



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1399 – Percutaneous Tibial Nerve Stimulation administered through the Urgent PC Neuromodulation System

Applicant: Endotherapeutics Pty Ltd

Date of MSAC consideration: MSAC 70th Meeting, 27 July 2017

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting two new Medical Benefits Schedule (MBS) items for percutaneous tibial nerve stimulation (PTNS) administered through the Urgent PC Neuromodulation System in patients with idiopathic overactive bladder (IOAB) was received from Endotherapeutics Pty Ltd by the Department of Health.

2. MSAC's advice to the Minister

After considering the evidence presented in relation to safety, clinical effectiveness and cost-effectiveness MSAC supported public funding of PTNS for treatment of IOAB.

In relation to the fees, MSAC advised that the component costs to the overall fee needed further justification. They should comprise a facility component, a component for the PTNS leads, a component for the nursing time to administer the service, and a component for supervision of the nurse.

MSAC advised that a specialist should be involved in determining the suitability of the patient for this service, both initially and subsequently for continuation to tapering and maintenance after the initial 12-week course of therapy. To achieve the intended separation of this role from the delivery of the service itself, the specialist should bill for these determinations through a standard MBS consultation item (eg 104 or 105).

3. Summary of consideration and rationale for MSAC's advice

In November 2016 MSAC deferred its advice for MBS listing of PTNS for treatment of IOAB. As noted in the public summary document for [Application 1399](#), at that time MSAC requested the following:

- economic modelling of PTNS compared with sacral nerve stimulation (SNS) over 3 years;
- clarification/justification of the roles for nurses, GPs, patients and specialists;
- clarification of the frequency and duration of treatment;
- a cost breakdown and international comparison of the pricing for the service; and

- justification for rates of uptake and substitution of other treatments.

MSAC recalled that IOAB can have a marked adverse effect on quality of life and can be difficult to treat with established interventions. MSAC recalled it had noted that PTNS appears to be an effective treatment relative to best supportive care in patients unsuitable for other available first and second line management or for whom other treatments are not effective. MSAC has also previously acknowledged that PTNS appears to be comparatively safe and well tolerated, with adverse events generally mild and transient in nature.

MSAC advised that the requirement for patient cooperation with the protocol does not need to be included in the item descriptor.

At its November 2016 meeting, MSAC had requested clarification of the proposed frequency and duration of treatment. In its reconsideration, MSAC noted that the initial protocol consists of twelve 30 minute PTNS sessions delivered weekly, after which response is assessed and patients with adequate response move into a 3 month tapering period. MSAC noted that no tapering regimen was provided, but suggested that this could be roughly five treatments over 12 weeks. MSAC noted that the applicant indicated that, after this time, monthly maintenance treatment is effectively lifelong.

At its November 2016 meeting, MSAC had requested justification of the proposed ongoing requirement for a specialist beyond confirming the initial diagnosis and suitability for PTNS treatment. In its reconsideration, MSAC noted that the applicant had indicated that specialist urologists/urogynaecologists should be responsible for administering the initial treatment protocol of 12 weeks PTNS therapy in order to review the patient's response to treatment. The applicant noted that this would be assessed by the specialist based on the patient's urinary (voiding) diary. The applicant proposed that, where patients have demonstrated a response to treatment, and wish to continue beyond the initial 12 weeks, this may be administered by a GP or trained practice nurse under supervision. MSAC noted that, under United States guidelines, the specialist must be in the clinic and attend sessions 1, 6 and 12 during the initial treatment period. MSAC considered that this approach to supervision appeared reasonable. MSAC advised that the appropriate place for PTNS is in an ambulatory primary care setting, with intermittent specialist attendance funded separately from the delivery of PTNS.

