

# MSAC Application 1727

## Deep Brain Stimulation for Treatment-Refractory Obsessive- Compulsive Disorder

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated [Application Form Instructions](#) to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted. The separate [MSAC Guidelines](#) should be used to guide health technology assessment (HTA) content of the Application Form

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: [hta@health.gov.au](mailto:hta@health.gov.au)

Website: [www.msac.gov.au](http://www.msac.gov.au)

# PART 1 – APPLICANT DETAILS

## 1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): N/A

Corporation name: N/A

ABN: N/A

Business trading name: N/A

### Primary contact name: Dr Philip Mosley

Primary contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

### Alternative contact name: Prof. Peter Silburn

Alternative contact numbers

Business: REDACTED

Mobile: REDACTED

Email: REDACTED

## 2. (a) Are you a consultant acting on behalf on an applicant?

Yes

No

(b) If yes what is the Applicant(s) name that you are acting on behalf of?

N/A

## 3. (a) Are you a lobbyist acting on behalf of an Applicant?

Yes

No

(b) If yes, are you listed on the Register of Lobbyists?

N/A

(c) Have you engaged a consultant on your behalf?

Yes

No

## PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

### 4. Application title

Deep brain stimulation for treatment-refractory obsessive-compulsive disorder

### 5. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Obsessive-compulsive disorder (OCD) is a psychiatric condition that affects 1-2% of the Australian population. People with OCD experience intrusive thoughts, images or impulses that are distressing and provoke anxiety (e.g. a fear that their skin is contaminated with germs or that their loved one will develop cancer). These are accompanied by mental rituals or behaviours (compulsions) that must be carried out to neutralise the obsessions (e.g. repetitive handwashing, saying prayers). Conventional therapy for OCD involves antidepressant medication and a type of psychological therapy that encourages sufferers to challenge their obsessions. However, a small number of people have severe OCD that is refractory to extensive trials of medication and psychotherapy. These individuals have lives that are dominated by their OCD and cannot work or sustain relationships.

### 6. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

Deep brain stimulation (DBS) is a surgical treatment that involves the implantation of permanent stimulating electrodes within the brain, targeted to a specific region in the subcortex (the inner region of the brain). These electrodes are connected to a small battery that typically sits under the skin of the chest wall. Each electrode delivers a very small field of targeted electricity that changes the activity of neurons (brain cells) in that region. The DBS device can be adjusted post-operatively without the need for further surgery, to vary the size, shape and position of the stimulation field. DBS is an established therapy for neurological conditions such as Parkinson's disease and has been used extensively in Australia and overseas with an estimated >150,000 devices implanted.

### 7. (a) Is this a request for MBS funding?

- Yes  
 No

### (b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)  
 New MBS item(s)

### (c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service/technology:

40850; 40851; 40852; 40854; 40856; 40858; 40860; 40862

### (d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

- An amendment to the way the service is clinically delivered under the existing item(s)  
 An amendment to the patient population under the existing item(s)  
 An amendment to the schedule fee of the existing item(s)  
 An amendment to the time and complexity of an existing item(s)  
 Access to an existing item(s) by a different health practitioner group  
 Minor amendments to the item descriptor that does not affect how the service is delivered  
 An amendment to an existing specific single consultation item  
 An amendment to an existing global consultation item(s)  
 Other (please describe below):

**(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?**

N/A

**(f) Is the proposed service seeking public funding other than the MBS?**

Yes

No

**(g) If yes, please advise:**

N/A

**8. What is the type of medical service/technology?**

Therapeutic medical service

Investigative medical service

Single consultation medical service

Global consultation medical service

Allied health service

Co-dependent technology

Hybrid health technology

**9. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):**

N/A

**10. Does your service rely on another medical product to achieve or to enhance its intended effect?**

Pharmaceutical / Biological

Prosthesis or device

No

**11. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?**

N/A

**(b) If yes, please list the relevant PBS item code(s):**

N/A

**(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?**

N/A

**(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?**

N/A

**12. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?**

N/A

**(b) If yes, please provide the following information (where relevant):**

N/A

**(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?**

N/A

**(d) Are there any other sponsor(s) and/or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?**

N/A

**(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):**

N/A

**13. Please identify any single and / or multi-use consumables delivered as part of the service?**

N/A

## PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

14. (a) If the proposed medical service involves use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer, or any other type of therapeutic good, please provide details

