Australian Government

Department of Health

Application

1515 - Endoscopic placement and removal of an intra-gastric balloon (IGB) for the management of overweight and obesity, in a high-risk patient group who have failed first line treatments

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):
Corporation name: REDACTED
ABN: REDACTED
Business trading name: REDACTED

Primary contact name: REDACTED

Primary contact numbers
Business: REDACTED
Mobile: REDACTED
Email: REDACTED

Alternative contact name: REDACTED

Alternative contact numbers
Business: REDACTED
Mobile: REDACTED
Email: REDACTED

2. (a) Are you a consultant acting on behalf of an Applicant?

☐ Yes
☒ No

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

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?

☐ Yes
☐ No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

4. Application title

Endoscopic placement and removal of an intra-gastric balloon (IGB) for the management of overweight and obesity, in a high-risk patient group who have failed first line treatments.

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)

Obesity is a worldwide epidemic; obesity is defined as BMI > 3035 kg/m^2. This application focuses on the population with a BMI≥30< 35 kg/m^2 accompanied with other major medical conditions such as high blood pressure and diabetes (with the key focus being on patients with uncontrolled diabetes). The life expectancy of this group of obese adult is 2-4 years lower than those with normal weight (ANPHA, PSC 2009).
Obesity is a complex chronic disease with genetic, environmental, physiological and behavioural determinants that requires long-term care. In 2014-15, 63.4% of Australians aged ≥18 years were above normal weight, with 27.9% being obese (ABS cat 4364.0.55.001). It is estimated that ≈15% of Australians have a BMI≥30< 35 kg/m^2 (see Table 1). Obesity is often associated with a broad range of complications including type 2 diabetes, cardiovascular disease, dyslipidaemia, sleep apnoea, osteoarthritis, and specific cancers, which significantly impair quality of life. The total burden of disease due to obesity, as reported in the Medibank Obesity Report, was $37.7 billion in 2008-09. The latest Price Waterhouse Coopers report estimated the downstream effects of obesity on other health care costs, productivity etc., in 2014-15 to be at $8.6 billion.

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).

The intra-gastric balloon (IGB) system is designed to assist weight loss by partially filling the stomach and inducing satiety. The balloon is placed in the stomach endoscopically and then filled with saline, causing it to expand into a spherical shape. The filled balloon is designed to act as an artificial bezoar and move freely within the stomach. The maximum placement period for the intra-gastric balloon is 6 months, and it must be removed at that time or earlier. This submission is focused on evidence pertaining to Orbera™, but the MBS item codes requested are not restricted to a particular IGB device.

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:

NA

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

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

NA

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

i. ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. ☒ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
iii. ☐ A new item for a specific single consultation item
iv. ☐ A new item for a global consultation item(s)

An MSAC review of IGB was undertaken in 2008. However, the nominated population was different to the one seeking new MBS items numbers in this submission. The benefits of weight loss in obese people is not novel to Australian clinical practice; but its safety, effectiveness and cost-effectiveness in the proposed patient population have not previously been evaluated by MSAC, nor is there an MBS item (current or former) that specifically describes the proposed service. In this way, the service and therapeutic intervention it describes is new to the MSAC.

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

☐ Yes
☒ No

(g) If yes, please advise:

NA

8. What is the type of service:

☒ 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)*:

i. ☐ To be used as a screening tool in asymptomatic populations
ii. ☐ Assists in establishing a diagnosis in symptomatic patients
iii. ☐ Provides information about prognosis
iv. ☐ Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. ☐ Monitors a patient over time to assess treatment response and guide subsequent treatment decisions
vi. ☐ Is for genetic testing for heritable mutations in clinically affected individuals and, when also appropriate, in family members of those individuals who test positive for one or more relevant mutations (and thus for which the Clinical Utility Card proforma might apply)

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?

☐ Yes
☒ No

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

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

☐ Yes (please provide PBAC submission item number below)
☒ No

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

Trade name: Not relevant
Generic name: Not relevant

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

☐ Yes
☒ No

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

Billing code(s): NA
Trade name of prostheses: NA
Clinical name of prostheses: NA
Other device components delivered as part of the service: NA

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

☐ Yes
☒ No

(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?

☒ Yes
☐ No

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

Spatz3 Balloon: ARTG 174506; Emergo Asia Pacific Pty Ltd – T/a Emergo Australia

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

- Prince Medical Aspirating Needle - Product Code AS2640718; ARTG entry 163942
- Prince Medical Extraction Forceps - Product Code AS2290718; ARTG entry 163943

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

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

Type of therapeutic good: Medical Device Included Class IIb
Manufacturer's name: REDACTED
Sponsor's name: REDACTED

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

☐ Class III
☐ AIMD
☒ N/A

15. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

☐ Yes (If yes, please provide supporting documentation as an attachment to this application form)
☒ No

16. (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

☒ Yes (if yes, please provide details below)
☐ No

ARTG listing, registration or inclusion number: 226685

TGA approved indication(s), if applicable: Not applicable.

TGA approved purpose(s), if applicable: The system is a gastric balloon inflated in the stomach for temporary use in weight-loss therapy in patients meeting criteria based on Body Mass Index (BMI) and applicable health reasons, as specified. The system works by creating a feeling of satiety and delayed gastric emptying, reducing the desire for food. Patients are to be evaluated and the system removed or replaced every six months (180 days).

17. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

☐ Yes (please provide details below)
☐ No

Date of submission to TGA: NA
Estimated date by which TGA approval can be expected: NA
TGA Application ID: NA
TGA approved indication(s), if applicable: NA
TGA approved purpose(s), if applicable: NA

18. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

☐ Yes (please provide details below)
☐ No

Estimated date of submission to TGA: NA
Proposed indication(s), if applicable: NA
Proposed purpose(s), if applicable: NA

PART 4 – SUMMARY OF EVIDENCE

19. **Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only).** ***Please do not attach full text articles, this is just intended to be a summary.***

Obesity Class 1: BMI ≥30<35 kg/m^2 who have comorbidities and who have failed first line treatments.

Device of Interest: Intragastric Balloon – Orbera™ (BIB)

Comparator – placebo/do nothing/watch and wait in people with a BMI ≥30 <35 kg/m^2

Secondary comparators: lifestyle modifications/exercise or pharmacotherapy (that is first line treatments) or surgery can be utilised as secondary comparators that can be used in a common comparator analysis, were an indirect analysis deemed to be appropriate.

The columns labelled **Class 1** (relevant population), **2** (which relates to BMI ≥35 <40 with comorbidity) and **3** (BMI ≥40) relate to obesity class and are used to identify the types of patients included. Only studies with patients from class 1 are relevant. However, despite some studies not analysing data by class, there are benefits in presenting such data as supplementary, and therefore these further studies are also included in the table below.

Following a comprehensive review, it was identified that very few studies included only BMI ≥30<35 kg/m^2 or reported results separately for the <35 BMI group. The key focus was on Orbera™ studies (though the search terms included intragastric balloon as a search term) randomised and non-randomised studies) including BMI 30-40 are listed, plus meta-analyses of Orbera™ studies.

While bariatric surgery is not a comparator in the BMI ≥30<35 kg/m^2 group, Orbera™ vs. bariatric surgery and bariatric surgery vs. lifestyle randomised studies that include some patients in the BMI≥30 <35 kg/m^2 range are presented as supplementary data. In a similar light, studies reporting on pharmacotherapy were included (though only 1 was identified).

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
1	IGB + lifestyle vs. lifestyle (Equivalent to IGB vs. placebo)	Courcoulas, A., B. K. Abu Dayyeh, L. Eaton, J. Robinson, G. Woodman, M. Fusco, V. Shayani, H. Billy, D. Pambianco and C. Gostout (2017). "Intragastric balloon as an adjunct to lifestyle intervention: A randomized controlled trial." International Journal of Obesity 41(3): 427-433.	X ~50%	X ~50%	-	IGB plus lifestyle (n = 125) vs. lifestyle alone (n = 130). IGB at baseline: mean age 38.7 ± 9.4 y, mean BMI 35.2 ± 3.17 kg/m2, mean EW 28.4 ± 10.0 kg). BMP at baseline: mean age 40.8 ± 9.6 y, mean BMI 35.4 ± 2.7 kg/m2, mean EW 28.7 ± 8.1 kg) in this group. At 26 weeks (IGB removal), 71.8% of the IGB + lifestyle subjects achieved ≥ 25% EWL with a mean percent total body weight loss (%TBL) for the group of 10.5% ± 6.6 compared to 31.9% of subjects in the lifestyle alone group achieving ≥ 25% EWL with a mean %TBL of 4.7% ± 5.1 ($p < 0.001$; ITT analysis). At 52 weeks (26 weeks after IGB removal), 45.9% of the IGB + lifestyle subjects achieved ≥ 25% EWL with a mean %TBL for the group of 7.7% ± 7.65 compared to 32.6% of subjects in the BMP achieving ≥ 25% EWL with mean %TBL of 3.9 ± 6.1 ($p < 0.001$, ITT analysis). Lifestyle = a 12-month lifestyle program that incorporated: a low calorie (1000–1500 calories per day) diet, daily food and exercise diary, encouragement to exercise and emphasis on behavioural change during a total of 21 visits (9 visits in months 1–6, 12 visits in months 7–12).	https://www.ncbi.nlm.nih.gov/pubmed/28017964	2017 Abstract published as: Abu Dayyeh, et al; Gastro-intestinal Endoscopy 2015: 81(5 SUPPL. 1): AB147.

