 1 | | 3 | | 5 | | 6 | | 6 |
| **Revised estimated volume increases to the MBS (based on PBAC minutes)** |
| Injection administration | | 1 | | 2 | | 3 | | 5 | | 7 | | 7 |
| Consultation | | 1 | | 2 | | 3 | | 5 | | 7 | | 7 |
| Ultrasound (adult) | | 1 | | 1 | | 2 | | 3 | | 3 | | 3 |
| Ultrasound (paediatric) | | 1 | | 1 | | 1 | | 2 | | 2 | | 2 |
| Anaesthesia items (paediatric only)  | | 1 | | 1 | | 1 | | 2 | | 2 | | 2 |

Abbreviations. FY: Financial Year; MBS: Medicare Benefits Scheme

Source: Table 18, p17 of the ADAR; *Table 19, p51 of the November 2024 PBAC commentary,* *6.04 incobotulinumtoxinA ratified minutes and recalculated by the Department*

The redacted values correspond to the following ranges

1 500 to <5,000

2 5,000 to < 10,000

3 10,000 to < 20,000

4 0 to < 500

5 20,000 to < 30,000

6 30,000 to < 40,000

7 40,000 to < 50,000

The financial implications to the MBS from the ADAR and revised by the Department resulting are summarised in Table 9. As shown, the net cost of listing incobotulinumtoxinA to the MBS is expected to be $0 to < $10 million in 2025-26, increasing to $0 to < $10 million in 2030-31 based on a 100% rebate when the costs are revised to use the utilisation estimates in the PBAC minutes, correct the number of specialist consultations and include anaesthesia costs for children.

The ADAR claimed that as most patients have long term chronic conditions, the overall copayment figures are expected to be low, so Medicare rebates will likely cover close to 100% of the benefit from these utilised services. MBS costs have been presented with a 100% rebate as some services may be classified as a ‘hospital treatment’ if incobotulinumtoxinA is administered at a hospital (or with the direct involvement of the hospital).

Table 9. Net financial implications to the MBS

| **MBS Item Description**  | **FY 2025-26** | **FY 2026-27** | **FY 2027-28** | **FY 2028-29** | **FY 2029-30** | **FY 2030-31** |
| --- | --- | --- | --- | --- | --- | --- |
| **Estimated net financial impact on MBS** |
| Injection Administration | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Consultation | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Ultrasound - Adult | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Ultrasound - Paediatric | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| **Net cost to the MBS** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 |
| **Net cost to the MBS (80% benefit)** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 |
| **Revised Estimated net financial impact on MBS (based on utilisation accepted by the PBAC)** |
| Injection administration | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Consultation | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Ultrasound (paediatric and adult)  | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Anaesthesia (paediatric) | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| **Net cost to the MBS (without anaesthesia) 100%** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 2 | **$**| 2 |
| **Net cost to the MBS (with anaesthesia) 100%** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 2 | **$**| 2 |
| **Net cost to the MBS (with anaesthesia, no ultrasound) 100%** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 2 | **$**| 2 |

Source: Table 18, p17 of the ADAR and recalculated by the Department

The redacted values correspond to the following ranges

1 $0 to < $10 million

2 $10 million to < $20 million

The applicant noted in their pre-MSAC response that the pivotal paediatric sialorrhea trial, SIPEXI, 42/283 (≈15%) of patients required concomitant GA without reasons reported. The applicant believed it would not be appropriate to consider 100% of children aged 2-17 will require general anaesthesia to receive incobotulinumtoxinA injections for sialorrhea alone. A large proportion would receive sedation and/or local analgesia instead to receive injections for sialorrhea, or receive other injection treatments (such as for spasticity) as well while anaesthetised. The applicant also noted the Department’s revised utilisation estimates based on the PBAC minutes. They noted that 12% of stroke and TBI patients will have at least one chronic health condition lasting for at least 6 months, so it would be extreme to consider that all of these patients will have sialorrhea. The provided Table 10 with original utilisation that PBAC considered on balance were reasonable (6.04 incobotulinumtoxinA, ratified minutes, Nov 2024, paragraph 7.10) along with net cost to the MBS showing what they considered a more likely 25% and 50% of paediatric patients utilising anaesthesia.

Table 10. Revised financial estimates provided in Pre-MSAC response

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **FY 2025-26** | **FY 2026-27** | **FY 2027-28** | **FY 2028-29** | **FY 2029-30** | **FY 2030-31** |
| Injection administration | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Consultation | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Ultrasound (adult) | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Ultrasound (paediatric) | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Anaesthesia 16-30mins | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Pre-anaesthesia consult <15min | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Initiate anaesthesia management | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Total Anaesthesia | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Total Ultrasound | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| **Net cost to the MBS (without anaesthesia) 100%** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 |
| Net cost to the MBS (without anaesthesia) 85% | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| **Net cost to the MBS (with 100% of patients receiving anaesthesia) 100%** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 |
| Net cost to the MBS (with anaesthesia) 85% | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| Net cost to the MBS (with anaesthesia, no ultrasound) 100% | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| **Net cost to the MBS (with 25% of patients receiving anaesthesia) 100%** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 |
| Net cost to the MBS (with 25% of patients receiving anaesthesia) 85% | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |
| **Net cost to the MBS (with 50% of patients receiving anaesthesia) 100%** | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 | **$**| 1 |
| Net cost to the MBS (with 50% of patients receiving anaesthesia) 85% | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 | $| 1 |

Source: Table 1, p2 of pre-MAC response by the applicant

The redacted values correspond to the following ranges

1 $0 to < $10 million

## Other relevant information

The applicant advised they will provide training workshops throughout the year in injections and ultrasound use with the aid of a sonographer. Workshops are provided for a range of existing indications which incobotulinumtoxinA treats and will be provided for use in the chronic sialorrhea population also.

## Applicant comments on MSAC’s Public Summary Document

The applicant had no comment.

## Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](http://msac.gov.au/internet/msac/publishing.nsf/Content/Home-1)

1. Hockstein, N.G., et al., Sialorrhea: a management challenge. Am Fam Physician, 2004. 69(11): p. 2628-34.; Kalf, J.G., et al., Impact of drooling in Parkinson's disease. J Neurol, 2007. 254(9): p. 1227-32.; Rodrigues, B., et al., Silent saliva aspiration in Parkinson's disease. Mov Disord, 2011. 26(1): p. 138-41.; Scully, C., et al., Drooling. Journal of Oral Pathology & Medicine, 2009. 38(4): p. 321-327.; Akbar, U., et al., Incidence and mortality trends of aspiration pneumonia in Parkinson's disease in the United States, 1979-2010. Parkinsonism Relat Disord, 2015. 21(9): p. 1082-6. [↑](#footnote-ref-2)
2. Jost, W.H., et al., SIAXI: Placebo-controlled, randomized, double-blind study of incobotulinumtoxinA for sialorrhea. Neurology, 2019. 92(17): p. e1982-e1991. [↑](#footnote-ref-3)
3. Berweck, S., et al., Placebo-controlled clinical trial of incobotulinumtoxinA for sialorrhea in children: SIPEXI. Neurology, 2021. 97(14): p. e1425-e1436. [↑](#footnote-ref-4)