Type of therapeutic good: Deep brain stimulation system: Percept PC BrainSense B35200

Manufacturer's name: Medtronic Inc

Sponsor's name: Medtronic Australasia Pty Ltd

- (b) Has it been listed on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)? If the therapeutic good has been listed on the ARTG, please state the ARTG identification numbers, TGA-approved indication(s), and TGA-approved purpose(s).

ARTG ID: Insert ID number here: 351630

TGA approved indication(s), if applicable: Obsessive-Compulsive Disorder

TGA approved purpose(s), if applicable: Deep brain stimulation

- (c) If a medical device is involved, has the medical device been classified by TGA as a Class III OR Active Implantable Medical Device (AIMD) under the TGA regulatory scheme for devices?

Class III

AIMD

N/A

- (d) Is the therapeutic good classified by TGA for Research Use Only (RUO)?

No

15. (a) If not listed on the ARTG, is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

N/A

- (b) If the therapeutic good is not ARTG listed, is the therapeutic good in the process of being considered by TGA?

N/A

- (c) If the therapeutic good is NOT in the process of being considered by TGA, is an application to TGA being prepared?

N/A

## PART 4 – SUMMARY OF EVIDENCE

16. Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At ‘Application Form lodgement’, please do not attach full text articles; just provide a summary. .

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
1.	Randomised, double-blind, placebo-controlled trial.	Mosley <i>et al.</i> (2021). A randomised, double-blind, sham-controlled trial of deep brain stimulation of the bed nucleus of the stria terminalis for treatment-resistant obsessive-compulsive disorder.  Translational Psychiatry.	9 participants with treatment-refractory <sup>5</sup> OCD. Electrodes implanted in the bed nucleus of the stria terminalis. 3-month, delayed-onset, sham-controlled design. Followed by open-label stimulation. Statistically-significant benefit of active DBS over sham. 7 of 9 participants had a clinically-significant response to DBS at 12-months open-label stimulation. Mean reduction in OCD symptoms 49%.	<a href="https://doi.org/10.1038/s41398-021-01307-9">https://doi.org/10.1038/s41398-021-01307-9</a>	29 <sup>th</sup> March 2021
2.	Randomised, double-blind, placebo-controlled trial.	Luyten <i>et al.</i> (2016). Electrical stimulation in the bed nucleus of the stria terminalis alleviates severe obsessive-compulsive disorder.  Molecular Psychiatry	17 participants with treatment-refractory OCD. Electrodes implanted in the bed nucleus of the stria terminalis. 6-month, crossover, On/Off design after stimulation optimisation. Statistically significant benefit of active DBS over sham. 67% of participants had a clinically-significant response to DBS at last open-label follow up. Mean reduction in OCD symptoms 45%.	<a href="https://doi.org/10.1038/mp.2015.124">https://doi.org/10.1038/mp.2015.124</a>	24 <sup>th</sup> August 2015
3.	Randomised, double-blind, placebo-controlled trial.	Denys <i>et al.</i> (2010). Deep brain stimulation of the nucleus accumbens for treatment-refractory obsessive-compulsive disorder.  Archives of General Psychiatry	14 participants with treatment-refractory OCD. Electrodes implanted in the nucleus accumbens. 1-month, crossover, On/Off design after stimulation optimisation. Statistically significant benefit of active DBS over sham. 9 of 14 participants had a clinically-significant response to DBS at end of stimulation optimisation phase. Mean reduction in OCD symptoms after crossover and maintenance phase 52%.	<a href="https://doi.org/10.1001/archgenpsychiatry.2010.122">https://doi.org/10.1001/archgenpsychiatry.2010.122</a>	4 <sup>th</sup> October 2010