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
2	IGB + behavioural modification vs. behavioural modification (Equivalent to IGB vs. placebo.)	Fuller, N. R., S. Pearson, N. S. Lau, J. Wlodarczyk, M. B. Halstead, H. P. Tee, R. Chettiar and A. J. Kaffes (2013). "An intragastric balloon in the treatment of obese individuals with metabolic syndrome: A randomized controlled study." Obesity 21(8): 1561-1570.	X	X	-	N=66 (BMI: 30-40 kg/m2; mean 36) were randomized to IGB for 6 months, with a 12-month behavioural modification (IGB Group; ''IGBG'', N=31), or 12 month behavioural modification alone (Control Group; ''CG'', N=35). The primary outcome was percentage change in body weight. Results: At 6 months, there was a significantly greater weight loss in the IGBG: -14.2 vs. -4.8; P < 0.0001. Significantly greater reduction in waist circumference, and an improvement in quality of life, with a trend for a larger % metabolic syndrome remission (50% vs.30%; NS). At month 12, the differences in weight loss were enduring: -9.2 vs. -5.2; P=0.007. Behavioural modification: At baseline, the study dietitian/exercise physiologist provided each subject with a written guide as to the specific types of foods and the quantities which could be consumed, in addition to a tailored exercise program. Each subject also received a pedometer and was encouraged to walk at least 10,000 steps daily.	https://www.ncbi.nlm.nih.gov/pubmed/?cmd=HistorySearch&querykey=7	2013

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
3	Prospective (non-randomised) case-control study. IGB vs. no intervention	Gomez, V., G. Woodman and B. K. Abu Dayyeh (2016). "Delayed gastric emptying as a proposed mechanism of action during intragastric balloon therapy: Results of a prospective study." Obesity 24(9): 1849-1853.	X	X	-	N=29, IGB group N=15, Control N=14. Mean age 38 yr, Baseline: IGB: BMI 34.7±3.42, Control BMI 35.6±2.84 (BMI 30-40 eligible). At baseline, 1- and 2-h gastric retention values were comparable between the groups but increased in the IGB group at weeks 8 and 16 (during IGB treatment) and then returned to baseline levels at 27 and 39 weeks. Total WL% at 26 weeks (time of balloon removal) and 52 weeks (28 weeks) after balloon removal), was -14±7.8 versus -5.4 ±4 (P=0.003) and -10.6±7.9 versus -3.3±5 (P=0.01), respectively for IGB vs. control.	https://www.ncbi.nlm.nih.gov/pubmed/?cmd=HistorySearch&querykey=13	2016
4	Prospective cohort study, pre-test vs. post-test comparison	Benamouzig R, Uzzan B, Airinei G, et al. Effects of intragastric balloon on weight loss, physical activity, plasma leptin and ghrelin in obese patients, with long-term follow-up. Journal of Gastroenterology and Hepatology Research. 2013;2(8):744-749.	X	X	-	Adults BMI> 30 kg/m^2 with at least 1 co-morbidity, or BMI > 35 kg/m2 (N=67). Mean BMI of 36.6±3.3 kg/m^2. Results: EWL of 40.0±4.9 % before balloon to 31.3±7.7% after 6 months with balloon (p=0.0001); an EWL of 30.8% ±17.8%. EWL≥30% at 6 mth was 52% (35/67). Long-term follow-up at median 53 mth (N=29, 46% of total): EWL ≥30% was 31% (9/29).	http://www.ghrnet.org/index.php/joghr/article/view/457/342	2013

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
5	Prospective cohort, pre-test vs. post-test comparison Reports results for 30-35 BMI subgroup.	Herve, J., Wahlen, C.H., et al. (2005). "What becomes of patients one year after the intragastric balloon has been removed?" Obes Surg 15(6): 864-870.	X	X	X	N=100 with IGB inserted, Mean BMI = 34.03 kg/m^2, (range 25.3–60.2), Mean age = 34.8 years, Co-morbidities (Listed), presented in up to 28%. Results at 6 mth: Overall mean weight loss = 12 kg, Overall mean %EWL = 39.8%, **Baseline BMI 30-34.9: Mean weight loss = 11.7 kg 6 mth, 7.8 12 mth, Mean %EWL = 41.2 6 mth, 27.1 12mth** Baseline BMI 35-39: Mean weight loss = 16.6 kg 6mth, 11.1kg 12 mth, Mean %EWL = 42.4% 6mth, 26.4% 12mth. Baseline BMI >40 kg/m^2: Mean weight loss = 17.2 kg 6mth, 15.7 12mth, Mean %EWL = 25.9% 6mth, 20.4% 12mth.	https://www.ncbi.nlm.nih.gov/pubmed/15978160	2005
6	Prospective cohort Single or repeat IGB, pre-test vs. post-test comparison	Dumonceau, J. M., E. Francois, A. Hittelet, A. I. Mehdi, M. Barea and J. Deviere (2010). "Single vs repeated treatment with the intragastric balloon: A 5-year weight loss study." Obesity Surgery 20(6): 692-697.	X	X	-	N=99 single IGB, N=19 repeat IGB. BMI 30-35 kg/m^2, comorbidities NR. Baseline BMI single IGB 34.0 (31.2–36.9), repeat IGB 31.9 (31.2–37.7) kg/m^2. Comorbidities listed, up to 32% with dyslipidaemia, 11% with diabetes. Results: Median weight loss single IGB lower with second vs first IGB (9.0 vs 14.6 kg; 30.4% vs 49.3% excess weight [EW]; P=0.003). Those with repeat treatment (n=19) had greater weight loss at first IGB extraction (14.6 vs 11.0 kg; 49.3% vs 30.7% EW; P=0.026) and 1 year later (12.0 vs 6.0 kg; 40.9% vs 20.8% EW; P=0.008).	https://www.ncbi.nlm.nih.gov/pubmed/20352524	2010

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
7	Prospective, cohort study, pre-test vs. post-test comparison	Ganesh, R., Rao, A.D., et al. (2007). "The bioenteric intragastric balloon (BIB) as a treatment for obesity: Poor results in asian patients." Singapore Med J 48(3): 227-231.	X	X	-	N=20 (17 female, 3 male) with IGB + 1,000 kcal diet, Mean BMI = 31.5 kg/m2 (range 28–39), Mean age = 40 years (range 28–52); Co-morbidities: Orthopaedic (65%), diabetes mellitus (5%), hypertensive (10%), hyperlipidaemia (15%), respiratory problems (20%). Treatment difference results at up to 1 year: Maximum mean weight loss = 5.9 kg ($p<0.0001$ vs baseline), Mean weight loss = 4.4 kg at 6 months ($p<0.001$), Mean weight loss = 1.5 kg after 1 year ($p>0.05$)	https://www.ncbi.nlm.nih.gov/pubmed/?cmd=HistorySearch&querykey=14	2007
8	Prospective cohort, pre-test vs. post-test comparison Abstract report only, limited data provided.	Iordache, N. (2005). 'Intragastric balloon endoscopically assisted treatment for obesity. Personal experience', Archives of the Balkan Medical Union, 40 (2), 73–75.	X	-	-	N=54 with IGB. Mean BMI at baseline 32 $\pm$ 4.5 kg/m^2 (range 30-43). Comorbidities NR. Results: Mean BMI at 6mths 28.8 $\pm$ 4.7 kg/m^2. Patients with diabetes and arterial hypertension presented normal values after treatment. Mean BMI reduction = 3.2 kg/m2 ($p<0.05$)	http://www.balkanmedicalunion.com/en/current-issue/	2005
9	Prospective cohort, pre-test vs. post-test comparison	Mion, F., Napoleon, B. et al (2005). 'Effects of intragastric balloon on gastric emptying and plasma ghrelin levels in non-morbid obese patients', Obesity Surgery, 15 (4), 510–516.	X	X	-	N=17 with IGB insertion plus 1,300 kcal diet, Mean BMI 34.4 kg/m^2, (range 30.1–40.0), Mean age = 34.9 years. Co-morbidities NR. Results: Mean %WL = 9.4 ± 1.8% at removal/6mth $p<0.0001$ [95% CI 8.5, 10.3] vs. baseline mean weight loss = 8.7 ± 1.6 kg (range 0–21) $p<0.0001$ [95% CI 7.9, 9.5] at 1 month post-IGB removal/7mth, Mean BMI loss = 3.1 ± 0.7 kg/m^2 $p<0.0001$ [95% CI 2.7, 3.5] at 7mth.	https://www.ncbi.nlm.nih.gov/pubmed/15946431	2005

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
10	Prospective cohort, pre-test vs. post-test comparison	Tai, C.M., Lin, H.Y., et al. (2013). "Effectiveness of intragastric balloon treatment for obese patients: One-year follow-up after balloon removal." Obes Surg 23(12): 2068-2074.	X	X	-	N=28 compared the effectiveness of IGB + 800-1200 kcal/day diet. Mean BMI 32.4 $\pm$ 3.7 kg/m^2 (range 27-40.9), median age 31.5 yr (range 20-55). Comorbidities: 64% had metabolic syndrome. Results: The BMI significantly fell from 32.4±3.7 to 28.5±3.7 kg/m2 (P<0.01) at 6mth. All The median value of %EWL of all patients at BIB removal was 40.1. The incidence of metabolic syndrome decreased from 56.3 to 31.3 % in patients with BMI <32 and 75.0 to 33.3 % in patients with BMI $\geq$32 after IGB. Compares BMI 27-32 with BMI>32-40	https://www.ncbi.nlm.nih.gov/pubmed/23832520	2013
11	email Survey	Eduardo Grecco, Luiz Gustavo de Quadros, André Teixeira, Thiago Souza, Jimi Scarparo, Artur A. Parada, Ricardo Dib, Josemberg Campos and Rena Moon (2018). "Brazilian Intragastric Balloon Consensus Statement (BIBC): practical recommendations based on experience of over 40,000 cases" Surgery for Obesity and Related Diseases, http://dx.doi.org/10.1016/j.soard.2017.09.528	-	-	-	The overall Brazilian expert data encompassed 41,186 IGBs, with a mean percentage total body weight (%TBW) loss of 18.4 ± 2.9%. The most frequently used IB was Orbera™, totalling 32,735 implants (78.2%). The adverse event rate after the adaptation period was 2.5%, the most common being hyperinflation (0.9%) and spontaneous deflation (0.8%) of the device. The early removal rate due to intolerance was 2.2%.	http://www.soard.org/article/S1550-7289(17)30962-0/fulltext	2017

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12	MA	Al-Bawardy, B., S. S. Mukewar, A. Genco, M. P. Galvao Neto, G. Lopez-Nava, N. Kumar, C. C. Thompson, E. B. Wilson, S. Shaikh, N. Zundel, C. J. Gostout and B. K. Abu Dayyeh (2015). "Meta-analysis of the Orbera™ intragastric balloon for the endoscopic management of obesity." Gastrointestinal Endoscopy 81(5 SUPPL. 1): AB462.	-	-	-	A random-effect meta-analysis and meta-regression were performed. Results: Eighty studies including 8506 patients were included in this meta-analysis. The pooled percent total body weight (%TBW) lost after a single six-months IGB insertion was 12.7% [95% CI 8.5-16.9], 13% [95% CI 11.7-14.7], 10 [95% CI 6.6-13.6], and 6.2 [95% CI 1.4-10.9] at 3, 6, 12, and 36 months respectively. The pooled incidences of side-effects were: pain 33.7%, nausea 29%, GERD 18.5%, early removal 7.5%, gastric ulcers 2%, migration 1.4%, small bowel obstruction 0.3%, perforation 0.1%, and death 0.08%.	http://www.giejournal.org/article/S0016-5107(15)01888-X/abstract	2015

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13	MA	ASGE Bariatric Endoscopy Task Force and ASGE Technology Committee (2015). "ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies." Gastrointestinal endoscopy 82(3): 425-438.e425.	-	-	-	Based on a meta-analysis of 17 studies including 1683 patients, the percentage of excess weight loss (%EWL) with the Orbera™ IGB at 12 months was 25.44% (95% confidence interval [CI], 21.47%-29.41%) (random model) with a mean difference in %EWL over controls of 26.9% (95% CI, 15.66%-38.24%; P <= .01) in 3 randomized, controlled trials. Furthermore, the pooled percentage of total body weight loss (% TBWL) after Orbera™ IGB implantation was 12.3% (95% CI, 7.9%-16.73%), 13.16% (95% CI, 12.37%-13.95%), and 11.27% (95% CI, 8.17%-14.36%) at 3, 6, and 12 months after implantation, respectively. There was a <=5% incidence of serious adverse events as set by the PIVI document to indicate acceptable safety profiles. Our task force consequently recognizes the Orbera™ IGB for meeting the PIVI criteria for the management of obesity.	https://www.ncbi.nlm.nih.gov/pubmed/26232362	2015

