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# Final Decision Analytic Protocol (DAP) to guide the assessment of intra-abdominal vagal nerve modulation for the management of obesity

February 2013

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## MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Minister for Health and Ageing (the Minister) to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Minister on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

### Purpose of this document

This document is intended to provide a draft decision analytic protocol that will be used to guide the assessment of an intervention for a particular population of patients. The final protocol was developed after consideration of relevant stakeholder input to earlier drafts of the protocol. The final protocol provides the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the question for public funding the assessment is intended to answer:

**P**atients – specification of the characteristics of the patients in whom the intervention is to be considered for use

**I**ntervention – specification of the proposed intervention and how it is delivered

**C**omparator – specification of the therapy most likely to be replaced by the proposed intervention

**O**utcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention

## Purpose of application

A proposal for an application requesting Medicare Benefits Schedule (MBS) listing of surgical procedures for implanting and removing an implantable medical device that modulates the activity of the vagal nerve, which is used in the management of obesity, was received from Device Technologies Australia Pty Ltd by the Department of Health and Ageing in March 2012. The proposal relates to an intervention that is not currently reimbursed under the MBS.

The Deakin Health Economics Unit at Deakin University, under its contract with the Department of Health and Ageing, has developed this decision analytical protocol to guide the preparation of an assessment of the safety, effectiveness and cost-effectiveness of intra-abdominal vagal nerve modulation when used in the management of obesity to inform MSAC's decision-making regarding public funding of the intervention.

## Background

### Current arrangements for public reimbursement

Intra-abdominal vagal nerve modulation therapy is currently not publicly funded.

### Regulatory status

Current approvals by the Australian Register of Therapeutic Goods (ARTG) for devices that are used in intra-abdominal vagal nerve modulation therapy are summarised in Table 1.

**Table 1: Australian Register of Therapeutic Goods listings of devices used in intra-abdominal vagal nerve modulation therapy**

| ARTG Number | Class* | GMDN Name | Unique Product Identifier | Intended purpose |
|---|---|---|---|---|
| 192882 | AIMD | Gastric contractility modulation system | EnteroMedics Maestro Implant Kit | The neuroregulator and leads are intended to be used as part of the Maestro Rechargeable System to generate and deliver vagal blocking (VBLOC) therapy to the vagal nerve for weight reduction in obese patients. |
| 192883 | AIMD | Gastric contractility modulation system pulse generator | EnteroMedics Maestro Rechargeable Neuroregulator | The subcutaneously implanted rechargeable neuroregulator is intended to be used as part of the Maestro Rechargeable System to generate vagal blocking (VBLOC) therapy for weight reduction in obese patients. |
| 193393 | III | Electrode/lead, stimulator, implantable, vagus nerve | EnteroMedics Maestro Anterior Lead | The implanted lead is intended to be used as part of the Maestro Rechargeable System to deliver vagal blocking (VBLOC) therapy to the anterior trunk of the vagal nerve for weight reduction in obese patients. |
| 193394 | III | Electrode/lead, stimulator, implantable, vagus nerve | EnteroMedics Maestro Posterior Lead | The implanted lead is intended to be used as part of the Maestro Rechargeable System to deliver vagal blocking (VBLOC) therapy to the posterior trunk of the vagal nerve for weight reduction in obese patients |
| 193373 | III | Active-implantable-device communicator | EnteroMedics Maestro Mobile Charger | The external device is intended to be used as part of the Maestro Rechargeable System to provide the power necessary to recharge the neuroregulator battery and provide a communications path between the clinician programmer and neuroregulator. |
| 194020 | III | Active-implantable-device communicator | EnteroMedics Maestro Patient Transmit Coil | The external transmit coil is intended to be used as part of the Maestro Rechargeable System during recharging and to provide a communications path between the clinician programmer and neuroregulator. |
| 194021 | III | Active-implantable-device communicator | EnteroMedics Maestro Patient Transmit Coil | The external transmit coil is intended to be used as part of the Maestro Rechargeable System during recharging and to provide a communications path between the clinician programmer and neuroregulator. |
| 193395 | III | Active-implantable-device communicator | EnteroMedics Maestro Clinician Transmit Coil | The external transmit coil is intended to be used in the operating room as part of the Maestro Rechargeable System to provide a communications path between the clinician programmer and neuroregulator. |
| 193392 | III | Programmer, implantable stimulator, vagus nerve | EnteroMedics Maestro Clinician Programmer Kit | The programmer and cable are intended to be used as part of the Maestro Rechargeable System to configure, monitor and change settings of the implanted neuroregulator. |
| 193391 | III | Active-implantable-device communicator | EnteroMedics Maestro Patient Kit | The external devices are intended to be used as part of the Maestro Rechargeable System to provide the power necessary to recharge the neuroregulator battery and provide a communications path between the clinician programmer and neuroregulator. |
| 193038 | I | Cable, <specify> | N/A | Cable to connect a Clinical Programmer (laptop) with the Mobile Charger. |
| 193040 | I | Battery charger | N/A | A device which connects to a power outlet and an AC recharger port on a mobile charger in order to charge a battery, restoring the battery to an appropriate working condition |
| 195224 | I | Holder, <specify> | N/A | A belt used to stabilize the position of a transmit coil during the recharging or communication with the implanted device. |

ABBREVIATIONS: ARTG – Australian Register of Therapeutic Goods; GMDN – Global Medical Device Nomenclature; AIMD – active implantable medical device

* Medical devices are classified in to 5 classes based on the level of risk and the intended purpose of the device: I – low risk; IIa – low-medium risk; IIb – medium-high risk; III – high risk; AIMD – high risk active implantable medical device

## Intervention

### Description

Currently only one system is registered by the Therapeutic Goods Administration for intra-abdominal vagal nerve modulation therapy - the Maestro Rechargeable System™ (the device). This specific system is described as consisting of a neuroregulator and two implantable flexible leads with electrodes. The electrodes are placed laparoscopically, under general anaesthesia, at the anterior and posterior intra-abdominal vagal nerve trunks and connected to the implantable neuroregulator, which is placed subcutaneously on the abdominal wall below the rib margin. The neuroregulator is powered by an internal rechargeable battery. A mobile, external controller that is connected via a small, flexible cable to a cutaneous transmit coil positioned over the implanted device allows the physician to control and upload information from the device. Treatment can be reversed by a physician turning off the neuroregulator or by removal of the device and leads.

MBS listing of the following three surgical procedures is proposed:

(i) subcutaneous placement of an implantable neuroregulator;

(ii) placement of associated leads and electrodes so that they are connected to the vagal nerve; and

(iii) removal of the neuroregulator and electrodes *(note: leads are not specified).*

Billington et al, 2009[1], report that intermittent blocking of the activity of the vagal nerve by means of a neuroregulator may lead to weight loss via several potential mechanisms including: inhibition of gastric accommodation leading to early satiation (fullness); and, inhibition of gastric contractions leading to enhanced satiety (reduced hunger). Intra-abdominal vagal nerve modulation therapy has been investigated and is proposed for use in the management of obesity.

