



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

Application 1168: Injection Of Botulinum Toxin In Refractory Migraine

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 refractory migraine in July 2012. PBAC decided not to recommend the requested listing and referred questions to MSAC for advice to be included in any 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 considered any other matters which were relevant.

Responses to PBAC requests for MSAC advice

MSAC advised that it would support \$124.85 as the MBS fee for injecting botulinum toxin in refractory migraine, with reference to the 1 November 2012 MBS fees for MBS items 18350, 18351, 18372 and 18373 as benchmarks. 18350 and 18351 are to inject botulinum toxin for hemifacial spasm; 18350 is for the Botox[®] brand which has the majority of the botulinum toxin market for this indication. 18372 and 18373 are to inject botulinum toxin for bilateral blepharospasm; 18372 is for the Botox[®] brand which has the majority of the botulinum toxin market for this indication.

MSAC advised that the consultation item(s) likely to be required to assess and reassess each patient would be MBS item 110 (noting that neurologists, who are nominated to inject botulinum toxin for migraine, are consultant physicians) for an initial assessment if referred for this purpose, and MBS item 116 for an initial assessment for this purpose (if part of the ongoing management by the neurologist, 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 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 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 by neurologists for injecting botulinum toxin (Botox[®] brand) for the benchmark indications of hemifacial spasm (18350) and bilateral blepharospasm (18372), weighted by the total number of services rendered for these two items. For the two consultant physician items (110 and 116), the average fee charged was calculated for the neurology specialty only (for greater accuracy).

MSAC further advised that, in the context of proposed MBS items to inject proposed PBS listings of botulinum toxin, 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 (outside the hospital setting).

MSAC advised against including any consequences for the Extended Medicare Safety Net (EMSN) in the economic evaluation or the financial analysis. In support of this advice, MSAC first noted that the consultant physician and GP items identified already (110, 116, 23, and 36) have an EMSN cap, and second, foreshadowed its intention to advise that a cap should apply to the proposed MBS item for the purposes of the EMSN. Specifically, in the event of a PBAC recommendation to list botulinum toxin for refractory migraine, MSAC would revisit this matter and advise the Minister on the amount of an EMSN cap for the corresponding MBS item to inject the botulinum toxin. In this context, MSAC accepted ESC advice that the cost of the (per injection) out-of-pocket payment should be multiplied by four to give an annual estimate. MSAC requested that the bulk billing rate and the weighted average fee charged for patient-billed items 18350 and 18372 be obtained for the most recent financial year as the basis for reconsidering the EMSN consequences at that time. MSAC further noted that the current MBS items to inject botulinum toxin are the subject of a review, which may also provide relevant information.

Item number	Proposed item
Brief description	Inject botulinum toxin for migraine
Fee	\$124.85
Government pays (rebate)	\$106.15 (85%)
Patient pays (OOP)	\$4.61
Total (average fee charged)*	\$110.76

* The average fee charged is less than the MBS fee because of the high rate of bulk billing. The amount charged for a bulk-billed service is the MBS rebate, not the MBS fee.

Item number	110	116	23	36
Brief description	Initial consultant physician attendance	Subsequent consultant physician attendance	GP attendance < 20 minutes	GP attendance > 20 minutes
Fee	\$150.90	\$75.50	\$36.30	\$70.30
Government pays (rebate)	\$128.30 (85%)	\$64.20 (85%)	\$36.30 (100%)	\$70.30 (100%)
Patient pays (OOP)	\$42.57	\$22.38	\$5.04	\$4.67
Total (average fee charged)	\$170.87	\$86.58	\$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 neurologists would be likely to have important consequences for patient safety or for the effectiveness and safety of botulinum toxin in the proposed indication. 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 refractory migraine, it would revisit the wording of the proposed MBS item descriptor. Specifically, the Committee foreshadowed its intention to advise that the definition of eligible patients should be aligned with any PBAC-recommended PBS restriction and to consider excluding the billing of attendance items to assess or reassess the patient on the same occasion of service, especially for subsequent injections (with the proposed fee allowing time for assessing and injecting). In relation to this proposed exclusion, MSAC referred to data indicating that, of the 11,733 services rendered in 2011-12 for the benchmark MBS items 18350, 18351, 18372 and 18373, 64% had a consultant physician attendance co-claimed on the same day, and 25% had a specialist attendance co-claimed on the same day. MSAC requested that a breakdown of these co-claimed services for the most recent financial year be presented to better inform its consideration of possible exclusions at that time. 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. MSAC also considered the possibility of limiting the item to appropriately trained neurologists, but accepted advice that this issue would be appropriately handled as part of any extension of the PBS arrangements for botulinum toxin.

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 refractory migraine, MSAC deferred the application for the requested MBS item to inject botulinum toxin until such time as PBAC makes a decision regarding the corresponding PBS listing of botulinum toxin. In doing so, PBAC will take into account responses to the questions it has posed to MSAC. 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 refractory migraine, 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 possible exclusion of other attendance items to be billed to the patient on the same occasion of service; provide advice on the amount of any cap for the Extended Medicare Safety Net; and consider changes in the estimates of costs to the MBS.