MSAC noted that the incremental cost effectiveness ratio (ICER) for PTNS was high compared to the comparators of SNS and botulinum toxin type A (Botox) therapy. The economic evaluation of PTNS compared with best supportive care resulted in an ICER of \$52,748 per QALY, compared with \$16,522 per QALY for SNS and \$7,225 per QALY for botulinum toxin type A therapy. MSAC noted that economic modelling of PTNS compared with SNS indicated that PTNS was less effective over 3 years, with cost savings of \$30,685 per QALY forgone. MSAC agreed with ESC that the cost-effectiveness of PTNS compared with SNS was not consistent in the international literature and this may be due to differences in the relative costs of the treatment in different countries. MSAC noted that there was no high quality head-to-head comparison of PTNS and SNS to inform the economic evaluation.

MSAC considered that reducing the cost of PTNS as proposed by the applicant would impact the ICERs for these comparisons. MSAC noted that the resubmission and the applicant's pre-MSAC response provided additional details regarding the cost breakdown. MSAC noted the applicant's pre-MSAC response conceded that the cost for delivery of the service should be reduced and the \$80 for unspecified/unknown additional costs should be removed, bringing the costs to \$357 for each initial treatment and \$270 for each maintenance treatment. MSAC advised that the proposed cost for PTNS was still overstated. MSAC made the following comments regarding the fee for the two proposed MBS items for PTNS:

- the inputs to setting each MBS fee should include components for the clinical staff, facility fee (\$50) and PTNS leads, with reference to relevant MBS and international benchmarks for costing each of these inputs;
- co-claiming with consultation items (MBS items 104 and 105) should not be allowed (other than at 1, 6 and 12 weeks, as above);
- likely patient out-of-pocket costs may be informed by the predicted versus actual analysis of MBS item 18379 for intravesical injection of botulinum toxin type A into the bladder wall for IOAB, for which the average fee charged was ~\$400–450;
- MSAC was wary of a payment model where therapy is delivered by nurses, but doctors attract a fee beyond appropriate supervision; and
- overall, MSAC considered that a fee in the range of \$120 to \$200 would likely be at the upper limit of what was supportable as the service is likely to be provided by supervised trained nurses, require less than 45 minutes overall, and the cost of the leads varies internationally.

MSAC noted the applicant's comments regarding the rates of uptake and substitution of other treatments. MSAC considered that the number of patients who would access the service and continue to use it indefinitely is uncertain. MSAC acknowledged that uptake is likely to be limited by the availability of trained specialists and available PTNS neurostimulation systems in Australia and that uptake of botulinum toxin type A and SNS has been relatively small. MSAC noted that uptake of the service should be reviewed after listing as the treatment is easy to administer and the prevalent population is large. The likelihood of the claimed cost offsets being realised is also likely to be small as PTNS is more likely to displace botulinum toxin type A and SNS to a later line of treatment than replace to them.

MSAC supported MBS listing of PTNS in an ambulatory primary care setting with limited intermittent specialist attendance, but noted that the Department may need to revise the appropriate fee for the service.

4. Background

Application 1399 was considered at the November 2016 MSAC meeting. MSAC deferred its advice for public funding of this service due to the need for additional information regarding the proposed item descriptor, costing and implementation of the service and considered that there was a need to substantially decrease the proposed fee.

MSAC requested the following information before it could finalise its advice:

- Justification of the proposed ongoing requirement for a specialist beyond confirming the initial diagnosis, with consideration of potential roles, with training, for general practitioners, incontinence nurses or patient self-administration.
- Clarification of the proposed frequency of treatment, particularly as the frequencies used in the trials appear to be at the upper limits, and the overall duration of treatment compared with other therapies.
- A more detailed cost breakdown and rationale for the proposed MBS fee, with further comparison to international prices, and inclusion of sensitivity analyses by the amount of the proposed fee, out-of-pocket payments and costs to other funding programs.
- Present economic modelling with comparison to SNS over a three-year time horizon (time to battery replacement).
- Present justification for the rates and extents of uptake and substitution for other later-line treatments in the financial analyses.

See MSAC Public Summary Document Application 1399, November 2016.