For the review of MBS items for the surgical treatment of obesity (Application 1180r) considered by MSAC in November 2011, obesity was generally defined as a disease in which fat has accumulated to the point where health is impaired, and more specifically, defined as a body mass index (BMI) of over 30 kg/m$^2$ for adults. BMI is an index of weight-for-height that is commonly used to classify overweight and obesity in adults. BMI is calculated as weight in kilograms divided by the square of height in metres. "Clinically severe obesity" is defined as BMI ≥ 40 kg/m$^2$, or between 35 kg/m$^2$ and 40 kg/m$^2$ where there are other major medical conditions such as high blood pressure or diabetes.

Obesity is a multifactorial disease that may have a variety of underlying causes, including physical illness, genetics, behavioural and psychological factors, and lifestyle choices. Obesity is associated

[1] Billington C.J., Kow L., Collins J., Wray N.H., Tweden K.S., Vollmer M.C., Wilson R.R., Yurik T.M., Freston J.W. and Toouli J. Correlations between enhanced satiety and reduced calorie intake during intermittent vagal block (VBLOC Therapy) to treat obesity. *Gastroenterology* 2009;136:5 SUPPL. 1 (A386)

with an increased risk for a number of comorbidities including diabetes, cardiovascular disease, high blood pressure, stroke, high cholesterol, obstructive sleep apnoea, osteoarthritis, and some cancers[2],[3]

### Delivery of the intervention

The implanted part of the device consists of leads with electrodes and a neuroregulator. During a laparoscopic surgical procedure, the surgeon makes three to five incisions to implant the electrodes. Through the incisions, the surgeon places small electrodes around both of the patient's vagal nerve trunks near the bottom of the oesophagus. The surgeon then places the neuroregulator under the skin. The device connectivity is checked by an impedance assessment. The patient requires an overnight stay in hospital due to the use of a general anaesthetic in the vast majority of cases. The requirement for an overnight hospital stay is driven by the need for observation as the reaction to general anaesthesia and laparoscopy is unpredictable because of the patient's potentially increased risk of complications due to co-morbidities, and to monitor the patient's reaction to the implanted device . Patients are given information about intra-abdominal vagal nerve modulation therapy, and its care including programming, interrogation and the need to charge the device each day.

Once implanted, the device remains in the patient. Treatment can be started and stopped by a physician turning on/off the neuroregulator. The strength of the signal can be adjusted to suit the individual patient. The device is programmed (by the physician) to be on for twelve plus hours per day and to be turned off during the night (as there is usually no need to have appetite suppressed during the night).

The initial follow-up of a patient following placement of the device involves:

- a consultation for the programming of the device and initiation of therapy in the 2nd week following placement
- a consultation for adjustment of the amplitude of the signal delivered by the device (according to patient tolerance) in the 4th week following placement. Further adjustments, if necessary, could be made by nurse practitioners (under supervision of a physician).

Beyond the initial follow-up, follow-up is comparable to that given to patients undergoing other forms of bariatric surgery in that regular medical visits would be used to monitor a patient's weight loss, make adjustments to the strength of the signal from the device and to monitor for adverse events. There would also be utilisation of ancillary services e.g., blood tests, imaging, and consultations with allied health professionals such as dieticians, exercise physiologists and psychologists. The applicant indicates that the neurostimulator is likely to need to be replaced approximately every 5 years. However, leads and electrodes are anticipated to require replacing approximately every 15-20 years. Each of these would require a surgical procedure.

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[2] Source: Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA.* Oct 13 2004;292(14):1724-1737.

[3] Source: Australian Bureau of Statistics, 2012. Overweight and Obesity in Adults, Australia, 2004-5. Catalogue number 4719.0 - Available online at: http://www.abs.gov.au/ausstats/abs@.nsf/mf/4719.0/

## Prerequisites

It is proposed that the procedure would be delivered by bariatric surgeons who are members of the Obesity Surgery Society of Australia and New Zealand (OSSANZ) and that OSSANZ would determine the training and accreditation requirements. The proposal suggested that the medical service should be funded only if delivered directly by a bariatric surgeon.

*PASC noted the advice received from OSSANZ during the consultation phase of development of the DAP that indicated that OSSANZ is not a credentialling body and there is currently no mechanism to prevent any general surgeon from performing bariatric surgery.*

PASC noted that the review of existing MBS items for bariatric surgery (Application 1180r), considered by MSAC in November 2011, reported that there is a steep learning curve associated with bariatric surgery. Best practice guidelines relating to weight loss surgery recommend that bariatric surgeons undertake the same procedures frequently (50-100 cases per year) operating in properly equipped, high volume weight loss centres with integrated and multidisciplinary treatment[4].

*PASC advised that any application to MSAC should include a description of the strategies that would be implemented to ensure safety and best practice surgery particularly if the likely number of patients that will undergo intra-abdominal vagal nerve modulation therapy will be low (e.g., 100-200 per year as predicted in the proposal for an application [Part B – eligibility]).*

The projections in the proposal appear to be low, especially when considered alongside utilisation of MBS items for other bariatric surgeries as shown in Table 2. It should be noted that some items included in this table (e.g., MBS item 30518 - partial gastrectomy), while including procedures for management of obesity (e.g., sleeve gastrectomy), will also include use of the procedure for other indications. The proposal suggests that the number of patients using intra-abdominal vagal nerve modulation therapy will be limited by the number of surgeons trained to perform the procedure and by the positioning of the intervention relative to other forms of bariatric surgery.

**Table 2: Utilisation of MBS items relating to bariatric surgery for obesity**

| MBS Item number | MBS item descriptor | Utilisation in 2011/2012 financial year |
|---|---|---|
| 30511 | MORBID OBESITY, gastric reduction or gastroplasty for, by any method | 8,876 |
| 30512 | MORBID OBESITY, gastric bypass for, by any method including anastomosis | 400 |
| 30518 | PARTIAL GASTRECTOMY | 2,310 |

[4] Source: Kelly J, Tarnoff M, Shikora S, Thayer B, Jones DB, Forse RA et al 2005, 'Best practice recommendations for surgical care in weight loss surgery', *Obesity Research,* 13: 227- 233.

### Co-administered and associated interventions

The surgical procedures for implanting and removing the implantable medical device used to deliver intra-abdominal vagal nerve modulation therapy for which listing on the MBS is to be requested, will also involve the services of an anaesthetist and an assistant surgeon.

In addition, patients will require supply of the devices required to deliver intra-abdominal vagal nerve modulation therapy (e.g., the neuroregulator and implantation kit and other items listed in Table 1).

The proposal states that the device is currently priced at $17,850. This cost represents the device portion of intra-abdominal vagal nerve modulation therapy.

*PASC noted that, currently, the device is not listed on the Prostheses List and listing would be conditional on the device meeting the five criteria for listing on the Prostheses List, including the criterion that the professional service associated with the implantation of the device must have a relevant MBS item number.*

In considering the Review of items for the surgical treatment of obesity in November 2011, MSAC agreed that bariatric surgery interventions should be performed in the context of a multidisciplinary service – with a concentration of surgical experts working not only with physicians, but also with dieticians, exercise physiologists, and psychologists.