	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
4.	Randomised, double-blind, placebo-controlled trial.	Mallet <i>et al.</i> (2008). Subthalamic nucleus stimulation in severe obsessive-compulsive disorder.  New England Journal of Medicine	16 participants with treatment-refractory OCD. Electrodes implanted in the subthalamic nucleus. 6-month, crossover, On/Off design after stimulation optimisation. Statistically significant benefit of active DBS over sham. Mean reduction in OCD symptoms with active stimulation over sham of 32%.	<a href="https://doi.org/10.1056/NEJMoa0708514">https://doi.org/10.1056/NEJMoa0708514</a>	13 <sup>th</sup> November 2008
5.	Non-randomised trial examining neurocircuitry of response to DBS for OCD.	Li <i>et al.</i> (2020). A unified connectomic target for deep brain stimulation in obsessive-compulsive disorder.  Nature Communications	50 participants with treatment-refractory OCD were combined in an analysis of data from 4 different centres in Europe. Amongst participants, electrodes were implanted in the nucleus accumbens, subthalamic nucleus & anterior limb of the internal capsule. A common fibre bundle (neural pathway) was associated with reduction of OCD symptoms irrespective of target. The response of any one participant could be accurately predicted based on the incorporation of this tract by the field of stimulation.	<a href="https://doi.org/10.1038/s41467-020-16734-3">https://doi.org/10.1038/s41467-020-16734-3</a>	3 <sup>rd</sup> July 2020
6.	Non-randomised trial examining neurocircuitry of response to DBS for OCD.  Replication of Li <i>et al.</i>	Smith <i>et al.</i> (2021). Replicable effects of deep brain stimulation for obsessive-compulsive disorder.  Brain Stimulation	10 participants with treatment-refractory OCD. Electrodes implanted in the ventral striatum and anterior limb of the internal capsule. Open-label stimulation. 7 of 10 participants had a clinically-significant response to stimulation with a mean reduction in OCD symptoms of 44%. Using the common fibre bundle identified in Li <i>et al.</i> , the response of individual participants to DBS could be predicted.	<a href="https://doi.org/10.1016/j.brs.2020.10.016">https://doi.org/10.1016/j.brs.2020.10.016</a>	1 <sup>st</sup> January 2021



	Type of study design	Title of journal article or research project	Short description of research	Website link to journal article or research	Date of publication
7.	Review of above RCTs	Visser-Vandewalle <i>et al.</i> (2022) Deep brain stimulation for obsessive-compulsive disorder: a crisis of access.  Nature Medicine	A review of the evidence base for DBS in treatment-refractory OCD written by an international group of neurosurgeons, neurologists and psychiatrists. The conclusion of the article is that DBS fulfils scientific and clinical criteria as an effective and safe therapy.	<a href="https://doi.org/10.1038/s41591-022-01879-z">https://doi.org/10.1038/s41591-022-01879-z</a>	15 <sup>th</sup> July 2022

17. Identify yet-to-be-published research that may have results available in the near future (that could be relevant to your application). Do not attach full text articles; this is just a summary.

	Type of study design	Title of research	Short description of research	Website link to research	Date
1.	Data Registry	Mosley <i>et al.</i> Data Registry of Deep Brain Stimulation for Obsessive-Compulsive Disorder  MRFF Research Data Infrastructure Grant Application  Application ID:MRFFRD000095	This project comprises investigators from each Australian centre offering DBS for OCD. We will construct a data registry to collate all previous and prospective cases of DBS for OCD. We will collect data on electrode placement, psychiatric outcomes and adverse events, in order to refine the efficacy and safety profile of this therapy. The outcomes of this registry will be publicly available via a web interface and de-identified neuroimaging data will be shared with scientific researchers for analysis. This project aligns with the guidance of the Royal Australian and New Zealand College of Psychiatrists in their most recent clinical memorandum on DBS: that i) DBS for OCD is now supported by worldwide evidence but ii) Given the limited number of persons eligible for and taking up this therapy, rigorous collection of outcome data for all cases is mandated.	N/A	Submitted February 2022  Grant outcomes expected Late 2022.  If grant successful, registry expected to be published 2024.

## PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

18. List all appropriate professional bodies/organisations representing the health professionals who provide the service. For **MBS-related applications ONLY**, please attach a brief 'Statement of Clinical Relevance' from the most relevant college/society.

Neurosurgical Society of Australasia

Australian and New Zealand Association of Neurologists

Royal Australian and New Zealand College of Psychiatrists

19. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):

Royal Australian and New Zealand College of Psychiatrists

20. List the consumer organisations relevant to the proposed medical service (noting there is **NO NEED** to attach a support letter at the 'Application Lodgement' stage of the MSAC process):

Beyond Blue

SANE

21. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:

Abbott

Boston Scientific

22. Nominate two experts that can be contacted about the proposed medical service, and current clinical management of the condition:

Name of expert 1: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **REDACTED**

Justification of expertise: **REDACTED**

Name of expert 2: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **REDACTED**

Justification of expertise: **REDACTED**

# PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

## **PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION**

### **23. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease (in terms of both morbidity and mortality):**

Obsessive-compulsive disorder (OCD) is a psychiatric condition with an estimated lifetime prevalence of between 1-2 %. OCD is characterised by the intrusion of ego-dystonic, anxiety-provoking thoughts, urges or images (obsessions), generally accompanied by repetitive mental acts or behaviours (compulsions), which are carried out to neutralise the obsessions, or to mitigate anxiety associated with them. The phenomenology of these obsessions is broad. People with OCD may be excessively concerned with germs, preoccupied with symmetry or disturbed by intrusive violent, sexual or religious thoughts. Compulsions such as cleaning, ordering, checking and repeating may consume waking hours. Secondary anxiety and depressive disorders are common. OCD typically develops in childhood and young adulthood and is highly impairing. The World Health Organisation rates OCD as a leading global cause of disability and the rate of suicide in OCD is increased by a factor of 10 over the general population.

The mainstay of treatment for OCD involves a combination of pharmacological (antidepressant) and psychological (cognitive behavioural therapy; CBT) approaches. However, many sufferers still have clinically-significant symptoms despite drug treatment even after augmented therapy with a combination of antidepressants and the addition of an atypical antipsychotic. The most effective psychological treatment for OCD involves deliberate exposure to anxiety-provoking situations with the expectation that this anxiety (and the need to maintain compulsive rituals) will habituate over time. However, individuals with severe OCD commonly find this process intolerable and cannot engage fully in treatment or else do not habituate despite persistent exposure. The net result is that there exists a subgroup of people with OCD who are treatment-refractory, remain highly-disabled and who have limited therapeutic options available to them to improve their quality of life. It is important to note that the number of individuals with very severe and highly treatment-refractory OCD qualifying for deep brain stimulation is likely to be low (see below) but these are some of the sickest people in Australian society, unable to work or sustain relationships, at high risk of suicide.

### **24. Specify the characteristics of patients with (or suspected of having) the medical condition, who would be eligible for the proposed medical service/technology (including details on how a patient would be investigated, managed and referred within the Australian health care system, in the lead up to being eligible for the service):**

Eligible patients would have a confirmed diagnosis of severe, treatment-refractory OCD made by a specialist psychiatrist. The minimum duration of the illness would be at least 5 years. The severity of the illness would be assessed using the Yale Brown Obsessive Compulsive Scale, which is a clinician-administered semi-structured interview and is the gold standard instrument for assessing people with OCD. A score of greater than 24/40 denotes a severe level of OCD symptoms and patients would be required to score above this threshold on 2 separate occasions at least 2 weeks apart. Treatment refractoriness would be confirmed with a corroborated history of treatment defined by insufficient response to at least: i) two trials of selective serotonin reuptake inhibitors at maximum tolerated dose for at least 12 weeks, ii) one trial of clomipramine at maximum tolerated dosage for at least 12 weeks, plus iii) one augmentation trial with an antipsychotic for at least eight weeks in combination with one of the aforementioned drugs, plus iv) one complete trial of exposure-based psychotherapy confirmed by a psychotherapist.

