



Australian Government

Department of Health

RATIFIED PICO

Application 1595:

**Closed-loop upper airway stimulation (UAS)
for moderate to severe obstructive sleep
apnoea (OSA), for patients who have failed
or are intolerant to continuous positive
airway pressure (CPAP)**

Summary of PICO/PPICO criteria to define the question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Component	Description
Patients	Patients aged ≥ 18 years with a BMI ≤ 32 kg/m ² and moderate to severe obstructive sleep apnoea (OSA), defined as having an Apnoea Hypopnea Index (AHI ^a) ≥ 15 and ≤ 65 , and who have been confirmed to have failed or cannot tolerate continuous positive airway pressure (CPAP) therapy or bi-level positive airway pressure (BIPAP) therapy. Patients with total concentric collapse at the soft palate level are not eligible.
Intervention	Implantation of an Upper Airway Stimulator System, including a respiratory sensing lead that senses breathing patterns, which is linked to an implantable pulse generator that delivers mild stimulation to the hypoglossal nerve via a stimulation lead.
Comparator	Main comparator: Conservative medical management (e.g. weight and alcohol reduction; sleep hygiene). Supplementary comparator: Upper airway surgical procedures, such as uvulopalatopharyngoplasty (UPPP). <i>Note: PASC determined that bariatric surgery^b is <u>not</u> adjunctive in the treatment of OSA in obese patients, given the restriction of the eligible population to those with a BMI ≤ 32 kg/m².</i>
Outcomes	<p>Efficacy/effectiveness</p> <ul style="list-style-type: none"> • Apnoea Hypopnoea Index (AHI) • Oxygen Desaturation Index (ODI) • Quality of Life <ul style="list-style-type: none"> ○ Epworth Sleepiness Scale (ESS) ○ Functional Outcomes of Sleep Questionnaire (FOSQ) <p>Safety</p> <ul style="list-style-type: none"> • Procedure related adverse events • Device related adverse events • Other adverse events <p>Healthcare resources</p> <ul style="list-style-type: none"> • Cost to deliver intervention <ul style="list-style-type: none"> ○ Subcutaneous placement of electrical pulse generator ○ Surgical placement of lead and connection to hypoglossal nerve ○ Surgical placement of respiratory sensing lead ○ Surgical repositioning or removal of electrical pulse generator <p>Total Australian Government Healthcare costs</p> <ul style="list-style-type: none"> • Total cost to the Medicare Benefits Schedule (MBS) • Total cost to other healthcare services

^a Apnoea Hypopnea Index measures the number of apnoea episodes per hour of sleep

^b Australian Guidelines for bariatric surgery suggest individuals with a BMI of 40kg/m², or with a BMI of 35kg/m² and one or more obesity-related complications should be eligible for surgery (1)

Current and Proposed Clinical Management Algorithms

PASC noted consultation feedback that DISE is not routinely used in Australia to select patients for OSA surgery. Confirmation (and justification) is needed if DISE will routinely be used to select patients for UAS, with associated reflection in the current and proposed algorithms.