5. Proposal for public funding

The applicant’s proposed MBS item descriptors and fees for PTNS are shown in **Error! Reference source not found.** and To ensure that points (c) and (d) of the item descriptor are clear, the applicant in its pre-MSAC response suggested they be reworded to replace “otherwise not suitable” with the phrase “or not suitable candidates for...”. The applicant believes that specialists currently treating IOAB (urologists, gynaecologists and urogynaecologists) are best placed to determine which treatment a patient should receive given their expertise and an assessment of the patients medical history, diagnosis and current physical state.

Table 2.

Table 1: The applicant’s proposed MBS item descriptor and fee for PTNS initial treatment protocol

Category 3 – Therapeutic Procedures
<p>MBS [item number]</p> <p>Percutaneous Tibial Nerve Stimulation, neuromodulation initial treatment protocol, for the treatment of overactive bladder if:</p> <p>(a) the patient has been diagnosed with idiopathic overactive bladder, and</p> <p>(b) the patient has been refractory to, or contraindicated/not suitable for, conservative treatments including anti-cholinergic agents, and</p> <p>(c) the patient is contraindicated or otherwise not suitable for botulinum toxin type A therapy, and</p> <p>(d) the patient is contraindicated or otherwise not suitable for sacral nerve stimulation, and</p> <p>(e) the patient is willing and able to comply with the protocol.</p> <p>For each patient — applicable not more than once except if the patient achieves at least a 50% reduction in overactive bladder symptoms from baseline at any time during the treatment period.</p> <p>A session should last for a minimum of 45 minutes, of which neurostimulation should last for 30 minutes per session. These sessions are intended to be delivered one per week, for 12 weeks. Claims for this item may not exceed 12 sessions in a calendar year.</p> <p>Fee: \$425</p>

To ensure that points (c) and (d) of the item descriptor are clear, the applicant in its pre-MSAC response suggested they be reworded to replace “otherwise not suitable” with the phrase “or not suitable candidates for...”. The applicant believes that specialists currently treating IOAB (urologists, gynaecologists and urogynaecologists) are best placed to determine which treatment a patient should receive given their expertise and an assessment of the patients medical history, diagnosis and current physical state.

Table 2: The applicant’s proposed MBS item descriptor and fee for PTNS (tapering and maintenance treatment)

Category 3 – Therapeutic Procedures
<p>MBS [item number]</p> <p>Percutaneous Tibial Nerve Stimulation, neuromodulation tapering and maintenance treatment, for the treatment of overactive bladder if:</p> <p>(a) The patient responded to neurostimulation initial treatment protocol and achieved at least a 50% reduction in overactive bladder symptoms.</p> <p>A session should last for a minimum of 45 minutes, of which neurostimulation should last for 30 minutes per session. The interval between sessions should be adjusted with the aim of sustaining therapeutic benefit and no more than XX sessions in a XX month period.</p>

Category 3 – Therapeutic Procedures

Fee: \$425

In order to offer PTNS, the application advised that a physician must be adequately qualified to first diagnose IOAB and be capable of prescribing anticholinergic agents to treat the condition. The physician must be a specialist in the field of urology, continence and/or gynaecology.

In its pre-MSAC response, the applicant agreed that a specialist is required for initial consultation and that specialist urologists or urogynaecologists should be responsible for administering the initial treatment protocol of 12 weeks of PTNS therapy. The applicant considered that it is important for a specialist to make the determination on whether a patient has produced a satisfactory response to treatment, or alternatively make the decision to cease PTNS therapy in instances where the treatment is not producing the expected results. Where patients receiving PTNS treatment have demonstrated a response to therapy and wish to continue, it is appropriate for maintenance therapy to be administered by a trained practice nurse acting under supervision.

The applicant proposed fee was \$425 for each item. MSAC considered the applicant's proposed fee of \$425 per procedure should be substantially reduced, as it seemed high relative to the complexity and amount of time associated with the procedure.