Individuals identified by their treating psychiatrist as potentially suitable for deep brain stimulation (DBS) would be referred to a deep brain stimulation centre, namely a dedicated, experienced unit with strong affiliations with multidisciplinary research teams. Currently, there are three such centres in Australia: i)

Royal Melbourne Hospital, Melbourne, ii) St Vincents Hospital, Melbourne and iii) St Andrews Hospital, Brisbane. At this unit the patient would be evaluated by a neurosurgeon, neurologist and neuropsychiatrist experienced in DBS. A report would be prepared for review by the Mental Health Review Tribunal (note, legislative requirements differ between states in Australia as regards neurosurgery for psychiatric disorders). The purpose of the tribunal is to convene an independent panel of experts to ensure that the treatment is appropriate and the patient has the capacity to voluntarily consent to the procedure. Once this is accomplished and approved by the tribunal, implantation of the DBS device can proceed.

#### **PART 6b – INFORMATION ABOUT THE INTERVENTION**

##### **25. Describe the key components and clinical steps involved in delivering the proposed medical service/technology:**

The patient is admitted to the DBS unit and undertakes a magnetic resonance imaging (MRI) scan of the brain. The DBS neurologist and neurosurgeon visualise the subcortical structures that are to be targeted by the DBS electrodes. Using planning software, the target is mapped using the patient's brain anatomy to define a trajectory for each electrode to pass safely through the skull and into the brain to reach the defined target. On the day of the surgery the patient is anaesthetised and a metal stereotactic frame is attached to the patients skull. A Computed Tomography (CT) brain scan (with the frame attached) is fused to the existing MRI scan with medical software. This fused image is used to calculate the precise three-dimensional intra-cranial coordinates of the surgical target. Still under general anaesthesia the neurosurgeon drills a small burr hole on each side of the patient's skull and passes a recording electrode along a pre-determined trajectory to the target structure. Accurate placement in the target is confirmed using intra-operative microelectrode recording of local field potentials, and later by briefly rousing the patient from anaesthesia. At this time, the neurologist can assess the effect of intra-operative stimulation on the patient and screen for any unwanted motor or sensory effects (such as facial pulling, gaze deviation or paraesthesia). Once accurate placement is verified, permanent stimulating electrodes are inserted and their final position is verified using another CT brain scan. In DBS for OCD, one electrode is placed in each hemisphere of the brain.

The implanted stimulating electrodes are routed subcutaneously and connected to a pulse generator sited in the pectoral or abdominal fascia. Each electrode comprises between four to eight contacts, any number of which can be activated to deliver a small, focussed and continuous field of electricity in the local neural tissue. In the electrical circuit, the charge is delivered by means of at least one positive (anodal) and one negative (cathodal) terminal. Initially, the device is programmed with one contact as the cathode and the pulse generator as the anode, a configuration known as '*monopolar*'.

The DBS device is activated at a low level intra-operatively and the patient is moved to the intensive care unit for twenty-four hours, before returning to the surgical ward. Although an optimal contact has been identified in theatre, the lead neurologist reviews the patient several times per day during this time to corroborate the tolerability of therapy and to trial alternative contacts if necessary. Recovery from functional neurosurgery is relatively swift and persons with OCD are typically discharged home within 2-3 days of DBS device implantation.

Patients with OCD return to the clinic weekly to fortnightly during the initial postoperative months and are reviewed by the DBS clinicians including the unit psychiatrist. The DBS device is programmed to give greater stimulation amplitude at the chosen contact. This occurs non-invasively through a computer that communicates with the pulse generator in the patient's chest wall. Increases in stimulation are guided by the patient's level of symptom relief and the emergence of side effects. It may take six to twelve months to find the optimal stimulation parameters, with the slow accrual of benefits during this time. The patient's usual psychotropic medication is continued during this time.

##### **26. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?**

No.

**27. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?**

No.

**28. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency)?**

Not applicable.

**29. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:**

The implantation of the DBS device is a surgical procedure delivered in an inpatient hospital setting. It involves neurosurgery, neurology, psychiatry, radiology, anaesthetic and intensive care physicians.

