



**57th MSAC Meeting
29-30 November 2012**

Application 1221: Transurethral injection of Botulinum toxin into the bladder wall for urinary incontinence due to neurogenic detrusor overactivity.

Summary of consideration and rationale for MSAC's advice

MSAC noted that the application from Allergan in June 2012 preceded PBAC consideration of the associated request to extend the PBS listing of botulinum toxin to include urinary incontinence due to neurogenic detrusor overactivity in July 2012. PBAC decided to defer the requested listing and referred questions to MSAC for advice to be included in a minor resubmission from the applicant to PBAC. MSAC first considered the requests from PBAC because they helped focus on the matters to be addressed and then any other matters which were relevant.

Responses to PBAC requests for MSAC advice

MSAC advised that it would support \$229.85 as the MBS fee for injecting botulinum toxin in urinary incontinence, with reference to the 1 November 2012 MBS fee for MBS item 36851 (for cystoscopy with injection into the bladder wall) as the benchmark. MSAC further advised that, consistent with MBS item 36851, this should be rendered as a hospital inpatient service (noting that this includes same day hospital admission), and should always be accompanied by anaesthesia. These associated costs are also identified in the tables below.

MSAC advised that the consultation item(s) likely to be required to assess and reassess each patient would be MBS item 104 (noting that urologists, who are nominated to inject botulinum toxin for urinary incontinence, are specialists) for an initial assessment if referred for this purpose and MBS item 105 for an initial assessment for this purpose (if part of the ongoing management by the urologist, having been referred earlier) and also for subsequent reassessments. In addition, if general practitioners are to be included in the overall economic evaluation for any reason, such as for increased referral rates or for ongoing assessments, then the GP attendance item(s) likely to be required are MBS items 23 and 36.

MSAC advised that the implications for out-of-pocket (or private health insurance) payments are as set out for each identified MBS item (proposed and existing) in the tables below. Each amount is calculated as the difference between the relevant average fee charged for the most recent financial year and, except as noted below, the relevant rebate in the current Schedule of Medicare Benefits. For the proposed MBS item, the average fee charged was calculated as the average fee charged for MBS item 36851. For the two specialist items (104 and 105), the average fee charged was calculated for the urology specialty only (for greater accuracy). For the pre-anaesthesia consultation MBS items (17610 to 17625), the weighting to determine the average fee charged was determined by the proportion use of these items in association with MBS item 36851. Similarly, for the duration of anaesthesia MBS items (23020 to 24136), the weighting to determine the average fee charged was determined by the proportion use of these items in association with the initiation of anaesthesia for transurethral procedure MBS item (20910) and in association with MBS item 36851. These weightings were also used to determine the weighted average rebate paid for the most recent financial year.

MSAC further advised that, in the context of proposed MBS items to inject proposed PBS items, the relative influence of MBS costs on the overall economic evaluation for the PBS proposal is greater than usual. For this reason, MSAC advised PBAC and the applicant that the average fee charged in these tables should be included in the economic evaluation to reflect its opportunity cost from the health care system perspective (rather than the MBS fee as is recommended in PBAC's Manual of Resource Items and their Unit Costs). Similarly, the relevant costs to the MBS for inclusion in the financial analyses are also provided in the table, based on the most applicable rebate.

MSAC advised against including any consequences for the Extended Medicare Safety Net (EMSN) in the economic evaluation or the financial analysis because the EMSN does not apply to hospital inpatient services, and the other attendance items (104, 105, 23, and 36) already have EMSN caps applied.

Item number	Proposed item	17610 to 17625	20910	23020 to 24136	Total
Brief description	Inject botulinum toxin for urinary incontinence	Pre-anaesthesia consultation	Initiation of anaesthesia for transurethral procedure	Management of anaesthesia associated with 20910 for varying durations of anaesthesia	
Fee	\$229.85	\$43.00	\$79.20	\$19.80 (<15min) to \$2772 (24hr)	
Government pays (rebate)	\$172.40 (75%)	\$32.49		\$110.71	\$315.60
Patient/PHI pays	\$129.60	\$44.96		\$157.07	\$331.63
Total (average fee charged)	\$302	\$77.45		\$267.78	\$647.23

Item number	104	105	23	36
Brief description	Initial specialist attendance	Subsequent specialist attendance	GP attendance < 20 minutes	GP attendance > 20 minutes
Fee	\$85.55	\$43.00	\$36.30	\$70.30
Government pays (rebate)	\$72.75 (85%)	\$36.55 (85%)	\$36.30 (100%)	\$70.30 (100%)
Patient pays (OOP)	\$57.23	\$29.93	\$5.04	\$4.67
Total (average fee charged)	\$129.98	\$66.48	\$41.34	\$74.97