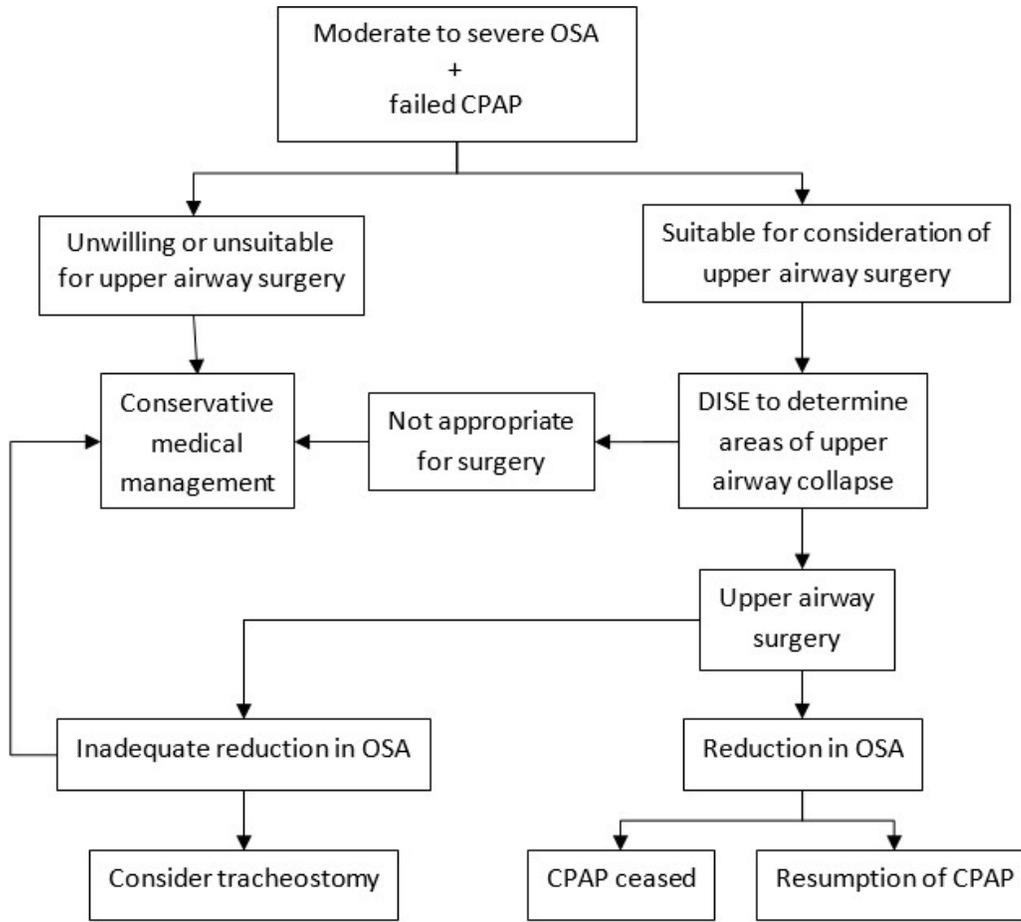
Current clinical management algorithm for identified population

The clinical pathway for patients who fail CPAP may be complex (Figure 5). Patients who are considered unsuitable or unwilling to have surgery may be managed conservatively by a sleep physician. Management may consist of lifestyle modifications such as weight loss, decrease in alcohol use and sleep position modification.

Some patients may be considered for upper airway surgery. A variety of upper airway surgeries exist, although only UPPP and maxillomandibular advancement (MMA) are specifically included on the MBS. MMA is rarely used to treat OSA although patients who have particular anatomic characteristics such as a receding chin may be suitable.(17)

Patients considered for UPPP must be carefully selected so surgery is targeted appropriately. Therefore, a DISE must be conducted prior to surgery. Patients may still use CPAP following surgery, as surgery may assist in increasing the tolerance and success of CPAP. Patients who fail surgery have limited options. Tracheostomy is rarely used but is a definitive treatment for OSA as the upper airway is bypassed, otherwise patients will continue to be conservatively managed.

Figure 5. Current clinical management algorithm



CPAP = continuous positive airway pressure treatment; DISE = drug induced sleep endoscopy; OSA = obstructive sleep apnoea