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
14	MA	Moura, D., J. Oliveira, E. G. H. De Moura, W. Bernardo, M. Galvao Neto, J. Campos, V. B. Popov and C. Thompson (2016). "Effectiveness of intragastric balloon for obesity: A systematic review and meta-analysis based on randomized control trials." Surgery for Obesity and Related Diseases 12(2): 420-429.	-	-	-	This systematic review shows the effectiveness of the IGB method compared to the sham/diet (s/d) method. For qualitative analysis, 12 studies were selected, and 9 of these were acceptable for quantitative analysis. Results The IGB/diet is more effective than s/d when comparing body mass index (BMI) loss with a mean difference of 1.1 kg/m2 by the Student's t test and 1.41 kg/m2 by the meta-analysis, with significant differences in both. It is also more effective in weight loss (WL), with a mean difference of 2 kg by the Student's t test and 3.55 kg by the meta-analysis. In the qualitative analysis of % excess WL (%EWL), the mean %EWL is 14.0% in favour of the IGB group compared to the s/d group by the Student's t test; however, no significant difference was found between these groups by quantitative analysis.	https://www.ncbi.nlm.nih.gov/pubmed/26968503	2014

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
15	MA	Popov, V.B., Ou, A., et al. (2017). "The impact of intragastric balloons on obesity-related co-morbidities: A systematic review and meta-analysis." Am J Gastroenterol 112(3): 429-439.	-	-	-	Meta-analysis: 10 randomized controlled trials (RCT) and 30 observational studies including 5,668 subjects were analysed. Results: There was moderate-quality evidence for improvement in most metabolic parameters in subjects assigned to IGB therapy as compared to conventional non-surgical therapy in RCTs: mean difference (MD) in fasting glucose change: -12.7 mg/dl (95% confidence interval (CI) -21.5, -4); MD in triglycerides: -19 mg/dl (95% CI -42, 3.5); MD in waist circumference: -4.1 cm (95% CI -6.9, -1.4); MD in diastolic blood pressure: -2.9 mm Hg (95% CI -4.1, -1.8). The odds ratio for diabetes resolution after IGB therapy was 1.4 (95% CI 1.3, 1.6). The rate of serious adverse events was 1.3%	https://www.ncbi.nlm.nih.gov/pubmed/28117361	2017 Abstract: Popov, V., A. Ou, A. Schulman and C. C. Thompson (2016). "The impact of intragastric balloons on obesity-related co-morbidities: A systematic review and meta-analysis." Gastroenterology 150(4 SUPPL. 1): S85.

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
16	IGB vs. pharmacotherapy	Farina, M. G., R. Baratta, A. Nigro, F. Vinciguerra, C. Puglisi, R. Schembri, C. Virgilio, R. Vigneri and L. Frittitta (2012). "Intragastric balloon in association with lifestyle and/or pharmacotherapy in the long-term management of obesity." Obesity Surgery **22**(4): 565-571	X	X	X	Adults with BMI 30-55 kg/m^2 randomised to IGB plus lifestyle modifications (N=30) or Pharmacotherapy plus lifestyle modifications (sibutramine; N=20). After IGB removed N=30, re-randomised to lifestyle (N=15) or sibutramine (N=15). Primary outcomes: percent of initial weight lost (%IWL), percent of excess BMI lost (%EBL) Results: At 1 year, the weight lost was significantly (P<0.05) greater in patients treated with either IGB/pharmacotherapy (%IWL=15.8±2.3%, %EBL=41.3±6.7%) or IGB/lifestyle (%IWL= 14.3±2.7, %EBL=34.9±6.5%) vs. pharmacotherapy group (%IWL=8.0±1.4%, %EBL=22.1±3.9%). (Note sibutramine has since been withdrawn for safety reasons). Life style modifications: a balanced 1,000 kcal/day diet, a lifestyle change program including increased physical activity (at least 30 min/day of moderate exercise for 5 days/week), plus sessions with physician and nutritionist every 4 weeks	https://www.ncbi.nlm.nih.gov/pubmed/21901285	2012

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
17	Prospective non-randomised cohort comparison. IGB vs. laparoscopic gastric banding or laparoscopic sleeve gastrectomy.	Nikolic, M., I. Kruljac, L. Kirigin, G. Mirosevic, N. Ljubicic, B. Pezo Nikolic, M. Bekavac-Beslin, I. Budimir and M. Vrkljan (2015). "Initial weight loss after restrictive bariatric procedures may predict mid-term weight maintenance: Results from a 12-month pilot trial." Bariatric Surgical Practice and Patient Care 10(2): 68-73.	X	X	X	N=44 with IGB, mean BMI 40.3 (32.6–60.8) N=21 LAGB, mean BMI 41.8 (36.2–50.0) N=15 LSG, mean BMI 46.8 (40.8–58.8) Percentage of body WL and percentage of excess weight loss (EWL) were calculated at baseline and after 1, 3, 6, and 12 months. Successful WL was defined as EWL > 20% for patients treated with BIB and > 50% for patients treated with LAGB and SG. Success in the 6th and 12th month was achieved in 80% and 58% of patients in the IGB group, 33% and 40% in the LAGB group, and 60% and 73% in the LSG group. In the IGB group, WL in the 1st month correlated positively with WL at the 6th and 12th month, and an initial WL > 6.5% best predicted success.	https://www.ncbi.nlm.nih.gov/pubmed/26594600	2015

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
18	Roux-en-Y gastric bypass (RYGB), laparoscopic adjustable gastric banding (LAGB), and an intensive lifestyle weight loss intervention (LWLI).	Courcoulas, A. P., S. H. Belle, R. H. Neiberg, S. K. Pierson, J. K. Eagleton, M. A. Kalarchian, J. P. De Lany, W. Lang and J. M. Jakicic (2015). "Three-year outcomes of bariatric surgery vs lifestyle intervention for type 2 diabetes mellitus treatment a randomized clinical trial." JAMA Surgery 150(10): 931-940. 2 year results	X	X	-	A 12-month, 3-arm RCT including 69 participants aged 25 to 55 years BMI 30 to 40 and T2DM. 43% had BMI >40 kg/m^2, Mean (SD) age was 47.3 (6.4) years and HbA1c level, 7.9% (2.0%). N=20 participants underwent RYGB; N=21, LAGB; and N=20, LWLI, Results: RYGB participants had the greatest mean weight loss from baseline (27.0%; 95%CI, 30.8-23.3) compared with LAGB (17.3%; 95%CI, 21.1-13.5) and LWLI (10.2%; 95%CI, 14.8-5.61) (P < .001). Partial and complete remission of T2DM were 50% and 17%, respectively, in the RYGB group and 27%and 23%, respectively, in the LAGB group (P < .001 and P = .047 between groups for partial and complete remission), with no remission in the LWLI group. At 3 years, any T2DM remission (partial or complete) was achieved in 40% of RYGB, 29% of LAGB, and no LWLI (p=0.0037) while complete remission was achieved in 15% of RYGB, 5% of LAGB and no LWLI group participants (p=0.21).	https://www.ncbi.nlm.nih.gov/pubmed/26132586	2015 Courcoulas 2015 (3 year results): Courcoulas, A. P., B. H. Goodpaster, J. K. Eagleton, S. H. Belle, M. A. Kalarchian, W. Lang, F. G. S. Toledo and J. M. Jakicic (2014). "Surgical vs medical treatments for type 2 diabetes mellitus: A randomized clinical trial." JAMA Surgery 149(7): 707-715.

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
19	LAGB vs. lifestyle change (LC; dietary and exercise advice, ± VLED)	Dixon JB, O'Brien PE, Playfair J, Chapman L, Schachter LM, Skinner S, Proietto J, Bailey M & Anderson M (2008), 'Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial', JAMA 299(3): 316-23.	X	X	-	Included BMI 30-40 kg/m^2 with recently diagnosed (<2 yr) T2DM. Patients in both groups received medical care for T2DM. LAGB group (N=30): Mean (SD) BMI 37.0 (2.7), Mean (SD) Age 46.6 (7.4). LC group (N=30): Mean (SD) BMI 37.2 (2.5), Mean (SD) age 47.1 (8.7). Results: Remission of T2DM achieved by 73% with LAGB, 13% in LC. LAGB and LC groups lost a mean (SD) of 20.7% (8.6%) and 1.7% (5.2%) of weight, respectively, at 2 years (P<.001). Remission of type 2 diabetes was related to weight loss (R^2=0.46, P<.001). and lower baseline HbA1c levels (combined R^2=0.52, P<.001). There were no serious complications in either group.	https://www.ncbi.nlm.nih.gov/pubmed/18212316	2008

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
20	RYGB vs. intensive lifestyle intervention	Ikramuddin, S., J. Korner, W. J. Lee, J. E. Connett, I. W. B. Inabnet, C. J. Billington, A. J. Thomas, D. B. Leslie, K. Chong, R. W. Jeffery, L. Ahmed, A. Vella, L. M. Chuang, M. Bessler, M. G. Sarr, J. M. Swain, P. Laqua, M. D. Jensen and J. P. Bantle (2013). "Roux-en-Y gastric bypass vs intensive medical management for the control of type 2 diabetes, hypertension, and hyperlipidemia: The diabetes surgery study randomized clinical trial." JAMA - Journal of the American Medical Association 309(21): 2240-2249.	X	X	-	BMI 30-39.9, T2DM ≥6 mths. N=60 RYGB, N=59 lifestyle. Remission of T2DM results: Partial at 12 mths:0% for Life vs 0% for RYGB ; at 24 mths: 0% for Life vs 42% for RYGB Fully at 12 mths: 0% for Life vs 0% for RYGB; at 24 mths: 0% for Life vs 25% for RYGB. At 3 years (Ikramuddin 2016): No lifestyle-medical management patient had remission of diabetes at 36 months, whereas 17% of RYGB patients had full remission and 19% had partial remission. Percent weight loss was mean (SD) 6.3% (16.1) in lifestyle-medical management vs. 21.0% (14.5) in RYGB ($P < 0.001$).	http://jamanetwork.com/journals/jama/fullarticle/1693889	2013 3 year results: Ikramiddin et al. (2016) Diabetes Care 39(9): 1510-1518.