MSAC noted that analysis of international prices suggested that the MBS fee proposed by the applicant of \$425 for PTNS per procedure is high compared to an average in the international literature of approximately \$254. However, it is possible that international prices include different components (noting that the applicant's proposed fee includes the costs of PTNS leads – see Table 3). MSAC also acknowledged that exchange rate movements over the course of the last year or so have altered price comparisons since the application, which considered international prices in setting a proposed fee.

The applicant indicated that the range of costs for PTNS procedures was between \$400 and \$462 per procedure. The breakdown of the applicant's estimated costs is shown in Table 3. Around half of the costs for PTNS identified by the applicant were attributed to the cost of clinical staff and the use of a consulting room. Over a quarter of the suggested MBS rate reflected the cost of the disposable PTNS leads (\$120 per treatment). The source of the remaining costs (\$80) was not specified and so was unknown.

Table 3: Breakdown in the applicant's PTNS cost

	Low Estimate	High estimate
	\$ per PTNS procedure	\$ per PTNS procedure
Cost to clinical staff	150	187
Cost of consulting room	50	75
PTNS lead	120	120
Unknown	80	80
Total cost	400	462

Source: Applicant's submission

In its pre-MSAC response, the applicant noted that, since the initial submission, the exchange rate has varied significantly and propose that the AU\$80.00 be excluded from the proposed

fee in light of this. For the initial treatment protocol, the applicant revised proposed fee was AU\$357.00. This is an approximate 20% reduction in the cost of administering PTNS therapy. For the tapering and maintenance treatment, the applicant revised proposed fee was AU\$270.00. This reduction represents an approximate 40% reduction in the ongoing cost of PTNS maintenance therapy.

6. Proposed intervention's place in clinical management

At its November 2016 meeting, MSAC acknowledged the clinical need for PTNS therapy. However, MSAC considered that the place of PTNS in the clinical pathway was uncertain as it could be considered as a replacement for botulinum toxin type A and SNS in second line therapy or as third line therapy after these treatments have been ruled out as options for the patient.

In its pre-MSAC response, the applicant stated that PTNS is most appropriately considered as a second line therapy intended for patients who are either refractory to or have failed first line conservative therapy, and benefits patients who are not suitable for SNS or botulinum toxin type A. PTNS is not intended to be used in conjunction with SNS or botulinum toxin type A.

7. Comparator

The evaluation for the original application suggested that, relative to the comparator (best supportive care); PTNS has minimally inferior safety and superior effectiveness. The initial economic assessment compared the three second line therapies (PTNS, SNS and botulinum toxin type A therapy) to best supportive care. This allowed the cost effectiveness comparison between PTNS and the MBS listed second line treatments to be conducted.

For the revised application, the comparator was SNS, noting that the applicant suggested that PTNS and SNS were not expected to be close substitutes.

8. Comparative safety

At its November 2016 meeting, MSAC acknowledged that PTNS appears to be well tolerated, with adverse events generally mild and transient in nature.

9. Comparative effectiveness

At its November 2016 meeting, MSAC acknowledged that PTNS appears to be effective in reduction of IOAB symptoms and improvement in patient quality of life compared with best supportive care. MSAC noted that, based on an indirect comparison, PTNS appears to be more effective in reduction of IOAB symptoms compared with botulinum toxin type A. It was not possible to conduct an indirect comparison between PTNS and SNS because the comparative evidence for SNS was limited to a single trial comparing botulinum toxin type A with SNS, available only in abstract form.

In its pre-MSAC response, the applicant stated that the first period of treatment is the initial protocol which consists of 12 PTNS sessions delivered at a treatment interval of one week. Following the initial treatment protocol, patients who have responded to PTNS, producing a > 50% reduction in IOAB symptom presentation as measured by a voiding diary, move into the tapering period. The tapering period is recommended to take three months, during which the interval between PTNS sessions is gradually increased out to one month. Once the tapering period is completed, the patient begins maintenance therapy whereby the patient receives PTNS treatment sessions at one month intervals.