Additional MSAC considerations and rationale

MSAC advised that there was no evidence to suggest that any variation in injecting performance across trained and experienced urologists (or other subspecialists such as urogynaecologists) would be likely to have important consequences for patient safety or for the effectiveness and safety of botulinum toxin in the proposed indication. MSAC also noted PBAC's comments that the proposed PBS restriction for botulinum toxin did not restrict treatment to patients with multiple sclerosis or spinal cord injury and that use in other patients was likely. The latter group potentially includes the large group of patients with idiopathic neurogenic detrusor overactivity. MSAC decided that the overall comparative effectiveness and safety of botulinum toxin were matters for PBAC to consider.

MSAC advised that, in the event of a PBAC recommendation to list botulinum toxin for urinary incontinence due to neurogenic detrusor overactivity, it would revisit the wording of the proposed MBS item descriptor. Specifically, the Committee foreshadowed its intention to exclude out-of-hospital injection and to advise that the definition of eligible patients should be aligned with any PBAC-recommended PBS restriction, preferring to include the ability to self-catheterise as a prerequisite to botulinum toxin therapy and the term “intravesical injection” rather than “transurethral injection”. MSAC also foreshadowed its intention to exclude the billing of attendance items to assess or reassess the patient on the same occasion of service, in the context of an in-hospital procedure, or of a urine flow or urodynamic study (e.g., MBS items 11900 or 11919) on the same occasion of service, given a urine flow study is a simple procedure that (if necessary) would form part of the MBS-funded botulinum toxin service, and urodynamic studies would have been billed separately (and prior) to the injection service to confirm detrusor involvement. MSAC agreed that assessment and reassessment were necessary aspects of managing therapy with botulinum toxin, and the frequency of these might change should botulinum toxin be funded for this purpose, but did not consider that this should form part of the process of injection, which would need to be arranged as a separate procedure on another day following assessment. If these proposed exclusions raise any concerns, MSAC requested that data for the most recent financial year be presented on the extent of co-claiming of the proposed exclusion alongside the benchmark MBS items 36851 on the same day, and 25% had a specialist attendance co-claimed on the same day. MSAC also considered the possibility of limiting the item to appropriately trained urologists and associated subspecialties like urogynaecologists, but accepted advice that this issue would be appropriately handled as part of any extension of the PBS arrangements for botulinum toxin.

MSAC noted that the proposed MBS item would exclude its use to inject any other medicine, and advised that injection of botulinum toxin should be excluded from MBS item 36851, but asked that the Department consider the timing of any implementation of this advice in relation to MBS item 36851.

MSAC noted the following advice in the ESC report and referred these to PBAC and the applicant:

- limiting the listing to individuals able to self-catheterise may reduce the extent of utilisation, and may also affect the extent of utility and resources needed for patients receiving botulinum toxin rather than best supportive care
- the retreatment interval might be six months rather than the projected nine months
- the referral rate to specialists might be greater than the projected 25%
- the key randomised trials (Study 515 and 516) handled missing data by using the last observation carried forward (LOCF) approach, which can introduce bias and frequently gives rise to confidence intervals that are narrower than is justified
- it is not clear whether the increased rate of urinary tract infections, urine retention and catheterisation with botulinum toxin is caused by the injection procedure or by patient self-catheterisation
- the SF-36 and EQ5D instruments were used in the key randomised trials and their results could be used to produce utility weights using accepted scoring algorithms
- the IQOL instrument used to produce utility weights is not directly suitable for this purpose.

MSAC advice to the Minister

After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness of the injection of botulinum toxin in the treatment of urinary incontinence related to neurogenic detrusor overactivity, MSAC deferred the application until its responses to PBAC's requests, its other advice, and further information from the applicant, are considered by PBAC. If PBAC refers more matters to MSAC for advice, or the applicant has reason to disagree with the advice given above, MSAC will support an expedited process for reconsideration. If PBAC subsequently decides to recommend to the Minister that botulinum toxin be listed on the PBS for the treatment of urinary incontinence related to neurogenic detrusor overactivity, MSAC will support an expedited process for reconsideration, to align MSAC support for public funding of the injection of botulinum toxin according to the circumstances recommended by PBAC. The purpose of this reconsideration would be to align the proposed MBS item descriptor with the proposed PBS restriction; consider the exclusion of other items to be billed to the patient on the same occasion of service; and consider changes in the estimates of costs to the MBS. MSAC also advised the Minister that the current MBS item 36581 should be rewritten to exclude its use for injecting botulinum toxin at a time considered reasonable.