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
21	RYGB vs. Sleeve gastrectomy (SG) vs. intensive medical therapy (IMT)	Kashyap, S. R., D. L. Bhatt, K. Wolski, R. M. Watanabe, M. Abdul-Ghani, B. Abood, C. E. Pothier, S. Brethauer, S. Nissen, M. Gupta, J. P. Kirwan and P. R. Schauer (2013). "Metabolic effects of bariatric surgery in patients with moderate obesity and type 2 diabetes: Analysis of a randomized control trial comparing surgery with intensive medical treatment." Diabetes Care 36(8): 2175-2182.	X	X	-	Patients with uncontrolled T2DM (HbA1c 9.7 $\pm$ 1%) N= 18 RYGB age 47.9 $\pm$ 9.7 yr, BMI 36.1 $\pm$ 2.6 kg/m^2 N= 19 SG age 47.5 $\pm$ 10.0 yr, BMI 36.4 $\pm$ 3.2 kg/m^2 N=17 IMT, age 50 $\pm$ 8.4 yr, BMI 35.8 $\pm$ 3.0 kg/m^2 Results at 2 years: HbA1c of 6.7 $\pm$ 1.2% for SG, 7.1 $\pm$ 0.8% for SG, and 8.4 $\pm$ 2.3% for IMT ($P<0.05$ for each surgical group versus IMT). Reduction in body fat was similar for both surgery groups, with greater absolute reduction in truncal fat in gastric bypass versus sleeve gastrectomy (216 vs.210%; P=0.04). Insulin sensitivity increased significantly from baseline in RYGB (2.7-fold; P = 0.004) and did not change in sleeve gastrectomy or IMT.	https://www.ncbi.nlm.nih.gov/pubmed/23439632	2013

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
22	RYGB vs usual care vs. usual care + pharmacotherapy (exenatide)	Liang Z, Wu Q, Chen B, Yu, P, Zhao H, Ouyang X. (2013) "Effect of laparoscopic Roux-en-Y gastric bypass surgery on type 2 diabetes mellitus with hypertension: A randomized controlled trial". Diabetes Research and Clinical Practice 101:50–6.	X	-	-	Required to have BMI >28 (Chinese population) N=36 RYGB, Mean age 51.75 ± 6.70, Mean BMI 30.34 ± 1.96. N=34 usual care, Mean age 50.94 ± 5.89, Mean BMI 30.28 ± 1.44 N=31 usual care + exenatide, Mean age 50.81 ± 5.44, Mean BMI 30.48 ± 0.94 At 12 months, diabetes remission had occurred in no patients in usual care or usual care + exenatide groups versus 90% in RYGB group, and there was a significant decrease in requirement of antihypertensive drugs in RYGB group compared with other 2 groups ($P < 0.05$).	https://www.ncbi.nlm.nih.gov/pubmed/23706413	2013

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
23	NHMRC Clinical Practice Guidelines	National Health and Medical Research Council (2013) Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia - Systematic Review. Melbourne: National Health and Medical Research Council.	-	-	-	Bariatric surgery is more effective than other treatment options in achieving significant weight loss in adult and adolescent patients with obesity. In adults, all classes of obesity are improved with various bariatric surgical types. Weight regain after bariatric surgery occurs regardless of the bariatric surgical type. Achieving long-term weight loss therefore requires weight maintenance strategies to be applied after bariatric surgery has been performed. Bariatric surgery is associated with significant short-term improvements in some cardio-metabolic risk factors and in short-term resolution of metabolic syndrome and newly developed (< 2 years) type 2 diabetes. However, data from over ten years or greater duration follow-up suggest that these benefits are not maintained long-term.	https://www.nhmrc.gov.au/guidelines-publications/n57	2013
24	MA	Colquitt, J. L., K. Pickett, E. Loveman and G. K. Frampton (2014). "Surgery for weight loss in adults." The Cochrane database of systematic reviews 8: CD003641.	-	-	-	Seven RCTs compared surgery with non-surgical interventions; however, the participants, types of surgery and the comparators differed between the studies. Meta-analysis of weight loss outcomes for surgery versus non-surgical interventions was considered inappropriate since the RCTs differed in the characteristics of their participants, interventions and comparators. Instead, outcomes were synthesised narratively. Compared with non-surgical interventions, surgery had a consistent effect on each of the outcome measures related to weight, regardless of the type of procedure.	https://www.ncbi.nlm.nih.gov/pubmed/25105982	2014

#	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Class 1	Class 2	Class 3	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
25	MA	Picot, J., J. Jones, J. L. Colquitt, E. Gospodarevskaya, E. Loveman, L. Baxter and A. J. Clegg (2009). "The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: A systematic review and economic evaluation." Health Technology Assessment 13(41).	-	-	-	A total of 5386 references were identified of which 26 were included in the clinical effectiveness review: three randomised controlled trials (RCTs) and three cohort studies compared surgery with non-surgical interventions and 20 RCTs compared different surgical procedures. Bariatric surgery was a more effective intervention for weight loss than non-surgical options. In one large cohort study weight loss was still apparent 10 years after surgery, whereas patients receiving conventional treatment had gained weight. Some measures of QoL improved after surgery, but not others. After surgery, statistically fewer people had metabolic syndrome and there was higher remission of Type 2 diabetes than in non-surgical groups.	https://www.ncbi.nlm.nih.gov/pubmed/19726018	2009

BMI, body mass index; EBL, excess BMI lost; EWL, excess weight loss; HPT, hypertension; IB or IGB, intragastric balloon; LAGB, laparoscopic adjustable gastric lap-banding; LSG, laparoscopic sleeve gastrectomy, RYGB, Roex-en-Y gastric bypass surgery; T2DM, type 2 diabetes mellitus; VLED, very low energy diet

Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). ***Please do not attach full text articles, this is just intended to be a summary.***

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words) (Only Orbera™ (BioEnterics Intragastric Balloon (BIB)) studies included)	Website link to research (if available)	Date
1	Observational, Prospective	NCT02828657: Orbera™ Post-Approval Study	FDA post-approval study designed to demonstrate the safety and effectiveness of ORBERA™ as an adjunct to weight reduction for obese adults (22 years of age and older) with a Body Mass Index (BMI) of ≥ 30 kg/m2 and BMI ≤ 40 kg/m2. Behavioral modification program in conjunction with endoscopic placement of a single ORBERA™ Study is currently recruiting participants Device: Orbera™	https://www.clinicaltrials.gov/ct2/show/NCT02828657?cord=Orbera&rank=1	June 2018
2	Interventional, Randomised	NCT01998243; Usefulness and Safeness of Intragastric Balloon Before Bariatric Surgery in Morbid Obesity	This study is designed to study whether the use of an IGB before bariatric surgery decreases surgical morbidity as well as other secondary outcomes including decreases mortality, and hospital stay. Study is currently recruiting participants Device: BioEnterics Intragastric Balloon	https://www.clinicaltrials.gov/ct2/show/study/NCT01998243?cond=intragastric+balloon&draw=1&rank=5	December 2016
3	Open label, single group assignment	NCT02880189: Combined Endoscopic Ultrasound Guided Core Liver Biopsy and Intragastric Balloon Placement for the Diagnosis and Management of Nonalcoholic Steatohepatitis and Obesity	This study is designed to investigate the impact of weight loss achieved with the IGB on NASH with early fibrosis in a select cohort of patients with obesity preselected to have a high pre-test probability of having NASH with early fibrosis based on MRE-Hepatogram. In addition, this study will explore potential non-invasive imaging criteria for NASH and early fibrosis using EUS-Elastography. Study not yet open Device: Orbera™	https://www.clinicaltrials.gov/ct2/show/NCT02880189?cond=Orbera&rank=3	May 2017

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words) (Only Orbera™ (BioEnterics Intragastric Balloon (BIB)) studies included)	Website link to research (if available)	Date
4	RCT, double blind	NCT00355979: Randomized Trial of Intragastric Balloon and Pharmacotherapy for Non-Morbid Obesity	The study aimed to compare the newer design balloon (BIB) is more reliable and predictable vs. Sibutramine (Reductil®), a serotonin and noradrenaline reuptake inhibitor. Since these two types of therapy are most efficient in non-morbid obese patients, the trial was designed to compare the effect of the two different weight reduction therapies in this group of patients in a randomised double-blind manner. Recruitment Status: unknown (likely terminated) Device: BioEnterics Intragastric Balloon	https://www.clinicaltrials.gov/ct2/show/NCT00355979?cond=Intragastric+Balloon&draw=1&rank=3	Oct 2006
5	Randomised, double blind, parallel assignment	NCT02129296: Intragastric Balloon, Air Versus Fluid Filled: Randomized Prospective Study	Morbidly obese patients are categorized into two groups: the 1st group to whom intragastric air filled balloon and the 2nd group to whom saline filled balloon is applied for treatment of their morbid obesity. The aim of study is to compare both types of balloons regarding safety, efficacy and tolerance. Recruitment status unknown. Device: BioEnterics Intragastric Balloon	https://www.clinicaltrials.gov/ct2/show/NCT02129296?cond=Intragastric+Balloon&draw=1&rank=7	August 2016

BMI, body mass index; BPD, biliopancreatic diversion; FBG, fasting blood glucose; EBL, excess BMI lost; EWL, excess weight loss; GERD, gastroesophageal reflux disease; HbA1c, glycosylated haemoglobin; LAGB, laparoscopic adjustable gastric lap-banding; LSG, laparoscopic sleeve gastrectomy; OSA, obstructive sleep apnoea; PIVI, Preservation and Incorporation of Valuable endoscopic Innovation; RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; T2DM, type 2 diabetes mellitus; VLED, very low energy diet

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

20. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):

A list of relevant information is provided in the table below.

Professional Body / Organisation	HCP Representing	Statement
The Obesity Surgery Society of Australia and New Zealand (OSSANZ)	Bariatric Surgeons	OSSANZ The Obesity Surgical Society of Australia and New Zealand <u>The Clinical Objectives are</u>: • To promote the advancement of knowledge, and maintain standards, in the clinical area of the diagnosis and the treatment of the disease of obesity, with particular emphasis on the use of surgical procedures; • To promote and foster research in the basic and clinical sciences related to the disease of obesity and its treatment; • To provide guidelines to relevant professional associations and colleges, as well as governments, on the training of clinicians and the practice of obesity surgery in Australasia; • To facilitate contact between persons interested in this and allied fields; and • To disseminate widely all information and new knowledge obtained. • To form a closer association of the obesity surgeons of Australia & New Zealand for the advancement of the obesity surgery & management. • It shall strive to maintain the character and standards of obesity surgery as outlined by The International Federation for the Surgery of Obesity.

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

Australian & New Zealand Obesity Society; Obesity Surgery Society of Australia and New Zealand; Gastroenterological Society of Australia; Australia & New Zealand Gastric & Oesophageal Surgery Association

22. List the relevant consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):

There is no relevant consumer organisation.