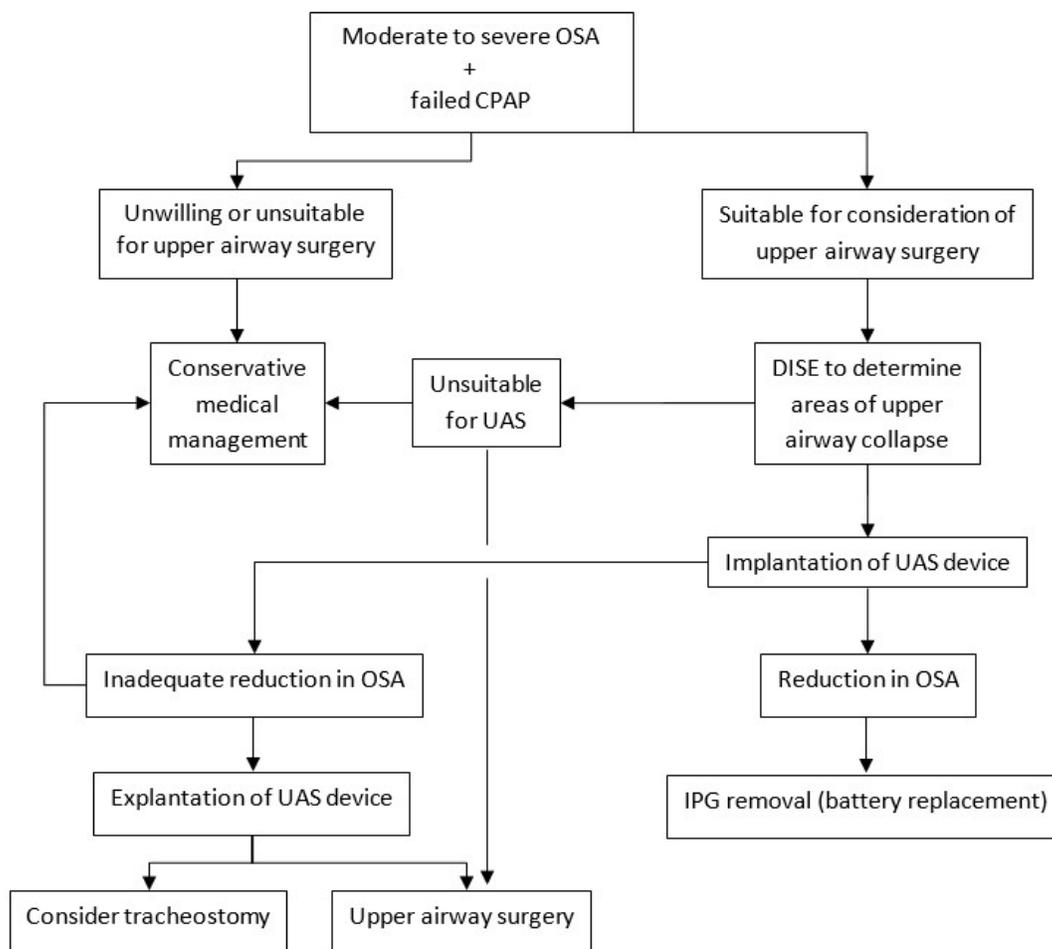
Note: (1) Bariatric surgery has been ruled out as adjunctive in the treatment of OSA in obese patients.

(2) The use of DISE needs to be confirmed and justified if it will routinely be used to select patients for UAS, with associated reflection in the current and proposed algorithms.

Proposed clinical management algorithm for identified population

The pathway following implementation of Inspire® therapy is similar to that following (UPPP) surgery or conservative management (Figure 6). However, it is unlikely that patients would use CPAP, as is the case with some patients following (UPPP) surgery. It is possible that some patients might proceed to surgery, although this is likely to be a smaller number than in the absence of closed-loop UAS, and in extreme cases, tracheostomy may be considered. Non-responders would likely be treated with conservative medical management.

Figure 6. Proposed clinical management algorithm



CPAP = continuous positive airway pressure treatment; DISE = drug induced sleep endoscopy; IPG = implantable pulse generator; OSA = obstructive sleep apnoea; UAS = upper airway stimulation

Note: (1) Bariatric surgery has been ruled out as adjunctive in the treatment of OSA in obese patients.

(2) The use of DISE needs to be confirmed and justified if it will routinely be used to select patients for UAS, with associated reflection in the current and proposed algorithms.

Proposed economic evaluation

PASC confirmed the economic evaluation should be a cost-utility analysis, unless evidence of superiority is not demonstrated.