The applicant stated that PTNS should be considered a life-long treatment, in the same way that SNS and botulinum toxin type A could be considered life-long treatments for IOAB as the patient requires ongoing intervention. IOAB is a chronic condition without cure; patients with IOAB will suffer from IOAB symptoms (if untreated) for their entire life. SNS and botulinum toxin type A injections require ongoing invasive surgical procedures for the life of the patient. Similarly, PTNS also requires follow-up sessions in the maintenance therapy phase of treatment.

10. Economic evaluation

The analysis below supplements the economic evaluation results provided to the November 2016 MSAC meeting. The following supplement to the economic evaluation compares the cost effectiveness of PTNS to SNS over a three-year period (time to battery replacement).

Table 4: Summary of economic evaluation

Assumption	Description
Perspective	<p>We have taken into account the resource costs related to the treatment pathway. This includes the costs faced by the patient (hospital fees) and government (via the MBS and PBS).</p> <p>Utility is measured for the individual receiving treatment.</p> <p>We do not account for other economic benefits such as increased labour force productivity or carer costs associated with each treatment pathway.</p> <p>We assume that the treatment does not extend life.</p>
Comparator	The comparator is SNS, noting that consultation with the applicant has suggested that PTNS and SNS are not expected to be close substitutes.
Type of economic evaluation	<p>A cost-utility analysis has been conducted to assess the cost effectiveness of PTNS. MSAC guidelines indicate that this is the preferred methodology for preparing therapeutic assessment reports.</p> <p>Cost-utility analysis measures the health outcomes as the incremental change in quality adjusted life years (QALYs), which is the difference in QALYs between the proposed and comparator treatment pathways. The incremental change in health outcomes is compared to the incremental change in resource costs (difference between costs for the proposed and comparator treatment pathway).</p> <p>Cost-effectiveness of the proposed treatment pathway is assessed as the cost per additional QALYs.</p>
Sources of evidence	The evidence which informed the cost-utility analysis is as per that set out in the original application.
Time horizon	<p>The cost-utility analysis is assessed over 3 years. This was chosen to reflect the expected battery life of the neurostimulator used for SNS. The stimulator battery must be replaced every 3 to 7 years depending on the signal strength required to control symptoms.</p> <p>Because of the relatively high initial cost of PTNS treatment, shortening the evaluation period will generally reduce the cost effectiveness of PTNS.</p>
Outcomes	QALYs are used to measure the outcome of difference.
Methods used to generate results	<p>We have used a Markov models to model patients undergoing PTNS. Separate transition matrices are developed for males and females, as well as age groups (age groups considered are 0-24, 25-34, 35-44, 45-54,55-64,65-74, 75-84 and 85+).</p> <p>200 people with IOAB symptoms (100 females and 100 males) enter the model once in the first modelled year. The age distribution of this population is based on the IOAB prevalence by age and sex. The same population is modelled for PTNS and SNS.</p> <p>Following initial therapy, patients who do not experience an improvement in symptoms cease treatment. In subsequent years, the cohort of patients continuing treatment is modelled using a three state Markov model. The states are:</p> <p>Continue PTNS treatment - patients who continue PTNS may in the future transition to any three of the states.</p> <p>Cease PTNS treatment – patients who cease PTNS can only transition to being deceased</p> <p>Deceased – patients who die permanently leave the model</p> <p>The model is estimated at the yearly frequency. Cost and utility estimates are both based on results from the model.</p>
Health states	The model has two health states: (i) IOAB with symptoms

Assumption	Description
	(ii) IOAB with relief of symptoms The model does not account for disease severity, due to a lack of disaggregated data in the literature.
Discount rate	5 per cent real discount rate for costs and outcomes, consistent with the MSAC guidelines.
Escalation	Costs are estimated in real 2015-16 terms, with no real escalation assumed for treatment costs. This assumes that in the long run, health care costs increase in line with expected inflation of 2.5 per cent.
Software packages used	Microsoft Excel 2010

Results of the economic evaluation

The economic evaluation compared the expected uptake of PTNS relative to SNS. This analysis was conducted based on an assumed population of 200 (100 females and 100 males) who enter the model once in the first year, with the age distribution of patients based on IOAB prevalence across age groups. The change in health costs associated with the respective uptake patterns is shown in table 5, which is expressed in undiscounted and present value terms over the 3-year evaluation period.