## Listing proposed and options for MSAC consideration

### Proposed MBS listing

The items proposed by the applicant for inclusion on the MBS relevant to intra-abdominal vagal nerve modulation therapy are summarised in Table 3.

**Table 3: Proposed MBS item descriptors**

| Category 3 - THERAPEUTIC PROCEDURES |
|---|
| MBS Item number XXXX<br>NEUROREGULATOR, subcutaneous placement of, including placement and connection of electrodes, to generate vagal blocking (VBloc) therapy for the management of obesity (Anaes.) (Assist.)<br>Fee: $334.25 Benefit: 75% = $250.70<br><br>MBS Item number XXXXX<br>LEADS, flexible with electrodes, surgical placement of, for the management of obesity, to a maximum of 2 leads (Anaes.) (Assist.)<br>Fee: $661.60 Benefit: 75% = $496.20<br><br>MBS Item number XXXXX<br>NEUROREGULATOR, subcutaneous removal of, including removal and dis-connection of electrodes (Anaes.) (Assist.)<br>Fee: $334.25 Benefit: 75% = $250.70<br><br>Notes: To refer to patient criteria and physician training requirements |

The proposal suggested that the proposed MBS items relating to the placement of a neuroregulator and placement of leads/electrodes most closely resemble placement of a neurostimulator (MBS item 39134) and placement of associated leads (MBS item 39138) for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris. However, there are other items currently on the MBS which also relate to interventions involving the placement of a neuroregulator or similar device (neurostimulator or pulse generator) and associated services. These items are listed within Attachment A.

*PASC noted that no MBS items relating to replacement of the neurostimulator and replacement of leads/electrodes were proposed despite the projection that the neurostimulator would need to be replaced approximately every 5 years and the leads/electrodes replaced every 15-20 years. PASC advised that it would be appropriate for a submission requesting subsidy of intra-abdominal vagal nerve modulation therapy to include a request for MBS items for the replacement of the neurostimulator and replacement of the leads and electrodes.*

### Wording of proposed listings

*PASC noted that the proposed MBS item descriptors include the term "VBLOC", which is a trademark. PASC resolved that it would be more appropriate for the MBS items descriptors to include the generic term of "intra-abdominal vagal nerve modulation".*

*PASC noted that the proposed MBS items descriptors do not consistently include a description of both the intervention and indication. This could make it difficult for physician to readily identify service related to intra-abdominal vagal nerve modulation therapy. For example, the item relating to "LEADS" does not refer to leads that are used to deliver vagal nerve modulation therapy. In addition, the item*

*relating to "NEUROREGULATOR, subcutaneous removal of…" does not refer to the indication (e.g., "for intra-abdominal vagal nerve modulation therapy used in the management of obesity"). PASC recommends that the item descriptors be amended to include a more precise description of the intervention and indication.*

*PASC also advised that the requested listing should be revised to exclude the possibility of other bariatric surgery interventions being used concurrently with intra-abdominal vagal nerve modulation.*

### Proposed fees

The Schedule fees for the proposed items are derived on the basis of a claim that the proposed items are comparable to MBS item descriptors for placement of a neurostimulator and associated leads for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris, namely MBS items 39134 and 39138, which have Schedule fees (1 November 2011) of $334.25 and $661.60 respectively.

Table 4 provides a comparison of Schedule Fees for items that relate to placement and removal of the neurostimulator/pulse generator and also fees for items that relate to placement and removal of associated leads and electrodes for other indications. Full details are provided in Attachment A.

*PASC noted that, for interventions involving the use of a neuroregulator, the fees for the removal of the neuroregulator are typically significantly lower (<50%) than the fee for placement of the neuroregulator. In contrast, the requested fee for removal of the neuroregulator for intra-abdominal vagal nerve modulation therapy is identical to the requested fee for the placement of the neuroregulator. PASC advised that any application requesting listing of this intervention would need to provide a breakdown of the inputs to the requested fees.*

**Table 4: Comparison of Schedule fees for MBS items relating to the placement, replacement, maintenance and removal of neurostimulators/pulse generators and associated leads and electrodes**

| MBS service | Applicant proposed | Neuropathic pain | Faecal incontinence | Urinary incontinence | Deep brain stimulation for Parkinson's |
|---|---|---|---|---|---|
| Placement of neurostimulator/pulse generator/neuromodulator* | $334.25 | $334.25 | $327.75 | $327.75 | $334.25 |
| Adjustment/programming of neurostimulator/pulse generator/neuromodulator* | | $125.40 | $123.05 | $123.05 | $186.15 |
| Replacement or neurostimulator/pulse generator/neuromodulator* | | | | $250.70 | $250.70 |
| Removal of neurostimulator/pulse generator/neuromodulator* | $334.25 | $156.45 | $153.40 | $153.40 | $250.70 |
| Placement of leads/electrodes* | $661.60 | $661.60 | $648.65 | | $516.60 |
| Replacement of leads/electrodes* | | $594.05 | $582.50 | $598.90 | $516.60 |
| Removal of leads/electrodes* | | $156.45 | $153.40 | | $516.60 |
| Removal of neurostimulator and leads (combined)* | | | | $516.60 | |

*Schedule Fees as at 1 November 2011

In relation to the fees for the surgical placement of the device, the proposal describes "as a rough guide a possible market price of between $3,000.00 and $4,000.00". In addition to the fee for surgical placement of the device, the proposal suggests that the proposed market price for the device (The Maestro System™) will be $17,850.

*PASC noted there will be a large difference between the Schedule fee for services relating to intra-abdominal vagal nerve modulation therapy and the fees charged in practice for the services. PASC noted that the reason for the difference between the proposed Schedule Fee and the market price is not explained in the proposal. As noted by the applicant, there is a differential between fees charged in practice and the MBS Schedule fee for other bariatric surgery interventions. As shown in Table 5, there are substantial differences between the fees charged in practice and the Schedule fee for other bariatric surgery items. Only around 1-5% of MBS services for gastroplasty (MBS Item 30511), gastric bypass and partial gastrectomy are bulk-billed for 2011-2012 financial year. PASC noted that the differential proposed for vagal nerve modulation therapy was substantially larger than that applying, on average, for other bariatric surgeries. PASC advised that any application requesting listing of services relating to intra-abdominal vagal nerve modulation therapy should provide a breakdown of inputs to the fees likely to be charged in practice including for the placement, replacement and removal of the neuroregulator and electrodes/leads and also for the device component should be provided with the submission.*

*PASC considered that the large differential between the Schedule fee and the fee likely to be charged in practice raised potential issues of equity of access for patients. The large price differential between the Schedule fee and the fee likely to be charged in practice means that intra-abdominal vagal nerve modulation therapy, if recommended for inclusion on the MBS with the proposed Schedule fees, would*

*remain unaffordable, and therefore inaccessible, for numerous Australians (unless made available to patients managed through public hospitals). Thus, there is the potential for the priority to receive treatment with intra-abdominal vagal nerve modulation would be determined by ability to pay.*