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

Spatz3 Balloon: ARTG 174506; Emergo Asia Pacific Pty Ltd – T/a Emergo Australia

24. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):

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), INDICATION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

25. 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:

A staggering 28.3% of Australians are classified as obese according to the latest Australian Health Survey (comparable to the ABS's estimate of 27.9%). A number of factors are known to increase the risk of developing CVD (cardiovascular disease). These include overweight and obesity (defined as a BMI≥30 kg/m2), tobacco smoking, high blood pressure, high blood cholesterol, insufficient physical activity, poor nutrition and diabetes.1

The population for which the MBS item is requested is as follows:

- People with BMI ≥30<35 kg/m^2 who have co-morbidities (in particular, have poorly controlled type 2 diabetes) and who have failed first line treatments.

Obesity imposes a considerable economic burden on society. Weight loss improves obesity-related comorbidities and may have a mortality benefit.

Evidence indicates that sustained weight loss delivers a variety of benefits, both cardiovascular and non-cardiovascular, with a positive incremental benefit in terms of quality of life, and these are reported below (as reported in NHMRC, 2013):

Benefit	References	Evidence Grade
Reduced cardiovascular risk	-	-
Reduced systolic blood pressure with weight loss of at least 2 kg	Aucott et al. 2009; Azadbakht et al 2007; Galani & Schneider 2007; Groeneveld et al. 2010; Shaw et al. 2006; Witham & Avenell 2010	A
Small improvements in lipid profiles with sustained weight loss	Aucott et al. 2009; Galani & Schneider 2007; Norris et al. 2005a; Shaw et al. 2006; Witham & Avenell et al. 2010	A
Reduced cardiovascular and all-cause mortality	Shea et al. 2010; Siebenhofer et al. 2009; Pontiroli & Morabito 2011; Uusitupa et al. 2009	C
Prevention and improved control of Type 2 diabetes	-	-
Prevention or delayed progression of type 2 diabetes	Dale et al. 2008; Galani & Schneider 2007; Knowler et al. 2009; Norris et al. 2005a; Uusitupa et al. 2009	A
Improved glycaemic control with a sustained weight reduction of 5 kg in adults with type 2 diabetes	Belalcazar et al. 2010; Buchwald et al. 2009; Cheskin et al. 2008; Christian et al. 2008; Dixon et al. 2008; Fried et al. 2010; Huisman et al. 2009; Nield et al. 2007; Norris et al. 2005b; Norris et al. 2005c; Pi Sunyer et al. 2007; Thomas et al. 2006; Wing 2010a	A

[1] http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129549614

Benefit	References	Evidence Grade
Clinically meaningful reduction in systolic blood pressure with weight loss of 2–3 kg from lifestyle interventions in adults with a BMI <35 kg/m^2 pre-diabetes or hypertension	Cheskin et al. 2008; Christian et al. 2008; Dale et al. 2008; Dixon et al. 2008; Galani & Schneider 2007; Horvath et al. 2008; Norris et al. 2005a; Pi-Sunyer et al. 2007; ter Bogt et al. 2009; ; Uusitupa et al. 2009; Wing 2010a; Witham & Avenell 2010	A
Improvements in other conditions	-	-
Improvements in markers of chronic kidney disease	Afshinnia et al. 2010; Navaneethan et al. 2009	B
Reduction in obstructive sleep apnoea	Foster et al. 2009; Greenburg et al. 2009; Tuomilehto et al. 2009	B
Improvements in Quality-of-life, self-esteem and depression	-	-
Improved quality of life, self-esteem and depression even if weight loss is not substantial	Blaine et al. 2007; Cooper et al. 2010; Morey et al. 2009; Picot et al. 2009; Villareal et al. 2011; Witham & Avenell 2010	C

Medical Condition (cont.)

Several studies point to a link between life expectancy and overweight and obesity (NPHT 2009):

- A large investigation into the effect of obesity on mortality (n=900,000) found that people who were moderately obese (BMI 30–35 kg/m^2) died 2–4 years earlier than those with an ideal weight. A BMI of 40–45 kg/m^2 reduced life expectancy by 8–10 years, comparable with the effects of lifelong smoking (PSC 2009).
- Estimates based on Australian data indicate that, at age 20, life expectancy is about 1 year less for adults who are overweight than for adults within the healthy weight range, and an average of around 4 years less for adults who are obese (Obesity Working Group).
- Other research estimating the effect of obesity on life expectancy (from age 40) found a mean loss of 7 years associated with obesity, similar to the life expectancy loss from smoking (Vic DHS 2008).
- Work commissioned by the National Preventative Health Taskforce indicates that if current trends in overweight and obesity in Australia continue, there will be approximately 1.75 million deaths at ages 20 years and over, and 10.3 million premature years of life lost at ages 20–74 years caused by overweight or obesity in 2011–2050, with an average of 12 years of life lost before the age of 75 years (Gray & Holman 2009).

There is increasing evidence that overweight and obesity are associated with the incidence of a range of comorbidities (Guh et al. 2009). The association between BMI and many of these diseases appears to be continuous, starting from BMIs of about 20–21 kg/m^2 (NZ MOH 2009). The association between BMI and cardiovascular risk factors (blood pressure, lipids, type 2 diabetes) contributes to the increased risk of cardiovascular disease experienced by people who are overweight or obese.

Lifestyle interventions can be effective in the short-term, however, weight loss is difficult to maintain in the long term (Wadden et al, 2011, and Wing and Phelan 2005). For those with severe obesity there are several Randomised Controlled Trials (RCT) (Dixon et al 2008, Dixon et al, 2012, O'Brien et al., 2006 and O'Brien et al., 2010) and case series (Colquitt et al, 2009) which suggest that Bariatric Surgery provides more predictable and sustainable weight loss than conservative regimes, and is generally very safe (Flum et al., 2009, Hutter et al., 2011).

The intensity of intervention depends on the degree of obesity and presence of comorbidities. Management begins in primary care, but moves to the specialist setting when initial measures have failed and surgery is considered.

For the general population, based on AUSDIAB 2012 data, the number of visits to a general practitioner (GP) in the previous 3 months was higher in those who were obese compared to those with a normal BMI and those who were overweight. Among those who were obese, approximately 22% had visited a GP three times or more in the previous 3 months compared to around 16% of those with a normal BMI and those who were overweight

Between 2005–06 and 2014–15, the number of weight loss surgery operations increased from around 9,300 to around 22,700. The proportion of all weight loss surgery operations in private hospitals remained stable at around 89% during this period. Between 2013-14 and 2014-15 there was a 7.7% increase in primary procedures, with 18,036 operations for primary procedures being reported in 2014-15 (AIHW, 2014). As noted earlier, the downstream effects of obesity on other health care costs, productivity etc., in 2013-14 were estimated at $8.6 billion. Obesity is considered to be the 2nd highest contributor to burden of disease (AIHW); and being overweight/obese are considered to be a risk factor for cardiovascular, T2DM and chronic kidney disease (AIHW).

Improvement of T2DM, including its remission, because of bariatric surgery has been recognized for more than a decade (Pories et al, 1995). Not all bariatric procedures are the same. Restrictive procedures, malabsorptive procedures, or a combination of both procedures each have their own categorical risks and benefits (Shah et al, 2006).

BMI ≥30<35 kg/m^2 and Type 2 Diabetes

According to the Australian Institute of Health and Welfare (AIHW) excess weight, especially obesity, is a major risk factor for Type 2 diabetes (T2DM), cardiovascular disease, some musculoskeletal conditions and some cancers, with almost 2 in 3 Australians classified as overweight or obese. The latest data from the ANDIAB study noted that in 2011 80% of people with diabetes were overweight or obese (>27 kg/m^2). AUSDIAB reported that in 2012 compared to those with a BMI in the normal range at baseline, the annual incidence of diabetes was approximately 2 and 5 times higher among those classified as overweight and obese, respectively.

Though intervening for patients with a BMI of 35-39.9 kg/m^2 with T2DM is within currently acknowledged guidelines for bariatric surgery, this is not universally the case for patients with a BMI≥30<35 kg/m^2 and comorbidities, though it is acknowledged as worthy treatment by the NHMRC and the Australian Diabetes Society.

Why is it important to treat patients with a BMI≥30<35 kg/m^2?

Remission in diabetes is beneficial to patients with a BMI≥30<35 kg/m^2. For people who are overweight/obese or diagnosed with prediabetes, modest weight loss is important.

Remission of diabetes is likely to be related to both weight loss and hormonal changes that occur after surgery (Malkani 2015). Weight loss after surgery is not due to intestinal malabsorption, but due to decreased food consumption from a potent reduction in appetite and reduction in desire for sugary and fatty foods. The basis for this satiating effect is the change in gut hormones that activate neural circuits that communicate with the liver, muscle, adipose tissue, and pancreatic islets. These hormones also play a role in glucose homeostasis independent of their effect on appetite (Scott et al 2011). It is hypothesised that ghrelin, PYY and GIP are hormones that significantly affect diabetic remission (Malkani 2015). A well-known important mechanism is a rapid decrease of insulin resistance after bariatric surgery. The effect of the bariatric surgery-induced insulin resistance decrease has been evaluated in many studies, as reported in an extensive review of gastrointestinal metabolic surgery and T2DM (Pok and Lee, 2014).

A meta-analysis of weight loss studies found that a mean weight loss of 5 to 8.5 kg (5% to 9%) was observed during the first 6 months from interventions involving a reduced-energy diet and/or weight-loss medications with weight plateaus at approximately 6 months (Franz et al, 2011). In studies extending to 48 months, a mean 3 to 6 kg (3% to 6%) of weight loss was maintained with none of the groups experiencing

weight regain to baseline. In contrast, advice-only and exercise-alone groups experienced minimal weight loss at any time point (Franz et al, 2007). With bariatric surgery, on average gastric bypass patients lose about 70% of their excess weight (Buchwald et al, 2004).

Though there are few studies assessing benefits of weight loss surgery for individuals with BMI≥30 kg/m^2, similar outcomes are seen, as a consequence of having an intervention, to those seen in patients with a BMI>35 kg/m^2. A systematic review found only three randomized trials enrolling 290 patients, and these trials confirmed superiority of surgical treatment with regard to weight loss and glycaemic control in this group (Maggard-Gibbons et al, 2013). In the Surgical Therapies and Medications Potentially Eradicate Diabetes Efficiently (STAMPEDE) trial, 36% of the patients had a BMI 27–34 kg/m^2, and had similar benefits from surgery as the group with BMI ≥35 kg/m^2 (Schauer et al, 2014). A systematic review and meta-analysis in 1,389 patients supported these findings in those with BMI<35 kg/m^2 (Parikh et al, 2013). However, in this group, there are no robust outcomes data beyond 5 years of follow-up (Maggard-Gibbons et al, 2013).