PTNS was estimated to be lower cost than the comparator, SNS. For the assumed population of 200, PTNS costs were around \$1 million lower than the SNS costs measured over 3 years. The analyst considered that this was likely to overstate the cost saving as 3 years is the lower bound of the time to battery replacement for sacral nerve stimulators – if the battery for the stimulator lasts longer than 3 years, the relative cost advantage of PTNS would be smaller. The lower costs also reflected differences in treatment outcomes. Fewer patients remained in PTNS treatment compared to SNS, which results in lower costs as more patients transition to lower cost best supportive care (incontinence aids and medication).

Table 5: PTNS cost impacts over 3 years

Type of resource cost	Undiscounted	Present value, 5 per cent discount rate
	\$mn	\$mn
PTNS initial treatment, taper and remainder of first year (success)	1.487	1.417
PTNS initial treatment (failure)	0.222	0.212
PTNS maintenance therapy	0.783	0.695
Incontinence aids	0.203	0.183
Medication	0.184	0.166
Complications from best supportive care	0.008	0.007
Total PTNS costs	2.887	2.680
Total SNS costs	3.933	3.690
Total PTNS costs incremental to SNS costs	-1.046	-1.010

In its pre-MSAC response, that applicant stated that the estimated uptake rate of PTNS therapy by IOAB patients would be significantly lower than the lower bound figure. This was because the uptake of PTNS therapy would be limited by the availability of trained specialists and available PTNS neurostimulation systems in Australia to administer the treatment.

Health outcomes

The model used to estimate the health outcomes of treatment indicated that PTNS treatment results in incrementally poorer health outcomes compared to SNS. PTNS was a less effective second line treatment for IOAB compared to SNS. Treatment with PTNS for the 200 patients over 3 years resulted in 377 QALYs (present value, 5 per cent discount rate), while SNS resulted in 409 QALYs. This result was principally due to a greater proportion of patients

discontinuing PTNS, as treatment must be repeated every month in order to maintain the treatment effect.

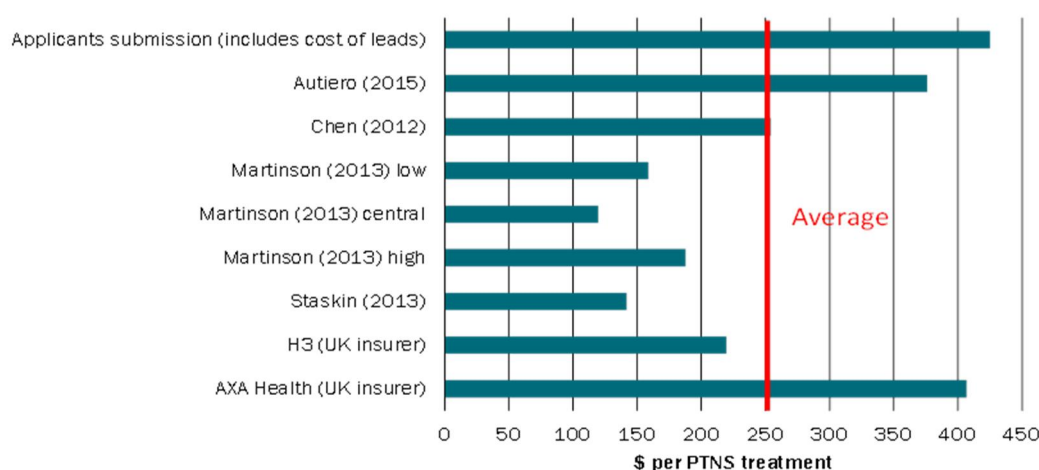
In this context, where PTNS is lower cost but less effective than the comparator, the ICER should be interpreted as a cost saving of \$30 685 for each QALY foregone.