**Table 5: Comparison of average fees charged and MBS Schedule fee for MBS items relating to bariatric surgery for obesity (2011/2012 calendar year)**

| MBS Item number | MBS item descriptor | MBS Schedule fee[2] | Average fee charged[1] | Proportion of services bulk-billed[1] |
|---|---|---|---|---|
| 30511 | MORBID OBESITY, gastric reduction or gastroplasty for, by any method | $849.55 | $1,865 | 1.0% |
| 30512 | MORBID OBESITY, gastric bypass for, by any method including anastomosis | $1,045.40 | $1,541 | 2.0% |
| 30518 | PARTIAL GASTRECTOMY | $987.50 | $1,479 | 5.0% |

[1] Source: Department of Health and Ageing
[2]Schedule Fees as at 1 November 2012

## Proposed population

The proposal suggested that intra-abdominal vagal nerve modulation therapy could be used in four potential target populations:

1. Patients with a BMI ≥ 40 kg/m$^2$ or BMI ≥ 35 kg/m$^2$ with at least one co-morbidity; the proposal indicates that the majority of patients that would be treated with intra-abdominal vagal nerve modulation therapy would be in this classification;
2. Patients who are deemed unsuitable for the alternative MBS funded forms of bariatric surgery such as gastric banding or sleeve gastrectomy;
3. Women who intend, or who are likely, to become pregnant;
4. Patients who are super obese (BMI > 55) and need to lose some weight prior to gastric bypass.

*PSAC advised that the target population should be revised by the removal of populations listed in the bulleted points labelled 2, 3 and 4 (above) for the following reasons.*

- *PASC advised that it would not be appropriate for an application to request listing for a population in whom other forms of bariatric surgery was unsuitable. PASC considered that patients in this category would generally be unsuitable due to contraindication for laparoscopic surgery. Given that laparoscopic surgery was required to implant the device to deliver intra-abdominal vagal nerve modulation such that if bariatric surgery was contraindicated then intra-abdominal vagal nerve modulation would also be contraindicated, PASC could not foresee that such a patient group existed. Advice received during the consultation phase of the DAP development process confirmed PASC's supposition that there was unlikely to exist a patient group in whom other bariatric surgeries were unsuitable but where intra-abdominal vagal nerve modulation therapy was suitable. Therefore PASC advised that it would not be appropriate for an application to request listing for a population in who other forms of bariatric surgery was inappropriate unless specific evidence of the effectiveness of the intervention in such a population was available (e.g., evidence from a trial where recruitment was limited to patients in whom other forms of bariatric surgery was inappropriate for clearly specified reasons).*

- *PASC considered that the eligibility criteria recommended for bariatric surgery generally (i.e., patients with BMI ⩾ 40 kg/m$^2$, or between 35 kg/m$^2$ and 40 kg/m$^2$ where there are other major medical conditions such as high blood pressure or diabetes) were also appropriate for obese women experiencing difficulties with fertility. Therefore, PASC resolved that there was no need for a specific MBS item for women intending to become pregnant.*
- *PASC noted that the proposal to make intra-abdominal vagal nerve modulation therapy available for super-obese patients was inconsistent with the applicant's statement (on p.19 of the proposal application [Part C]) that "… the patient population deemed suitable for gastric bypass is usually the super obese and these patients are not currently considered suitable for VBloc Therapy". During the consultation phase of the DAP development, it was clarified that intra-abdominal vagal nerve modulation therapy is not indicated for patients with a BMI > 55 kg/m$^2$ and therefore PASC resolved that there was currently no clinical place for intra-abdominal vagal nerve modulation therapy in the super obese who need to lose some weight prior to gastric bypass.*

*The PASC considered that it would be appropriate for the MBS item descriptor to limit use of intra-abdominal vagal nerve modulation therapy to patients 18 years and older.*

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*Table 6 provides an example of possible modifications to the requested MBS item descriptors that clarify the intervention and the patient population.*

**Table 6: Examples of alternate MBS item descriptions**

| Category 3 - THERAPEUTIC PROCEDURES |
|---|
| MBS Item number XXXX<br>NEUROREGULATOR, subcutaneous placement of, including placement and connection of electrodes, for vagal nerve modulation therapy for the management of patients 18 years and older with clinically severe obesity not in association with other bariatric surgeries (Anaes.) (Assist.)<br>Fee: $334.25 Benefit: 75% = $250.70 |
| MBS Item number XXXXX<br>LEADS, flexible with electrodes, surgical placement of, for vagal nerve modulation therapy for the management of 18 years and older patients with clinically severe obesity not in association with other bariatric surgeries (Anaes.) (Assist.)<br>Fee: $661.60 Benefit: 75% = $496.20 |
| MBS Item number XXXXX<br>NEUROREGULATOR, removal of, including removal and dis-connection of electrodes for vagal nerve modulation therapy, (Anaes.) (Assist.)<br>Fee: $334.25 Benefit: 75% = $250.70 |
| MBS Item number XXXX<br>NEUROREGULATOR, replacement of, including placement and connection of electrodes, for vagal nerve modulation therapy (Anaes.) (Assist.)<br>Fee: $TBD Benefit: 75% = $TBD |
| MBS Item number XXXXX<br>LEADS, flexible with electrodes, replacement of, for vagal nerve modulation therapy (Anaes.) (Assist.)<br>Fee: $TBD Benefit: 75% = $TBD |

TBD – to be determined

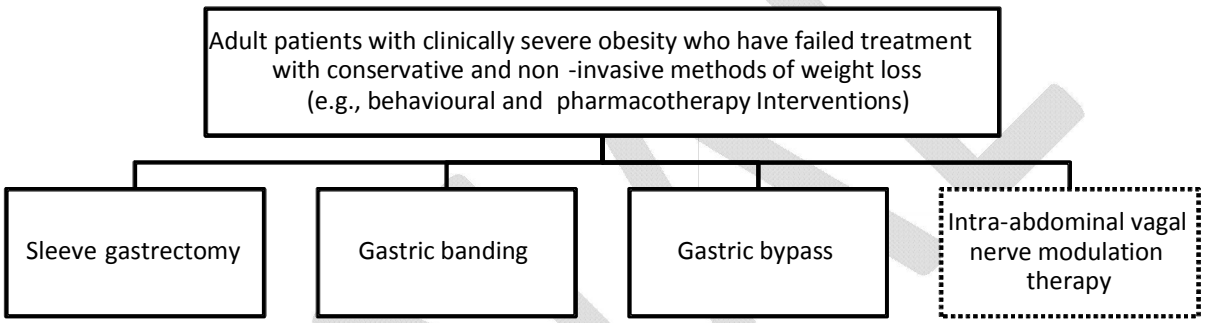
## Clinical place for proposed intervention

The proposal describes that the provision of MBS services relating to intra-abdominal vagal nerve modulation therapy should be limited to a hospital setting. *PASC noted that some follow-up services would be delivered in the community setting using existing MBS items.*