**30. If applicable, advise which health professionals will primarily deliver the proposed service:**

The targeting and implantation of the DBS system is delivered by a neurosurgeon and neurologist working in tandem. The follow up of the patients and programming of the device is delivered by a psychiatrist experienced in neurostimulation.

**31. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:**

Not applicable.

**32. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:**

Deep brain stimulation in Australia is only carried out in large, tertiary centres with appropriately-experienced multidisciplinary teams comprising neurosurgery, neurology, psychiatry and allied health clinicians. Deep brain stimulation for psychiatric indications has only been carried out at three centres: i) Royal Melbourne Hospital, Melbourne, ii) St Vincents Hospital, Melbourne and iii) St Andrews Hospital, Brisbane.

**33. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:**

Deep brain stimulation is only carried out by specialist neurosurgeons and specialist neurologists with relevant additional training and experience in functional neurosurgery.

**34. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):**

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

**(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:**

The deep brain stimulation system is implanted in an inpatient hospital but follow up and device adjustment takes place as an outpatient.

**35. Is the proposed medical service intended to be entirely rendered in Australia?**

- Yes  
 No – please specify below

**PART 6c – INFORMATION ABOUT THE COMPARATOR(S)**

**36. Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service):**

Severe obsessive-compulsive disorder (OCD) is currently managed by psychiatrists and clinical psychologists in the Australian health care system.

Pharmacological therapy for OCD comprises antidepressant therapy with serotonergic agents (selective serotonin reuptake inhibitors or the tricyclic antidepressant clomipramine). These may be augmented with an atypical antipsychotic. Clomipramine is regarded as the most effective drug treatment for OCD. It is often not used first line as it has anticholinergic properties that cause side effects such as dry mouth, constipation and urinary retention.

Effective psychological therapy comprises ‘*exposure and response prevention*’. In this style of therapy, the patient learns to gradually and deliberately place themselves in situations that trigger their obsessive fears, but without performing a neutralising compulsion. For example, a patient with contamination fears may progress over the course of therapy from being able to touch a chair and not wash their hands to being able to touch a toilet and not wash their hands. The principle is that the fear response central to OCD ‘*habituates*’ as the patient challenges themselves.

It is important to note that we propose that deep brain stimulation only be available if people with OCD *continue* to have severe and disabling symptoms *despite* adequate trials of these therapies. There are some individuals who, despite high dose pharmacotherapy and repeated courses of psychotherapy, are unable to habituate their fear responses and cannot attenuate their compulsive behaviour.

**37. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?**

- Yes (please list all relevant MBS item numbers below)  
 No

300, 302, 304, 306, 308 – provision of outpatient care by a psychiatrist

80100 – provision of focussed psychological care by a psychologist

**38. (a) Will the proposed medical service/technology be used in addition to, or instead of, the nominated comparator(s)?**

- In addition to (i.e. it is an add-on service)  
 Instead of (i.e. it is a replacement or alternative)

**(b) If yes, please outline the extent to which the current service/comparator is expected to be substituted**

We do not consider deep brain stimulation a substitution but an add-on for the small number of persons who remain highly treatment-refractory. In fact, published research has shown that DBS is synergistic with ongoing psychotherapy, through allowing patients to make gains with exposure and response prevention when previously their fear response did not habituate.

**PART 6c CONTINUED – INFORMATION ABOUT ALGORITHMS (CLINICAL MANAGEMENT PATHWAYS)s**

**39. Define and summarise the CURRENT clinical management pathway (algorithm) that patients follow when they receive the COMPARATOR service (i.e. the landscape before the proposed service is introduced). An easy-to-follow flowchart is preferred, depicting the current clinical management pathway), but dot-points would be acceptable. Please include health care resources used in the current landscape (e.g. pharmaceuticals, diagnostics and investigative services, etc.).**