Further, the applicant indicated that PTNS would almost entirely be used to treat patients who are contraindicated or refractory to SNS and botulinum toxin type A therapy (another second line treatment). The applicant suggested that comparing PTNS to SNS would not necessarily reflect the trade off in IOAB treatment as PTNS would be expected to provide patients with greater choice and allow more IOAB patients to receive second line treatment.

11. Financial/budgetary impacts

There was significant uncertainty around the costs for PTNS. The prices shown in Table 6 have been converted to Australian dollars and inflated to current Australian dollars.

Table 6: PTNS procedure cost, Australian dollars, December 2016



Data source: Applicant's submission, Autiero (2015), Chen (2012), Martinson (2013), Staskin (2013), H3 schedule of procedures < <http://www.h3insurance.com/wp-content/uploads/2015/08/H3-Insurance-Schedule-of-Procedures-201410.pdf>> and AXA Health schedule of procedures < <https://online.axapphealthcare.co.uk/SpecialistForms/SpecialistCode.mvc/Print?source=contracted>>

Assuming lower PTNS MBS item costs, of \$100, \$200 and \$300, resulted in significantly lower PTNS treatment costs.

Table 7: Cost sensitivity analysis, present value

Description	PTNS Costs	
	\$m	% change from central case
Central case	2.680	0%
PTNS MBS treatment fee of \$100	0.903	-66%
PTNS MBS treatment fee of \$200	1.450	-46%
PTNS MBS treatment fee of \$300	1.997	-25%
30% higher PTNS treatment path costs	3.484	30%
30% lower PTNS treatment path costs	1.876	-30%

Source: CIE.

12. Key issues from ESC for MSAC

ESC noted that the supplement to the contracted assessment report requested listing of a generic service and so was not specific to the applicant's device, and that Medtronic (which sponsors another PTNS device) had also provided commentary on the application.

ESC noted that PTNS is a reasonable treatment option due to its minimal invasiveness and should not necessarily be considered as a last resort therapy. Its place in the clinical pathway is uncertain, but could be considered as a replacement for botulinum toxin type A therapy and SNS as an initial second line therapy or after botulinum toxin type A and SNS have been ruled out as treatment options.

ESC noted that it was previously acknowledged that PTNS therapy has acceptable safety and clinical effectiveness in the proposed population.

ESC noted that the provision of the service by GPs and nurses rather than specialists had implications for the requested fee which should be reduced to reflect the likely use of the service. ESC noted that the estimated cost for specialist attendance was \$150 per session, whereas this would be around \$37 per session for an incontinence nurse. ESC acknowledged that, given the time required for each session (~45 minutes), having the physical infrastructure to provide these services may be a limitation for some practices.

ESC noted the analysis of the proposed fee conducted by the contracted assessors, which indicates that the MBS fee suggested by the applicant of \$425 is high compared with the average international price of around \$254 per PTNS session and that the proposed pricing includes the cost of the PTNS leads (electrodes). It was noted that there was a lack of clarity around what components were included in the reported international costs; however there was no evidence to suggest that these costs did not include the leads.

ESC noted that no additional details regarding the breakdown of the costs of the requested service were provided by the applicant to address the third of MSAC's November 2016 requests. There was still remaining concerns that patients may incur out of pocket costs for the PTNS leads. It was noted that in the cost breakdown the source of the "unknown" remaining costs (\$80) was still not specified.

ESC noted the following:

- economic modelling with comparison to SNS over a three-year time horizon as requested by MSAC was provided in the supplement to the contracted assessment.
- that this modelling suggested that PTNS was less effective than SNS over three years, with cost savings of \$30,685 per quality adjusted life year (QALY) forgone.
- that the cost-effectiveness of PTNS compared with SNS was not consistent in the international literature, with some finding that PTNS is more effective and less costly than SNS over two years (Martinson M et al 2013) while others found that PTNS was less effective and more costly than SNS over five years (Auterio SW et al 2015).
- that there was no further justification provided for the rates and extents of uptake and substitution for later line treatments.
- that the total IOAB population is very large and, though many do not seek treatment, a non-invasive alternative may increase demand for second line treatment.
- that for some patients PTNS may be an additional treatment rather than substituting for botulinum toxin type A therapy or SNS.