Clinical need for IGB

Endoscopic bariatric therapy (such as Orbera™) may be a useful alternative to pharmacological treatment for obesity, and it provides greater efficacy than pharmacologic and lifestyle interventions while offering lower risks than currently performed surgical procedures. Diet and exercise often don't produce significant and sustained weight loss. And although bariatric surgery produces durable weight loss and shows the most promise for diabetes resolution, only about 2 percent of people who qualify for surgery undergo it. Abu Dayyeh (gastroenterologist at the Mayo Clinic) notes that *There is a big gap in the management of obesity, where diet and exercise aren't enough, but patients either don't qualify for a surgical option or don't want it because of the cost and risks. People who fall into this gap represent the majority of those with mild to moderate obesity*.[2] A survey of 57 patients who underwent the Orbera™ system and completed a survey found that after removal of the balloon, the mean BMI was 31.5±4 kg/m^2; with 75% of patients reporting relief of clinical symptoms such as diabetes (Mitura, Garnusz, 2015). Therefore, there is sufficient evidence to support the beneficial effect of Orbera™ in patents with a BMI ≥30<35 kg/m^2 with co-morbidities, and currently are not provided with sufficient options once diet, physical activity and medication have failed. This application, were to it to be accepted, would enable this high risk group, the opportunity of being offered more interventional treatment options - namely, Orbera™. Orbera™ would be of great benefit, and fulfil the need for interventional treatment without exposing patients to surgery (which may be unwarranted at such a modest level of obesity).

26. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Patients 18 years of age or over that have:

- BMI ≥30<35 kg/m^2 who have comorbidities (in particular, have poorly controlled type 2 diabetes) and who have failed first line treatment options.

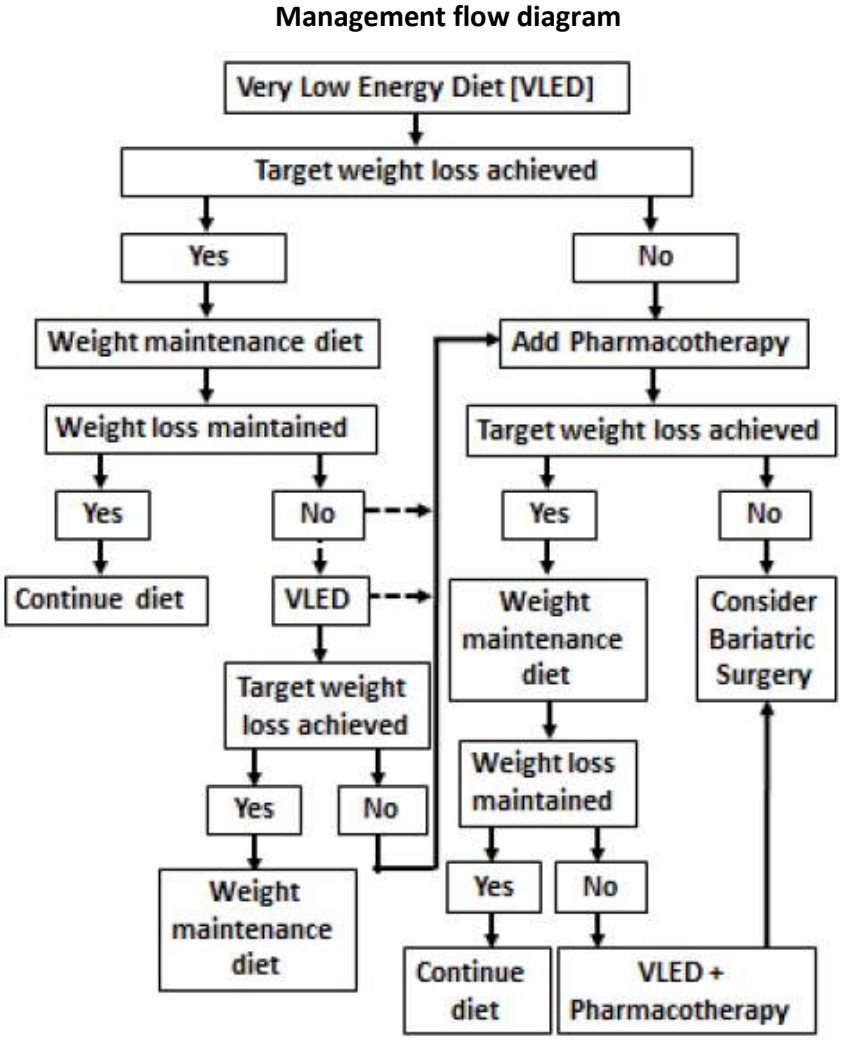
27. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

According to the obesity management algorithm, patients in these groups require intensive interventions. Three main options are available, and the choice of therapies should be guided by patient BMI, previous weight loss interventions and response.

[2] http://www.mayoclinic.org/medical-professionals/clinical-updates/endocrinology/intragastric-balloon-a-re-emerging-approach-for-obesity (accessed July 2017)

1. Very Low Energy Diet (VLED) is an initial option for individuals who have not tried this previously and are willing to use meal replacements. If effective in achieving adequate weight loss, the meal replacements can be reduced, and the diet can be replaced with a weight maintenance diet. If weight is regained the VLED can be reintroduced.
2. Pharmacotherapy can be considered in individuals who do not have an adequate initial response to the VLED, or who regain weight once the VLED is relaxed.
3. Bariatric surgery is an option for individuals BMI >40 kg/m^2 or >35 kg/m^2 with comorbidities that may improve with weight loss who do not respond to the VLED plus pharmacotherapy, or who have previously tried this approach without success, or who have type 2 diabetes.

Figure 1: Treatment Algorithm for weight loss



PART 6b – INFORMATION ABOUT THE INTERVENTION

28. Describe the key components and clinical steps involved in delivering the proposed medical service:

Upon referral to a bariatric surgeon or gastroenterologist, patients will be assessed for their suitability for placement of Orbera™. If suitable, patients will undergo an out-patient insertion starting with a pre-anaesthesia consultation. The patient will be placed under anaesthesia as the deflated Orbera™ is placed in the stomach using a flexible endoscope. Once the balloon is positioned in the stomach, Orbera™ is filled with a sterile saline solution. The tubing is then removed from Orbera™ and the balloon will free float in the patient's stomach.

After six months in-situ, the Orbera™ must be removed. Similar to the placement, the patient will be anaesthetised so that the physician can use a flexible endoscope to puncture the IGB with an aspirating needle. Upon aspiration, the saline is removed from the balloon. The balloon is then grasped and removed using the flexible endoscope.

In conjunction with the placement of Orbera™, the patient is provided with a lifestyle modification programme that begins with placement of the Orbera™ and extends for a 12-month period.

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

Orbera is a trademarked device. The Orbera™ Intragastric Balloon is indicated for placement for a maximum of six months and is not adjustable.

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

The placement and removal of IGB would be limited to:

- Surgeons, predominantly Bariatric, General or Upper GI surgeons
- Gastroenterologists

Referrals for this proposed medical service would be provided by:

- General Practitioners
- Surgeons without the necessary endoscopy skills

31. 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?

As noted earlier in questions 26 and 28, IGB for weight loss will involve a new approach towards managing a particular sub-group of patients, those with a BMI ≥30<35 kg/m^2, and aged ≥18 years with co-morbidities. Currently, this group of patients is not eligible for bariatric surgery, though the clinical benefits to this group have been shown. The lack of availability of bariatric surgery to this group is based on the perception that it is not cost-effective. IGB is a viable alternative to bariatric surgery for patients who fail weight loss or exercise programs or fail/ cannot tolerate weight loss medication. However, with the lower cost IGB, treating this group can be shown to be cost-effective and thereby providing a treatment option for this patient group that may otherwise be ineligible.

32. 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):

Placement of an intragastric balloon (IGB) is indicated for overweight or obese patients only with a minimum BMI of 27 kg/m^2. In addition, this medical service is contraindicated for patients who:

- Are pregnant or breast-feeding
- Have had prior gastrointestinal surgery
- Have had or currently have any inflammatory disease of the gastrointestinal tract including oesophagitis, gastric ulceration, duodenal ulceration, cancer or specific inflammation such as Crohn's disease
- Have had or currently have any potential upper gastrointestinal bleeding conditions such as oesophageal or gastric varices, congenital or acquired intestinal telangiectasis, or other other congenital anomalies of the gastrointestinal tract such as atresias or stenoses.
- Have a large hiatal hernia or > 5cm hernia
- Have a structural abnormality in the oesophagus or pharynx such as a stricture or diverticulum
- Have any other medical condition which would not permit elective endoscopy
- Have a major prior or present psychological disorder
- Have alcoholism or drug addiction
- Are unwilling to participate in an established medically-supervised diet and behaviour modification programme, with routine medical follow-up
- Are receiving aspirin, anti-inflammatory agents, anticoagulants or other gastric irritants, not under medical supervision

33. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:

Service delivery would require an anaesthetist to provide patient sedation and patient monitoring during the course of the service. Such services would include:

MBS Code: 17610 Pre-anaesthesia consultation, limited examination, up to 15 minutes

MBS Code: 20740 Initiation of management of anaesthesia for upper gastrointestinal endoscopic procedures

MBS Code: 23031 Anaesthesia time - 31 to 35 minutes

The implanting physician would require assistance from an endoscopy nurse during delivery of the service.

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

Surgeons or gastroenterologists will primarily deliver the service.

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

Delivery should be restricted to surgeons or gastroenterologists.

36. 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:

The manufacturer will provide training to surgeons, gastroenterologist, and their staff members on the safe and effective, on-label use of an IGB. Training will include information on the device, safety, and patient management, as well as provide hands-on experience and/or a visit to an experienced IGB physician user for proctoring and viewing of live cases. This training is provided at no cost to the HCP or the staff members.

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

- ☒ Inpatient private hospital
- ☒ Inpatient public hospital
- ☒ Outpatient clinic
- ☐ Emergency Department
- ☐ Consulting rooms
- ☒ Day surgery centre
- ☐ Residential aged care facility
- ☐ Patient's home
- ☐ Laboratory
- ☐ Other – please specify below

Specify further details here

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

Currently, treatment is generally provided in the private hospital setting. Data from AIHW indicates that 7 in 8 weight loss surgeries takes place in a private hospital setting.

The insertion or removal of an IGB will take place primarily in a theatre situated in either a Day Case facility or full-service hospital. However, there are cases where the hospital keeps the patient overnight and then they are counted as 1 day stay. This is purely based on hospital internal procedures.