*The proposal did not comment on the potential for access issues for patients in rural and remote communities. For example, if the device can only be implanted in major hospitals and there is a necessity for adjustments to be conducted at the same centres then potential difficulties for access to services arise for patients located in rural and remote areas.*

The proposal presented two clinical pathways for patients eligible for bariatric surgery. One pathway represented the "current" scenario and another pathway represented the "proposed" scenario*. PASC did not agree with the positioning of intra-abdominal vagal nerve modulation suggested in these pathways (i.e., that intra-abdominal vagal nerve modulation would principally be used in the population not suitable for currently available bariatric surgery procedures). PASC noted that, given that the majority of use of intra-abdominal vagal nerve modulation therapy would be in patients with clinically severe obesity where it would compete with other bariatric surgery interventions (particularly gastric banding), then it would be more appropriate for the algorithm to position intra-abdominal vagal nerve modulation therapy alongside other bariatric surgery interventions in the management algorithm rather than following other bariatric surgery interventions as shown in Figure 1.*

**Figure 1: Clinical management algorithm illustrating likely clinical positioning of intra-abdominal vagal nerve modulation therapy)**




## Comparator

The proposal nominated comparators for each of the requested target populations. As discussed in the section titled "Proposed population", PASC considered that the target population for intra-abdominal vagal nerve modulation therapy would be patients with clinically severe obesity, defined as BMI $\geqslant$ 40 kg/m2, or between 35 kg/m2 and 40 kg/m2 where there are other major medical conditions such as high blood pressure or diabetes. As discussed in the section titled "Clinical place for proposed intervention", it is likely that the clinical position of intra-abdominal vagal nerve modulation therapy would be as a competitor to other types of bariatric surgeries. A range of bariatric surgery procedures are currently funded through the MBS and these procedures vary with regards to cost, efficacy, side-effects and acceptability to patients. Gastric banding is the most widely used bariatric surgery procedure in Australia5 and was considered by PASC to be the most appropriate comparator. PASC did not agree with a claim made in the sponsor's response to the consultation draft DAP that the appropriate comparator for intra-abdominal vagal nerve modulation would be non-operative measures. PASC also did not accept claims that intra-abdominal vagal nerve modulation was reversible and gastric banding was not as the effect of a gastric band could be reversed by removal of the fill from the gastric band reservoir. PASC advised that claims for comparative advantage for intra-

[5] Source: Department of Health and Ageing, Draft report for reviewing existing MBS items. Available at http://www.health.gov.au/internet/main/publishing.nsf/Content/7C0B7F27D7F739B5CA25782A00821F3F/$File/DRAFT%20obesity%20report.pdf

abdominal vagal nerve modulation over gastric banding would need to be supported by the presentation of evidence in an application.

As discussed in the section titled "Proposed population", PASC considered that the target population for intra-abdominal vagal nerve modulation therapy would be patients with clinically severe obesity, defined as BMI $\geqslant$ 40 kg/m2, or between 35 kg/m2 and 40 kg/m2 where there are other major medical conditions such as high blood pressure or diabetes. As discussed in the section titled "Clinical place for proposed intervention", it is likely that the clinical position of intra-abdominal vagal nerve modulation therapy would be as a competitor to other types of bariatric surgeries. A range of bariatric surgery procedures are currently funded through the MBS and these procedures vary with regards to cost, efficacy, side-effects and acceptability to patients. Gastric banding is the most widely used bariatric surgery procedure in Australia6 and was considered by PASC to be the most appropriate comparator. PASC did not agree with a claim made in the sponsor's response to the consultation draft DAP that the appropriate comparator for intra-abdominal vagal nerve modulation would be non-operative measures. PASC also did not accept claims that intra-abdominal vagal nerve modulation was reversible and gastric banding was not as the effect of a gastric band could be reversed by removal of the fill from the gastric band reservoir. PASC advised that claims for comparative advantage for intra-abdominal vagal nerve modulation over gastric banding would need to be supported by the presentation of evidence in an application.

*However, as discussed in the section titled "Proposed population", PASC considered that the target population for intra-abdominal vagal nerve modulation therapy should only include patients with clinically severe obesity, defined as BMI ≥ 40 kg/m$^2$, or between 35 kg/m$^2$ and 40 kg/m$^2$ where there are other major medical conditions such as high blood pressure or diabetes. As discussed in the section titled "Clinical place for proposed intervention", PASC considered the clinical position of intra-abdominal vagal nerve modulation therapy would be as a competitor to other types of bariatric surgeries. A range of bariatric surgery procedures are currently funded through the MBS and these procedures vary with regards to cost, efficacy, side-effects and acceptability to patients. Gastric banding is the most widely used bariatric surgery procedure in Australia[7] and was considered by PASC to be the most appropriate comparator. PASC did not agree with a claim made in the applicants response to the consultation draft DAP that the appropriate comparator for intra-abdominal vagal nerve modulation would be non-surgical measures.*

## Clinical claim

The proposal claims that intra-abdominal vagal nerve modulation therapy is associated with an average excess weight loss (EWL) of at least 30%. Generally, 'excess weight' is usually calculated as

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6 Source: Department of Health and Ageing, Draft report for reviewing existing MBS items. Available at http://www.health.gov.au/internet/main/publishing.nsf/Content/7C0B7F27D7F739B5CA25782A00821F3F/$File/DRAFT%20obesity%20report.pdf

7 Source: Department of Health and Ageing, Draft report for reviewing existing MBS items. Available at http://www.health.gov.au/internet/main/publishing.nsf/Content/7C0B7F27D7F739B5CA25782A00821F3F/$File/DRAFT%20obesity%20report.pdf

weight (in kg) at the time of surgery minus 'ideal' or 'desirable' weight (in kg). Ideal/desirable weight is taken from a reference such as the revised Metropolitan Life height-weight tables[8]. Weight loss is then reported as a percentage of the excess weight (%EWL).

*It is not clear if the proposal is indicating that the <u>results</u> show an EWL greater than 30% or if the proposal is saying that the outcome that is to be reported is proportion of patients achieving an EWL >30% or if mean excess weight loss is to be reported and that a difference of >30% is clinically significant.*

In addition, it is claimed that there is a reduction in the prevalence of a number of co-morbidities, the main one being diabetes. Others include:

- cardiovascular disease;
- high blood pressure;
- stroke;
- high cholesterol;
- obstructive sleep apnoea;
- osteoarthritis, and
- some cancers.