ESC considered:

- that the shorter time frame favours PTNS due to higher upfront costs for SNS, as do high costs for SNS in Australia (which may have included some double counting in the modelling).

- that cost savings for PTNS may be over stated if SNS battery life is greater than three years and if the costs of SNS in Australia are overestimated in the modelling.

ESC advised that the wording in the proposed item descriptor should be amended in order to clearly specify the line of therapy intended for PTNS and that the wording was particularly unclear for points (c) and (d) where “otherwise not suitable” is open to interpretation.

ESC also noted:

- that it was unclear how the 50% reduction in IOAB symptoms in the item descriptor would be assessed in clinical practice.
- that no additional information was provided by the applicant regarding the appropriate frequency and duration of treatment.
- that there was a consensus that a specialist is required for initial consultation.

ESC considered that GPs trained in the use of PTNS should be able to deliver the service personally or oversee a trained nurse in order to improve access for patients and therefore maximise compliance. ESC also acknowledged the applicant’s comment in the response to the Medtronic Australia letter that specialists should still be able to offer the service themselves if desired. ESC advised that the options for who provides the service should be made explicit in the item descriptor. Dropping the restriction to specialists would widen access to the technology, and thus likely increase uptake rates and the numbers of patients treated.

ESC noted that, with adequate training, self-administration of PTNS or administration by a carer may be appropriate. This would impact on the suitability of an MBS listing and other funding arrangements may need to be considered for the device and its consumables.

From a consumer perspective, ESC noted there are advantages for PTNS as a non-invasive, alternative treatment for IOAB, but that convenience and patient costs are also factors to consider.

ESC noted that overall the revised contracted assessment report did little to address the issues raised by MSAC as set out in the PSD for [MSAC Application 1399](#). ESC noted that some of the requested information could be provided in the supplement to the contracted assessment, however other issues could not be addressed in this way and require engagement and further responses directly from the applicant. ESC suggested that the applicant address the following remaining areas for MSAC consideration:

- Provide a revised item descriptor reflecting the suitable line of treatment and appropriate frequency and duration of use.
- Clarify who would best render the service (specialist, GP, practice nurse, self-administration) and how it might best transition from one provider to another.
- The proposed fee needs to be commensurate with the provider and what needs to be done by the provider of the service including the level of supervision required. Unknown costs in the proposed fee should be specified to clarify what is driving the cost (for example, separate out time and expertise required for provision and/or supervision of the service from consumables, and fixed costs such as provision of a room).
- Advise as to the appropriate frequency of use, in particular during the tapering period.
- Advise as to the appropriate duration of use.

ESC KEY ISSUES	ESC ADVICE
Item descriptor	The applicant's suggested item descriptor included a proprietary request regarding the machine used to deliver the treatment due to 'safety purposes'. This is inappropriate.
Item descriptor	Clarification of the proposed frequency of treatment, particularly as the frequencies used in the trials appear to be at the upper limits, and the overall duration of treatment compared with other therapies.
Clinical algorithm	PTNS is a reasonable treatment option due to its minimal invasiveness and should not necessarily be considered as a last resort therapy. Its place in the clinical pathway is uncertain, but could be considered as a replacement for botulinum toxin type A and SNS as an initial second line therapy or after botulinum toxin type A and SNS have been ruled out as treatment options.
Implementation	Concern over the need for a specialist to deliver the therapy which would affect patient accessibility. Once a diagnosis is made by specialist, a GP should be able to perform the therapy personally or oversee a trained nurse – applicant agrees – should be explicit in the item descriptor.

13. Other significant factors

Nil

14. Applicant's comments on MSAC's Public Summary Document

The applicant had no comment.

15. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)