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

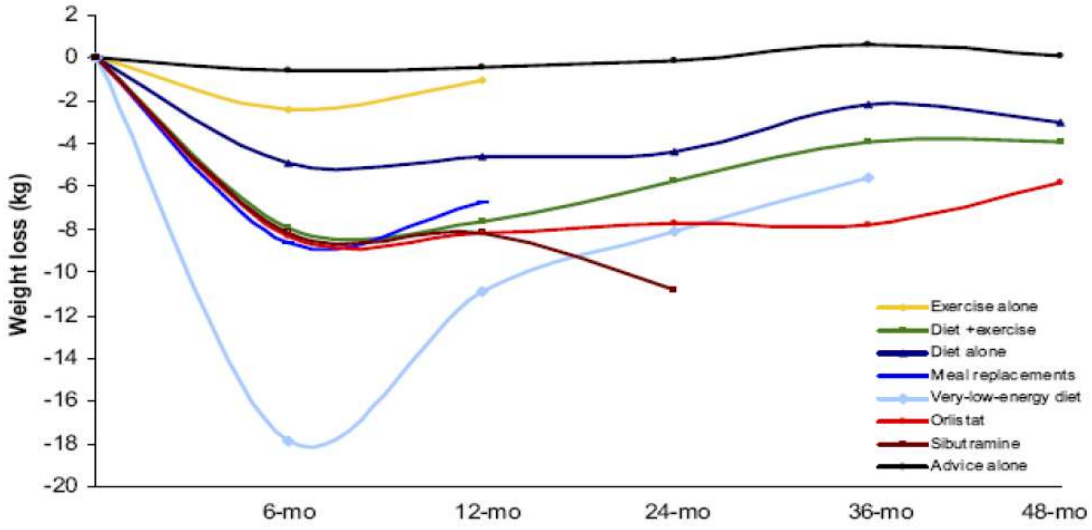
- ☒ Yes
- ☐ No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

39. 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 (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

For people with a BMI ≥30<35 kg/m2 with co-morbidities (particularly poorly controlled type 2 diabetes/metabolic disease and who are at increased cardiovascular risk), once diet and pharmacotherapy fail, they have exhausted their options as they are not eligible for bariatric surgery; it can therefore be considered that their comparator treatment option, at this stage, is placebo/do nothing/watch and wait. However, some people may continue to cycle through more diet/exercise and pharmacotherapy regimens until they give up. A study by UCLA found that the majority of people that were dieting regained all weight, plus more and that sustained weight loss was only achieved by a minority of participants in the study. Earlier data substantiate the conclusions from this study and showed that though very low energy diet seemed to work the best in weight reduction, the rebound effect was also substantive (see Figure below from Franz et al, 2007).

Figure 2: Weight gain is 90% irreversible for 90% of people



Franz, 2007 (n = 25455, 18199 completers)

The group of patients with BMI ≥30 kg/m2 (with comorbid conditions) is currently recommended for surgical intervention by the NHMRC and the Australian Diabetes Society; however, currently these are not reimbursed for bariatric surgery.[3] This application contends, that providing a less invasive option for weight loss will be cost-effective for patients that have failed to experience weight loss reduction with diet, exercise and medication. This less invasive option is Orbera™, one which is cost-effective in this population (as an example the average length of stay was 2.6 days (AIHW) for weight loss surgery (the majority being laparoscopic surgery), vs. a day procedure for Orbera™).

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

☐ Yes (please provide all relevant MBS item numbers below)

[3] See note TN.8.29 of the MBS schedule.

☒ No

41. Define and summarise the current clinical management pathways that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards including health care resources):

The treatment algorithm for the comparator is depicted in

Figure 1. Currently people with BMI≥30<35 kg/m2 continue to cycle through diet/exercise and pharmacotherapy options (first line treatment options) or give up trying to lose weight – they have no other alternatives. The availability of Orbera™ will offer a viable alternative to patients that have failed first line treatment options.

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

The insertion of the IGB (e.g. Orbera™) will be instead of the patient having no other alternative (comparator) given that another round of weight loss/medication/lifestyle change has been shown to be ineffective in most cases. In this group of patients, the weight loss required does not have to be substantial, in which case an alternative to bariatric surgery may be more appropriate, and more cost-effective.

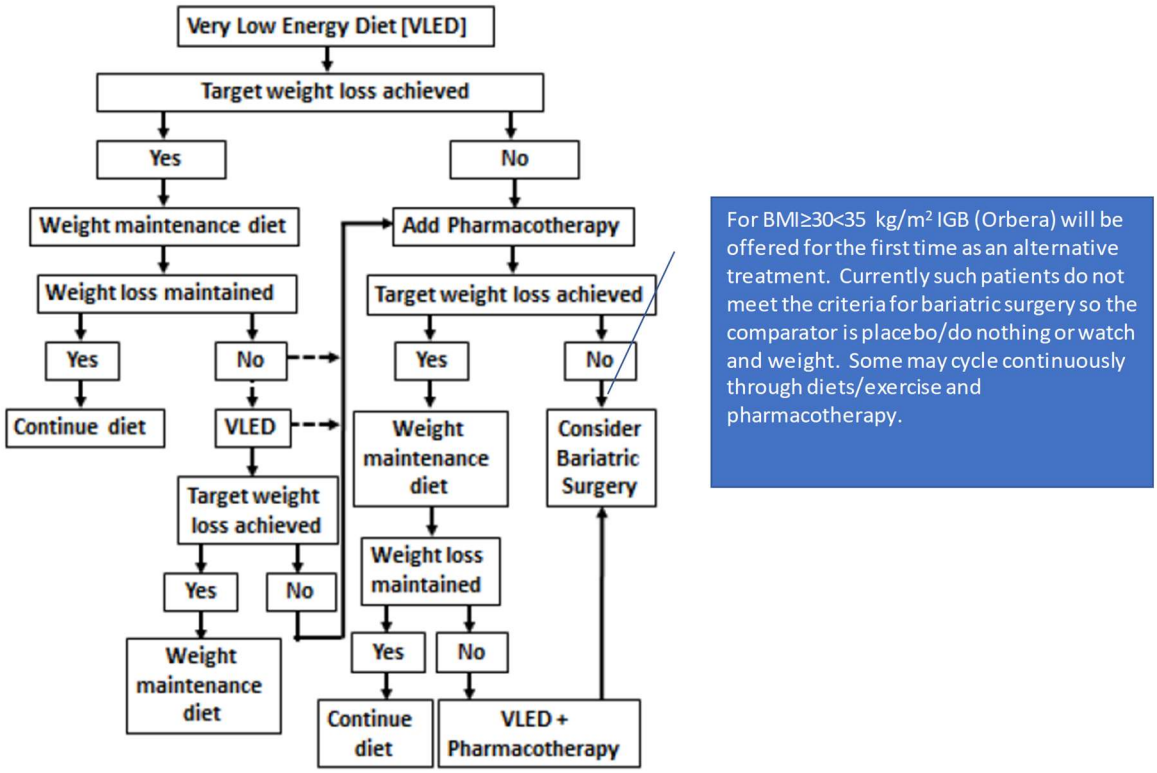
(b) If yes, please outline the extent of which the current service/comparator is expected to be substituted:

Between 1.6-2.6% of patients will proceed to have the IGB procedure, and this is a comparable uptake rate to that seen in bariatric surgery (see Table 1).

43. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service including variation in health care resources (Refer to Question 39 as baseline):

The point at which the IGB procedure will be introduced for the relevant patient population is presented in Figure 3 below.

Figure 3: Change in the treatment algorithm with the reimbursement of Orbera™



There are specific programs that are established following the IGB procedure (see Orbera™), and these are not dissimilar to those followed by patients that undergo bariatric surgery. The post insertion care is equally important and visits of at least once a month while the intra-gastric balloon is in place are scheduled. It is at a minimum during these visits that further information regarding the long-term success of the program are communicated and enhanced. The post-operative care programs that are in place may vary slightly depending on the clinic/hospital but essentially include education, support to change a person's lifestyle and eating habits. This support is provided by follow-up with a dietician, nurse and the surgeon.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

44. 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):

Statistically significant (P<0.05) and clinically relevant improvements in weight loss and health outcomes have been observed with Orbera™ (plus behavioural modification) at 6 months versus behavioural modification alone or behavioural modification plus pharmacotherapy in randomised, comparative trials (Courcoulas et al. 2017, Farina et al. 2012), with enduring weight loss noted at 12 months (Farina et al. 2012, Fuller et al. 2013). Improvements in insulin sensitivity and triglyceride levels were also noted (Farina et al. 2012). An increased rate of adverse events, including pain and nausea, was reported in these randomised, comparative studies, compared with the comparator.
Furthermore, reduction in diabetes incidence was achieved at various levels of BMI. At 6 months and 3 years, the clinical effectiveness of Orbera™ in terms of achieving T2DM remission over time is respectively, an average of 61% (Crea et al, 2009; Genco et al, 2005; Genco et al, 2013 and Spyrolpoulos et al, 2007) and 67% (Genco et al, 2013) which compares favourably to 63% (Lukas et al, 2014 and Milone et al, 2005) and only 27% (Yip 2013) with bariatric surgery.

45. Please advise if the overall clinical claim is for:

BMI≥30<35 kg/m2 population with comorbidities for patients who have failed first line treatment options – compared with placebo (do nothing approach), Orbera™ is superior.

☒ Superiority
☐ Non-inferiority

46. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes: Adverse event rates (primary adverse events are pain, nausea and gastro-oesophageal reflux).

Clinical Effectiveness Outcomes:

Primary Outcomes: Excess weight loss, Changes in rate of recorded diabetes or T2DM remission.

Secondary Outcomes: Quality of Life (IQoL Life), Blood Pressure, insulin sensitivity index, HbA1c.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