*PASC noted that an association between weight loss and rates of remission of diabetes has been established for other bariatric surgery interventions. However, PASC noted that the relationship between weight loss and rates of these events could vary depending on the mechanism used to achieve weight loss e.g., remission from type 2 diabetes is known to vary with the type of bariatric surgery procedure (where gastric bypass has been shown to be associated with higher rates of resolution of type 2 diabetes than restriction only interventions such as gastric banding - several hypotheses have been postulated to explain these findings, including calorie restriction, hormonal changes, and exclusion of the upper gastrointestinal tract)[9].*

*For this reason, PASC considered that it would be important for any application requesting the listing of services related to intra-abdominal vagal nerve modulation therapy to include evidence of impact on conditions that are thought to be related to obesity (e.g., diabetes, cardiovascular disease, etc). PASC noted that any assumption of a surrogate relationship between the endpoint of weight loss and reduction in risk of these other conditions should be supported by the presentation of evidence. PASC considered that it would not be appropriate to assume a relationship on the basis of data for other interventions as such an assumption would be fraught with a high degree of uncertainty.*

*If such evidence to link the endpoint of weight loss with endpoints of other conditions is not available, it would be important for any application to outline how the applicant intends to develop such evidence to permit review of any listing of intra-abdominal vagal nerve modulation therapy (e.g., by*

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[8] 1983 Metropolitan height and weight tables. Stat Bull Metrop Life Insur Co 1984; 64:2-9

[9] Tejirian et al. Bariatric Surgery and Type 2 Diabetes Mellitus: Surgically Induced Remission. J Diabetes Sci Technol. 2008;2(4):685-691

*participation in the OSSANZ registry such that data could be captured which is able to inform judgements about the safety and long term sustainability of weight loss).*

*PASC noted that the proposal did not state what claim would be made in relation to the comparative effectiveness and comparative safety of intra-abdominal vagal nerve modulation therapy relative to the appropriate comparator (i.e., gastric banding). The clinical claim for intra-abdominal vagal nerve modulation therapy versus gastric banding will determine the type of economic evaluation that should be presented in an application (see Table 7).*

**Table 7: Classification of an intervention for determination of economic evaluation to be presented**

<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="4">Comparative effectiveness versus comparator</td></tr>
<tr><td colspan="2">Superior</td><td>Non-inferior</td><td colspan="2">Inferior</td></tr>
<tr><td rowspan="6">Comparative safety versus comparator</td><td rowspan="3">Superior</td><td colspan="2" rowspan="3">CEA/CUA</td><td rowspan="3">CEA/CUA</td><td>Net clinical benefit</td><td>CEA/CUA</td></tr>
<tr><td>Neutral benefit</td><td>CEA/CUA*</td></tr>
<tr><td>Net harms</td><td>None^</td></tr>
<tr><td>Non-inferior</td><td colspan="2">CEA/CUA</td><td>CEA/CUA*</td><td colspan="2">None^</td></tr>
<tr><td rowspan="3">Inferior</td><td>Net clinical benefit</td><td>CEA/CUA</td><td rowspan="3">None^</td><td colspan="2" rowspan="3">None^</td></tr>
<tr><td>Neutral benefit</td><td>CEA/CUA*</td></tr>
<tr><td>Net harms</td><td>None^</td></tr>
</table>

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e., the conclusion is often not indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

^ No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention.

## Outcomes and health care resources affected by introduction of proposed intervention

### Clinical outcomes

The proposal describes that weight loss is expected due to intra-abdominal vagal nerve modulation therapy. A number of metrics could be used to report the extent of weight loss. The proposal appears to suggest that proportion of patients achieving various levels of EWL is a relevant metric.

In addition, the proposal suggests that prevalence of the following health outcomes is also a relevant health outcome to consider in the determination of comparative effectiveness of interventions for obesity:

- diabetes;
- cardiovascular disease;
- high blood pressure;
- stroke;
- high cholesterol;

- obstructive sleep apnoea;
- osteoarthritis; and,
- some cancers.

*PASC advised that it was important that any application should also present a comparison of intra-abdominal vagal nerve modulation therapy and other bariatric surgery interventions considering the following outcomes:*

- *rates of compliance with therapy (particularly in the context that the proposal states that the intra-abdominal vagal nerve modulation therapy device needs to be charged daily by the patient)*
- *maintenance of weight loss over long term horizons;*
- *impact on quality of life;*
- *impact on survival;*
- *incidence of safety-related events (e.g., rates of different types of complications; rates of infection; rates of reversal; rates of conversion from laparoscopic to open procedure; rates of revisional surgery and other major adverse events; rates of post-operative mortality); and*
- *incidence of adverse events secondary to vagal nerve inhibition*

*PASC noted that the advice from the applicant that the intensity (amplitude) of the signal delivered to the vagal nerve is adjusted "according to patient tolerance" and that, typically, vagal nerve modulation is delivered for 12 hours per day (turned off at night because therapy is not required while patient is sleeping). PASC advised that any application requesting availability of services relating to intra-abdominal vagal nerve modulation should provide any data available exploring whether there is a "dose-response" relationship between the strength and duration of the vagal nerve inhibition delivered and the outcomes achieved by a patient, including harms or adverse events associated with inhibition of the vagal nerve.*

*Given the "newness" of this intervention, PASC agreed that it would be appropriate for narratives from a patient perspective, describing patient experience with the intervention, to be presented from a broad range of patients (including those who have stopped using the device) and presented with an application.*

### Health care resources

*PASC reminded the applicant that the economic evaluation should take a health care perspective whereby costs borne by both the MBS, costs for the device, and out-of-pocket patient costs are included in the evaluation.*

The proposal claims that the healthcare resources used as part of intra-abdominal vagal nerve modulation therapy are very similar to those used for gastric banding or sleeve gastrectomy. It is also described that "the main differences, apart from the implanted prosthesis, are the duration of surgery, length of stay and post-operative care". *PASC suggested that the applicant should provide details in the application about the typical duration of surgery, the length of a typical hospital stay, and the typical follow-up post operatively and in the longer term both for intra-abdominal vagal nerve*

*modulation therapy and for other bariatric surgery interventions. If differences are claimed, it is important that such claims are supported by presentation of evidence.*

Healthcare resources that may be used in the lead-up to a bariatric surgery procedure include:

- prior to surgery, some bariatric procedures require a low calorie diet (including food substitution products) for two to four weeks prior to surgery consultations with the bariatric surgeon (for the purposes of determining eligibility for bariatric surgery)
- consultations with a psychologist
- assessments (e.g., blood tests, radiological assessments) to determine a patient's suitability for surgery

Healthcare resources that may be used in the delivery of a bariatric surgery procedure include:

- operating theatre and associated resources – time taken varies depending on procedure
- services delivered by a bariatric surgeon
- services delivered by an assistant surgeon
- services delivered by an anaesthetist
- implanted device e.g., gastric band or staples
- hospital bed-days

Healthcare resources that may be used following a bariatric surgery procedure include:

- consultations with the bariatric surgeon
- consultations with a medical practitioner to monitor weight loss and to monitor for potential adverse events
- consultations with a dietician
- consultations with a psychologist
- assessments (e.g., blood tests, imaging) to determine that a device has been correctly placed
- medications in the short term (e.g., analgesia) and long term (e.g., vitamin supplementation)
- band adjustments (gastric banding procedure only)
- adjustments to signal strength from the implanted device used to modulate the activity of the vagal nerve (intra-abdominal vagal nerve modulation therapy only)
- resources used to manage adverse events or complications
- some patients experiencing a substantial weight loss may be left with areas with excess skin which may require management by surgical resection;
- some patients experiencing a substantial weight loss may be able to undergo orthopaedic procedure that had previously been contraindicated due to the patient's obesity
- some patients experiencing a substantial weight loss may have resolution of co-morbidities e.g., diabetes, hypertension, hypercholesterolaemia, sleep apnoea, which may result in a reduction in the use of therapies used to manage these conditions.