1. Person is diagnosed with obsessive-compulsive disorder (OCD) by a psychiatrist.
2. Severity of symptoms is rated with the Yale Brown Obsessive-Compulsive Scale (Max score 40, score above 24 considered severe).
3. Pharmacological therapy is introduced and titrated to the maximum tolerated dose. First line medications include serotonergic antidepressants (selective serotonin reuptake inhibitors).
4. If the patient has residual symptoms the antidepressant is switched to another agent, or an atypical antipsychotic is combined with the antidepressant as an augmentation strategy.
5. If the patient has residual symptoms the tricyclic antidepressant clomipramine is trialled. Serum levels of clomipramine and its metabolites are used to define the appropriate therapeutic dose.
6. Alongside trials of medication, psychotherapy is instituted using the principles of exposure and response prevention. This is typically carried out by a clinical psychologist.
7. If the patient fails to respond and continues to exhibit severe symptoms, iterative trials of antidepressants, antipsychotics and psychotherapies are continued, often with diminishing returns.

**40. Define and summarise the PROPOSED clinical management pathway (algorithm) that patients would follow after the proposed service/technology is introduced, including variation in health care resources.**

1. Persons with severe obsessive-compulsive disorder (OCD) who had not responded to trials of at least two selective serotonin reuptake inhibitors, one trial of clomipramine, one trial of antipsychotic and at least one complete course of psychotherapy would be referred to a deep brain stimulation (DBS) unit for evaluation.
2. Clinicians at the DBS unit would confirm eligibility criteria and prepare a report for an independent mental health review tribunal.
3. The mental health tribunal would review the suitability of the candidate and their capacity to consent voluntarily.
4. With approval of the tribunal, the patient would undertake DBS device implantation and initial follow up would be conducted by the psychiatrist at the DBS centre, who would program the device.
5. Pharmacological therapy and psychotherapy would continue even after DBS device implantation. Published research has shown that one of the effects of DBS is to allow patients to accrue benefit from the psychotherapy – with a habituation of the fear response and ability to suppress compulsive rituals.

**PART 6d – INFORMATION ABOUT CLINICAL OUTCOMES**

**41. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):**

There are now four randomised, placebo-controlled, double-blind trials demonstrating the efficacy of deep brain stimulation (DBS) for severe, treatment-refractory obsessive-compulsive disorder (OCD), including in an Australian cohort, in addition to numerous open-label studies and studies characterising the neural basis of this beneficial effect. We propose that DBS is an accepted, evidence-based therapy for individuals with treatment-refractory OCD, with treatment refractoriness defined as a failure of adequate pharmaco- and psychotherapy. We consider that amongst those individuals who have failed to respond to best medical and psychological treatment and who still have severe symptoms, DBS has a high likelihood of delivering a clinically-significant benefit defined as a reduction in key symptoms of OCD.

There are risks associated with DBS that must be carefully considered, commensurate with it involving neurosurgery and implantation of a medical device. Intracerebral haemorrhage is rare but has been reported as a serious adverse event (less than 1% risk). The most common surgical complication is infection of the DBS system (2-5% risk), which although not typically life threatening, necessitates removal of the device and a course of intravenous antibiotics before re-implantation can be considered.

The implantation of the DBS system is a costly procedure. However, it is likely that the cost of this surgery is mitigated by the reduction in ongoing intensive psychiatric and psychological care, improved occupational functioning and reduced reliance on welfare. There are economic analyses in support of this contention (e.g. Ooms et al. 2017, Cost Effectiveness of DBS versus treatment as usual for OCD. Brain Stimulation).

**42. Please state what the overall clinical claim is:**

In persons with severe, treatment-refractory obsessive-compulsive disorder (OCD) who have not responded to sequential trials of medication and psychotherapy, deep brain stimulation reduces symptoms of OCD as assessed by the Yale Brown Obsessive-Compulsive Scale. Outcomes from active stimulation are superior to placebo (sham) and the response to DBS is durable.

**43. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator):**

Reduction in symptoms of obsessive compulsive disorder

Reduced rate of suicide

Increased rate of employment

Reduced use of psychiatric and psychological services



## PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

### **44. Estimate the prevalence and/or incidence of the condition in the proposed population:**

The prevalence of obsessive-compulsive disorder is estimated to be 1-2% in the general population. After appropriate treatment with an antidepressant and psychotherapy, the number of persons with residual symptoms has been estimated at 30% and following three consecutive pharmacotherapies and psychotherapy this number falls to 10%. In an American naturalistic sample, 1% of cases with OCD met the accepted eligibility criteria for deep brain stimulation – i.e. severe residual symptoms despite appropriate and adequate consecutive trials of pharmacotherapy and psychotherapy.