PASC noted significant equity issues, including the requirement for access to a multidisciplinary team and specialist surgical services, and the shortage of practitioners. There is potential for out-of-pocket costs for patients, and possible substantial cost implications if there is a gap between MBS and PLAC listings.

The applicant has advised it does not intend to launch the device in the private sector prior to Prostheses Listing, meaning out-of-pocket costs for the device are unlikely to arise. However, PASC's concern about other out-of-pocket costs should be discussed/addressed in the assessment report, especially given demand for the service is likely to exceed supply.

Category 3 – Therapeutic Procedures	
YYYYY	<p>Proposed item descriptor: Unilateral closed-loop hypoglossal nerve stimulation therapy with Inspire® Upper Airway Stimulation System through stimulation of the hypoglossal nerve, surgical placement of lead, including connection of lead to the hypoglossal nerve and intra-operative test stimulation for management of moderate to severe obstructive sleep apnoea in a patient who:</p> <p>a) has an Apnoea Hypopnoea Index of greater than 15 and less than 65; and</p> <p>b) is aged 18 and over; and</p> <p>c) has failed or is intolerant to continuous positive airway pressure therapy; and</p> <p>d) has a BMI \leq 32 kg/m²; and</p> <p>e) does not have complete concentric collapse of the upper airway.</p> <p>Once only per patient</p> <p>Multiple Operation Rule (Anaes.)</p> <p>MBS Fee: \$684.95 Benefit: 75% = \$513.75 (in-hospital/admitted patient only)</p>

Category 3 – Therapeutic Procedures	
ZZZZZ	<p>Proposed item descriptor: Unilateral closed-loop hypoglossal nerve stimulation therapy with Inspire® Upper Airway Stimulation System through stimulation of the hypoglossal nerve, surgical placement of respiratory sensing lead and intra-operative test stimulation for management of moderate to severe obstructive sleep apnoea in a patient who:</p> <p>a) has an Apnoea Hypopnoea Index of greater than 15 and less than 65; and</p> <p>b) is aged 18 and over; and</p> <p>c) has failed or is intolerant to continuous positive airway pressure therapy; and</p> <p>d) has a BMI \leq 32 kg/m²; and</p> <p>e) does not have complete concentric collapse of the upper airway.</p> <p>Once only per patient</p> <p>Multiple Operation Rule (Anaes.)</p> <p>MBS Fee: \$684.95 Benefit: 75% = \$513.75 (in-hospital/admitted patient only)</p>

Category 3 – Therapeutic Procedures	
AAAAA	<p>Proposed item descriptor: Unilateral closed loop hypoglossal nerve stimulation therapy with Inspire Upper Airway Stimulation System through stimulation of the hypoglossal nerve, surgical repositioning or removal of electrical pulse generator, inserted for management of moderate to severe obstructive sleep apnoea in a patient who:</p> <p>a) has an Apnoea Hypopnoea Index of greater than 15 and less than 65; and</p> <p>b) is aged 18 and over; and</p> <p>c) has failed or is intolerant to continuous positive airway pressure therapy; and</p> <p>d) has a BMI \leq 32 kg/m², and</p> <p>e) does not have complete concentric collapse of the upper airway.</p>

Category 3 – Therapeutic Procedures	
Once only per patient	
Multiple Operation Rule (Anaes.)	
MBS Fee: \$161.95	Benefit: 75% = \$121.50 (in-hospital/admitted patient only)

In line with PASC’s advice, an MBS Explanatory Note should be considered, outlining the requirement for clinical expertise and patient management within a multidisciplinary environment.

Consultation feedback

PASC noted the consultation feedback, highlighting the importance of:

- BMI restriction in trials;
- importance of multi-disciplinary care; and
- importance of appropriate selection for type of surgery or UAS.

PASC also noted the feedback that early research was underway to investigate use of UAS in children, and those with complete collapse.

Next steps

Upon ratification of PICO 1595, the application can PROCEED to the pre-Evaluation Sub-Committee (ESC) stage.

The applicant has elected to prepare its own ADAR (applicant-developed assessment report).

References

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