## Proposed structure of economic evaluation (decision-analytic)

*PASC considered that the appropriate research question to be investigated in an application for intra-abdominal vagal nerve modulation therapy would be:*

> *"What is the comparative safety, effectiveness, and cost-effectiveness of intra-abdominal vagal nerve modulation therapy versus other bariatric surgery interventions (particularly gastric banding) in a population of patients 18 years and older with BMI ≥ 40 or ≥ 35 with at least one co-morbidity?"*

The proposal does not outline a structure for a model (decision analytic) that could be used to conduct an economic evaluation comparing a scenario where intra-abdominal vagal nerve modulation therapy is available with the current scenario where it is not available.

*It will be important that any application present the structure of the decision analytic in both in a diagrammatic form and in a descriptive form (explaining in words what happens at the decision points and the transition points in the decision analysis). Decision and transition points in the diagrammatic representation of the decision analytic should be labelled and the written description of the decision analytic should include cross-references to the labelled points in the diagram summarising the structure of the economic evaluation. Ultimately, the presentation of the structure of the economic evaluation should make it apparent how the outcomes and health care resources identified as being important in determining the comparative clinical and economic performance of the proposed intervention versus the comparator(s) are incorporated into the economic analysis. This will permit the key drivers of the outputs (both costs and outcomes) of the economic analysis to be identified. The data sources for parameters in the model should also be specified.*

*Fundamentally, the model will provide a comparison of intra-abdominal vagal nerve modulation therapy versus other types of bariatric surgery (particularly gastric banding) in patients 18 years and older with clinically severe obesity. The structure of the model that will be used to conduct an economic analysis should make apparent any relationships that will be accepted as applying between weight loss and other patient-relevant outcomes such as prevalence of co-morbidities.*

*Although the proposal identifies some of the resources likely to be used prior to, in delivery of, and following placement of the device used for intra-abdominal vagal nerve modulation therapy, the proposal does not propose sources for the valuation each resource (i.e., the proposal does not identify sources for unit costs for resources e.g., the AR-DRG cost weight that applies for patients undergoing bariatric surgery is not identified.*

*Although the proposal presented a list of resources to be considered in the economic analysis (as summarised in Table 8), PASC noted that the list of resources was incomplete. PASC noted the use of additional services following implant of the vagal nerve modulation device (e.g., consultations with physicians and allied health professionals such as dieticians, exercise physiologists and psychologists). It resolved that the use of these resources should be considered in the analyses of both the economic and financial implications of making the intervention available. Claims for differences in use of resources would need to be supported by presentation of evidence (e.g., claims that there will be a*

*reduced need for routine monitoring by physicians would need to be supported with evidence demonstrating such a reduction).*

**Table 8: List of resources to be considered in the economic analysis**

| | Provider of resource | Setting in which resource is provided | Number of units of resource per relevant time horizon per patient receiving resource | Source of information of number of units* |
|---|---|---|---|---|
| Resources provided to identify the eligible population that would vary from current clinical practice | | | | |
| Resource 1 | Surgeon | Rooms | once | |
| Resource 2, etc | Pathologist | Collection centre | Standard bloods | |
| Resources provided in association with the proposed medical service to deliver the proposed | | | | |
| Resource 1 | Surgeon | Theatre | Approx one hour | |
| Resource 2 | Assistant surgeon | Theatre | Approx one hour | |
| Resource 3 | Anaesthetist | Theatre | Approx one hour | |
| Resources provided to deliver the comparator to deliver the current intervention | | | | |
| Resource 1 | Surgeon | Theatre | 45 to 90 minutes | |
| Resource 2 | Assistant surgeon | Theatre | 45 to 90 minutes | |
| Resource 3 | Anaesthetist | Theatre | 45 to 90 minutes | |
| Resources provided following the proposed intervention with the proposed medical service (from Step 8, e.g., resources used to monitor or in follow-up, resources used in management of adverse events, resources used for treatment of down-stream conditions conditioned on the results of the proposed intervention). Identify variations where these may vary across different decision options. | | | | |
| Resource 1 | Hospital | Hospital | One day | |
| Resource 2, etc | Surgeon | Rooms | Twice | |
| Resources provided following the comparator to deliver the current intervention (from Step 7, e.g., resources used to monitor or in follow-up, resources used in management of adverse events, resources used for treatment of down-stream conditions conditioned on the results of the proposed intervention). *Identify variations where there may be more than one comparator or where these may vary across different decision options.* | | | | |
| Resource 1 | Hospital | Hospital | Two to four days | |
| Resource 2, etc | Surgeon | Rooms | Once | |

## Attachment A

MBS items relating to the placement and removal of neurostimulators or pulse generators and associated leads and electrodes. Table 9 provides the MBS item descriptors for other services included on the MBS that involve the placement, management and removal of neurostimulators or other pulse generators and associated leads and electrodes.

**Table 9: Other MBS item descriptors relating to the placement, management and removal of neurostimulators or pulse generators and associated leads and electrodes***

| **Category 3 - THERAPEUTIC PROCEDURES** |
|---|
| ITEMS RELATING TO NEUROPATHIC PAIN |
| MBS Item 39130<br><br>EPIDURAL LEAD, percutaneous placement of, including intraoperative test stimulation, for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris, to a maximum of 4 leads<br><br>(Anaes.)<br><br>**Fee:** $661.60 **Benefit:** 75% = $496.20 |
| MBS Item 39131<br><br>ELECTRODES, epidural or peripheral nerve, management of patient and adjustment or reprogramming of neurostimulator by a medical practitioner, for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris - each day<br><br>**Fee:** $125.40 **Benefit:** 75% = $94.05 85% = $106.60 |
| MBS Item 39134<br><br>NEUROSTIMULATOR or RECEIVER, subcutaneous placement of, including placement and connection of extension wires to epidural or peripheral nerve electrodes, for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris<br><br>(Anaes.) (Assist.)<br><br>**Fee:** $334.25 **Benefit:** 75% = $250.70 |
| MBS Item 39135<br><br>NEUROSTIMULATOR or RECEIVER, that was inserted for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris, removal of, performed in the operating theatre of a hospital<br><br>(Anaes.)<br><br>**Fee:** $156.45 **Benefit:** 75% = $117.35 85% = $133.00 |
| MBS Item 39136<br><br>LEAD, epidural or peripheral nerve that was inserted for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris, removal of, performed in the operating theatre of a hospital<br><br>(Anaes.)<br><br>**Fee:** $156.45 **Benefit:** 75% = $117.35 |
| MBS Item 39137<br><br>LEAD, epidural or peripheral nerve that was inserted for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris, surgical repositioning to correct displacement or unsatisfactory positioning, including intraoperative test stimulation, not being a service to which item 39130, 39138 or 39139 applies<br><br>(Anaes.)<br><br>**Fee:** $594.05 **Benefit:** 75% = $445.55 |
| MBS Item 39138<br><br>PERIPHERAL NERVE LEAD, surgical placement of, including intraoperative test stimulation, for the management of chronic intractable neuropathic pain or pain from refractory angina pectoris, to a maximum of 4 leads<br><br>(Anaes.) (Assist.) |

**Fee:** $661.60 **Benefit:** 75% = $496.20

ITEMS RELATING TO FAECAL INCONTINENCE

MBS Item 32213

SACRAL NERVE LEAD(S), placement of, percutaneous using fluoroscopic guidance, or open, and intraoperative test stimulation, for the management of faecal incontinence in a patient who has an anatomically intact but functionally deficient anal sphincter with faecal incontinence refractory to at least 12 months of conservative non-surgical treatment

(Anaes.)