### **45. Estimate the number of times the proposed medical service/technology would be delivered to a patient per year:**

The implantation of the deep brain stimulation device is a once only procedure. Rarely (in approximately 2-5% of cases) an infection of the device necessitates hardware explantation, treatment with antibiotics and reimplantation at a later date. The device is programmed quite intensively (every 1-2 weeks) at the commencement of treatment but typically stable stimulation settings are obtained after 6-months and thereafter device programming is generally not carried out at a greater frequency than 6-monthly. The battery in the pulse generator depletes after 2-5 years and replacement is carried out as a day case procedure. Most device manufacturers are now making rechargeable devices that have a much longer lifespan.

### **46. How many years would the proposed medical service/technology be required for the patient?**

Treatment is ongoing and lifelong.

### **47. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:**

We estimate a low number = 5.

### **48. Estimate the anticipated uptake of the proposed medical service/technology over the next three years, factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors), as well as provide commentary on risk of 'leakage' to populations not targeted by the service.**

We anticipate that there will be a limited uptake of this therapy in Australia for two reasons. Firstly, deep brain stimulation is only intended to be used in this psychiatric population amongst those who are severely ill and highly treatment-refractory. Most people do not wish to consider neurosurgery unless they are highly disabled by their symptoms. Secondly, at present there are only a handful of multidisciplinary teams with the expertise to conduct this procedure (detailed elsewhere in this document). It is conceivable that these groups will have a role in training other centres (for example in South Australia and Western Australia) but any new centres will be required to develop their teams and workflow and this will take time. However, we still believe that the proposed amendment to the DBS item numbers is a worthwhile endeavour because these cases, however few, are some of the sickest individuals in Australia and absolutely debilitated by their symptoms.

## PART 8 – COST INFORMATION

**49. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:**

Item 40851 – Insertion of deep brain stimulation device by neurosurgeon = \$4,123.60

Item 40852 – Subcutaneous placement of pulse generator = \$354.40

Item 40858 – Placement of extension lead = \$547.70

Item 40860 – Target localisation (bilateral) = \$3,156.98

Item 40862 – Programming of DBS device (bilateral) = \$295.50 (estimate 20 programming sessions to optimise stimulation settings = \$5910

Cost of DBS hardware estimated at \$35,000

Total cost = \$49,092.68

**50. Specify how long the proposed medical service/technology typically takes to perform:**

The patient is admitted to hospital for a typical duration of 3-4 days. The surgical procedure itself takes 3-4 hours to perform in the hands of an experienced surgical team. Each subsequent programming session takes approximately 30-60 minutes to perform.

**51. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and usage characteristics that defines eligibility for the medical service/technology.**

Please note – we are proposing an amendment to all item numbers specified in question 7c. Thus, as an exemplar we provide an amendment for item 40862. We propose all item numbers in 7c be updated in the same manner.

Category 3 – Therapeutic Procedures
<p>40862</p> <p>Proposed item descriptor: DEEP BRAIN STIMULATION (unilateral) electronic analysis and programming of neurostimulator pulse generator for the treatment of:</p> <p>Parkinson’s disease where the patient’s response to medical therapy is not sustained and is accompanied by unacceptable motor fluctuations; or</p> <p>Essential tremor or dystonia where the patient’s symptoms cause severe disability; or</p> <p><i>Severe obsessive-compulsive disorder where the patient has a Yale-Brown Obsessive Compulsive Scale Score of greater than 24/40 despite two trials of selective serotonin reuptake inhibitors, one trial of augmentation with an atypical antipsychotic, one trial of clomipramine and at least one complete course of psychotherapy incorporating exposure and response prevention.</i></p> <p>Fee: \$197.40</p>

**52. If public funding is sought through an alternative (non-MBS) funding arrangement, please draft a service description to define the population and usage characteristics that defines eligibility for the service/technology.**

N/A