**Fee:** $648.65 **Benefit:** 75% = $486.50

MBS Item 32214

NEUROSTIMULATOR or RECEIVER, subcutaneous placement of, and placement and connection of extension wire(s) to sacral nerve electrode(s), for the management of faecal incontinence in a patient who has an anatomically intact but functionally deficient anal sphincter with faecal incontinence refractory to at least 12 months of conservative non-surgical treatment, using fluoroscopic guidance

(Anaes.) (Assist.)

**Fee:** $327.75 **Benefit:** 75% = $245.85

MBS Item 32215

SACRAL NERVE ELECTRODE(S), management, adjustment, and electronic programming of neurostimulator by a medical practitioner, for the management of faecal incontinence - each day

**Fee:** $123.05 **Benefit:** 75% = $92.30 85% = $104.60

MBS Item 32216

SACRAL NERVE LEAD(S), inserted for the management of faecal incontinence in a patient who had an anatomically intact but functionally deficient anal sphincter with faecal incontinence refractory to at least 12 months of conservative non-surgical treatment, surgical repositioning of, percutaneous using fluoroscopic guidance, or open, to correct displacement or unsatisfactory positioning, and intraoperative test stimulation, not being a service to which item 32213 applies

(Anaes.)

**Fee:** $582.50 **Benefit:** 75% = $436.90

MBS Item 32217

NEUROSTIMULATOR or RECEIVER, inserted for the management of faecal incontinence in a patient who had an anatomically intact but functionally deficient anal sphincter with faecal incontinence refractory to at least 12 months of conservative non-surgical treatment, removal of

(Anaes.)

**Fee:** $153.40 **Benefit:** 75% = $115.05

MBS Item 32218

SACRAL NERVE LEAD(S), inserted for the management of faecal incontinence in a patient who had an anatomically intact but functionally deficient anal sphincter with faecal incontinence refractory to at least 12 months of conservative non-surgical treatment, removal of

(Anaes.)

**Fee:** $153.40 **Benefit:** 75% = $115.05

ITEMS RELATING TO URINARY INCONTINENCE

MBS Item 36658

SACRAL NERVE STIMULATION for refractory urinary incontinence or urge retention, removal of pulse generator and leads

**Fee:** $516.60 **Benefit:** 75% = $387.45 85% = $442.90

MBS Item 36660

SACRAL NERVE STIMULATION for refractory urinary incontinence or urge retention, removal and replacement of pulse generator

**Fee:** $250.70 **Benefit:** 75% = $188.05 85% = $213.10

MBS Item 36662

SACRAL NERVE STIMULATION for refractory urinary incontinence or urge retention, removal and replacement of leads

**Fee:** $598.90 **Benefit:** 75% = $449.20 85% = $525.20

MBS Item 36665

Sacral nerve electrode or electrodes, management and adjustment of the pulse generator by a medical practitioner, to manage detrusor overactivity or non obstructive urinary retention - each day

**Fee:** $123.05 **Benefit:** 75% = $92.30 85% = $104.60

MBS Item 36666

Pulse generator, subcutaneous placement of, and placement and connection of extension wire(s) to sacral nerve electrode(s), for the management of

a) detrusor overactivity; or

b) non obstructive urinary retention

that has been refractory to at least 12 months medical and conservative treatment in a patient 18 years of age or older.

(Anaes.)

**Fee:** $327.75 **Benefit:** 75% = $245.85

MBS Item 36668

Pulse generator, removal of, if the pulse generator was inserted to manage:

a) detrusor overactivity; or

b) non obstructive urinary retention

that has been refractory to at least 12 months medical and conservative treatment in a patient 18 years of age or older.

(Anaes.)

**Fee:** $153.40 **Benefit:** 75% = $115.05

ITEMS RELATING TO DEEP BRAIN STIMULATION FOR PARKINSON'S DISEASE

MBS Item 40852

DEEP BRAIN STIMULATION (unilateral) subcutaneous placement of neurostimulator receiver or pulse generator for the treatment of:

| Category 3 - THERAPEUTIC PROCEDURES |
|---|
| • Parkinson's disease where the patient's response to medical therapy is not sustained and is accompanied by unacceptable motor fluctuations; or<br>• Essential tremor or dystonia where the patient's symptoms cause severe disability.<br>(Anaes.) (Assist.)<br>**Fee:** $334.25 **Benefit:** 75% = $250.70 |
| MBS Item 40856<br>DEEP BRAIN STIMULATION (unilateral) removal or replacement of neurostimulator receiver or pulse generator for the treatment of:<br>• Parkinson's disease where the patient's response to medical therapy is not sustained and is accompanied by unacceptable motor fluctuations; or<br>• Essential tremor or dystonia where the patient's symptoms cause severe disability.<br>(Anaes.)<br>**Fee:** $250.70 **Benefit:** 75% = $188.05 |
| MBS Item 40862<br>DEEP BRAIN STIMULATION (unilateral) electronic analysis and programming of neurostimulator pulse generator for the treatment of:<br>• Parkinson's disease where the patient's response to medical therapy is not sustained and is accompanied by unacceptable motor fluctuations; or<br>• Essential tremor or dystonia where the patient's symptoms cause severe disability.<br>(Anaes.)<br>Fee: $186.15 Benefit: 75% = $139.65 85% = $158.25 |
| MBS Item 40854<br>DEEP BRAIN STIMULATION (unilateral) revision or removal of brain electrode for the treatment of:<br>• Parkinson's disease where the patient's response to medical therapy is not sustained and is accompanied by unacceptable motor fluctuations; or<br>• Essential tremor or dystonia where the patient's symptoms cause severe disability.<br>(Anaes.)<br>**Fee:** $516.60 **Benefit:** 75% = $387.45 |
| MBS Item 40858<br>DEEP BRAIN STIMULATION (unilateral) placement, removal or replacement of extension lead for the treatment of:<br>• Parkinson's disease where the patient's response to medical therapy is not sustained and is accompanied by unacceptable motor fluctuations; or<br>• Essential tremor or dystonia where the patient's symptoms cause severe disability.<br>(Anaes.)<br>**Fee:** $516.60 **Benefit:** 75% = $387.45 |

*MBS Fees as at 1 November 2011