47. Estimate the prevalence and/or incidence of the proposed population:

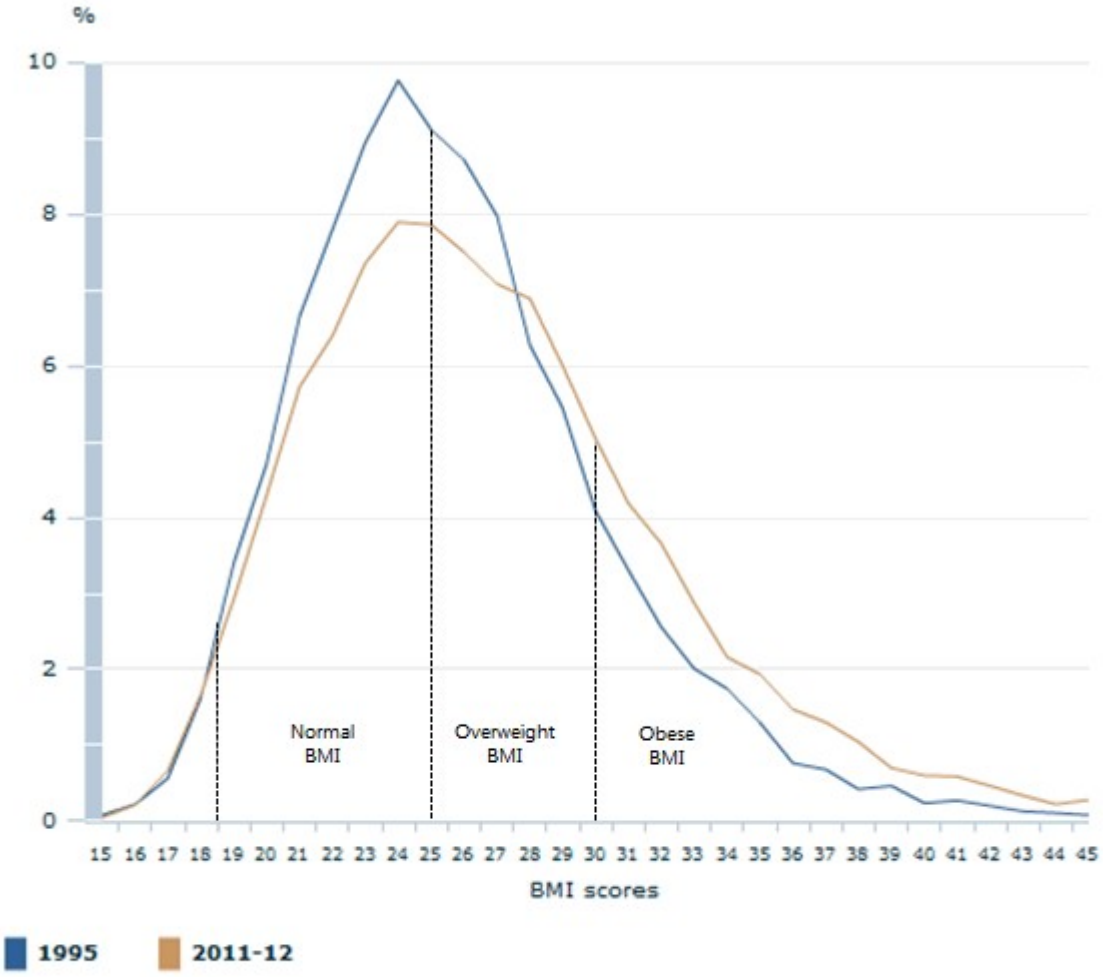
According to the AIHW, in 2014-15, 27.9% Australians, aged of 18-64, were classified as obese. At an estimated 24.7 million Australians in 2017, of which 61.5% is 18-64, the number of obese, provides a total eligible population with a BMI≥30 kg/m^2 for bariatric surgery of 882,441 (utilising Sharman et al, 2017 estimates). As indicated earlier, the vast majority of such people rebound with their weight loss and revert to their original weight or sometimes an even higher weight (see Figure 2). Using data presented in Question 50 below there are an estimated 2,278,575 people with a BMI≥30<35 kg/m^2; those that also have poorly controlled diabetes are estimated to be 157,426.

48. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year.

It is estimated that eligible patients will only have access to Orbera™ as a weight loss program at a max of one per year.

In 2011-12 the distribution of Australians with BMI ranges is presented below (ABS 4338.0):

Figure 4: Persons aged 18 years and over – BMI[a], 1995 and 2011-12



Footnote(s): (a) Based on Body Mass Index for persons whose height and weight was measured.

Source(s): Australian Health Survey: Updated Results, 2011-12

49. How many years would the proposed medical service(s) be required for the patient?

The maximum placement period for the Orbera™ System is 6 months, and it must be removed at that time or earlier.

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

As can be seen in Table 1, the projected numbers, are based on Sharman et al, 2017 and a further variety of sources. It is estimated that for patients with BMI ≥30<35 kg/m^2 there would be lower limit of 2,447 procedures (with an upper limit estimate of 4,093) in the first year following MBS funding. This compares to the 1,000 currently performed annual IGB procedures (with an indication limited to patients with a BMI≥27 in a private setting only).

Specifically, patients currently undergoing surgery have a mean BMI of 44.1, as reported by the Bariatric Surgery Registry. The distribution for those classified as class 1 (BMI ≥30<35 Kg/m2) is provided below in **Error! Reference source not found.** and this informs the 14.7% utilised in Table 1 below. This is therefore a modest proportion of patients who will be eligible in the "BMI ≥30<35 Kg/m^2 with a co-morbidity and uncontrolled diabetes" cohort.

Some more data regarding the distribution of patients currently undergoing bariatric surgery is provided in Figure 5.

Figure 5: Initial BMI classification for primary patients Feb 2012-30June 2016 (Bariatric Surgery Registry)

*The target population for the proposed medical service falls into the Obese: Class 1 category

Table 1: Estimated eligible patient numbers for the requested procedures

	% of Population	Number of Potential Patients	Source of Data
Australian Population		24,700,000	ABS – population clock
Population aged between 18-64:	61.5%	15,190,500	ABS - 3235.0
Proportion of Patients that have a BMI ≥30<35 kg/m^2	15%	2,278,575	ABS 4338.0 and **Error! Reference source not found.**
Proportion of Patients that have diabetes and BMI ≥30<35 kg/m^2	14.7%	334,950	Bariatric Surgery Registry
Australians with uncontrolled diabetes	47%	157,426	(Diabetes Australia)

	% of Population	Number of Potential Patients	Source of Data
If you need Proportion of those that could be eligible that are estimated to undertake an IGB procedures ≥30<35 kg/m^2 with uncontrolled diabetes: **Lower Limit Estimate**	1.6%	2,447	In 2011-13 Sharman et al, 2017 estimated that there were 882,441 patients eligible for bariatric surgery (aged 18-65)
Upper Limit Estimate	2.6%	4,093	In 2011-12, there were 13,718 procedures for weight loss (The Conversation)

From the 2008 MSAC submission for IGBs it was determined that an appropriate estimate of the number of patients who could potentially receive IGBs (for people with BMI≥35) would be those who fail to lose weight following conventional treatments but who are unsuitable for surgical treatment. This estimate is based on the number of patients who underwent surgery for obesity, and on an Australian study on the number of patients who were screened for surgery but were unsuitable (for various reasons). However, the rate of patients who initially refuse surgery were estimated to decrease once IGBs became funded for that indication. The 2008 MSAC submission estimated an upper limit of 8,000 IGB treatments per year. Given that the proposed population under consideration for this application is much smaller, the upper estimate of 4,093 IGB procedures per year is therefore considered conservatively robust and is utilised accordingly (see Table 1).
From above, it is estimates that between 2,447 and 4,093 IGB procedures are likely based on a willingness to undergo this procedure similar to that of bariatric surgery.

51. Estimate the anticipated uptake of the proposed medical service 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:

By way of providing context to the anticipated uptake of the IGB technology, it is noted that currently around 1,000 IGB procedures are performed annually in Australia. With the proposed MBS funding, the cost to patients would decrease (at least for those meeting the eligibility criteria). Conservatively, a substantive increase of the current procedure rate in the first year to 2,447; and assuming a 20% increase per annum would be 2,997 and 3,745 in the years thereafter is likely to represent the anticipated lower estimated demand with the upper estimated demand range of 4,093 in the first year; 5,012 and 6,014 in subsequent years (assuming comparable growth rates).

From a supply perspective, the manufacturer of Orbera™ is able to provide sufficient quantities and the required surgical training can be provided to an adequate number of surgeons to perform the IGB insertion to meet such a level of expected demand. With an estimated 25 physicians currently performing the IGB procedures across Australia (of which it is estimated that 50% of IGBs placed would be the Orbera™ system), the year 3 estimate of 3,745 procedures amounts to 150 insertions annually per surgeon (with a further 150 removals). This represents only one such insertion and removal per operating day per surgeon and therefore, the procedure is not expected to be supply constrained.

In terms of leakage, there is potential for IGBs to be used outside of the proposed population, but this risk is no more so than with gastric surgery or other similar procedures. It is anticipated that IGBs will result in a reduction in gastric surgery as the weight loss achieved may be sufficient for a portion of patients to avoid such surgery later in life and to achieve permanent weight reduction through lifestyle modification. This potentially translates into a saving to the Medicare budget.

PART 8 – COST INFORMATION

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

ITEM	COST	Source Estimate
Insertion of Device	-	-
Device: Orbera™	REDACTED	REDACTED
Medical Practitioner service		
Pre-operative assessment for complex medical problems	$85.55	MBS 17615#
Pre-anaesthesia consultation	$43.00	MBS 17610#
Initiation of anaesthesia for upper gastrointestinal endoscopic procedures	$99.00	MBS 20740#
Anaesthesia 41 to 45 minutes	$59.40	MBS 23032#
Placement of the intra-gastric balloon	$350	New MBS item
Medical Facility Fees	-	-
Cost of day hospital facility Operating room, special procedure suites and hotel costs	$1450- National average	DRG G47C: Gastroscopy, Minor Complexity [4]
Removal of Device		
Extraction Tools	REDACTED	REDACTED
Medical Practitioner service		
Pre-operative assessment for complex medical problems	$85.55	MBS 17615#
Initiation of anaesthesia for upper gastrointestinal endoscopic procedures	$99.00	MBS 20740#
Anaesthesia 31 to 35 minutes	$59.40	MBS 23031# (potentially 23023)
Removal of the intra-gastric balloon	$250	New MBS item
Accommodation Fees	-	-
Cost of day hospital facility Operating room, special procedure suites and hotel costs	$1450 - National average	DRG G47C: Gastroscopy Minor Complexity

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* National Efficient Price Determination 2016-17

[4] $4,682 National Efficient Price Determination 2017-18 DRG cost weight 0.3097.

53. Specify how long the proposed medical service typically takes to perform:

Based on discussions with trained physicians the following timing and costs in question 54 were derived:

Placement of Intragastric Balloon:

- Time to prepare for the service (pre-service time): 10 minutes
- Time taken to perform the 'actual' service (intra-service time): 20 minutes
- Time taken post service (after care time): 10 minutes

Total time required: **40 minutes**.

Removal of Intragastric Balloon:

- Time to prepare for the service (pre-service time): 10 minutes
- Time taken to perform the 'actual' service (intra-service time): 15 minutes
- Time taken post service (after care time): 10 minutes

Total time required: **35 minutes**.

54. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

Category 3 – Therapeutic Procedures Proposed item descriptor: Placement of IGB, taking 30 minutes or less, for a patient with obesity and comorbidities (BMI≥ 30<35 kg/m^2) (Anaes.) (Assist.) Can be delivered as a stand alone procedure. Multiple services Rule (See para T8.29 of explanatory notes to this Category) Fee: $350

Category 3 – Therapeutic Procedures Proposed item descriptor: IGB removal to which item XXXX* applies (Anaes.) (Assist.) Multiple services Rule (See para T8.30 of explanatory notes to this Category) Fee: $250

*Relating to the above procedure, for placement of IGB, as the second service would be performed only after the completion of the first.

MBS Extracts as references for similar procedures:

MBS Code	Description
13506	GASTRO-OESOPHAGEAL balloon intubation, for control of bleeding from gastric oesophageal varices (See para T8.2 of explanatory notes to this Category) Fee: $184.50 Benefit: 75% = $138.40 85% = $156.85
30294	ENDOSCOPIC DILATATION OF COLORECTAL STRICTURES including colonoscopy (Anaes.) (See para T8.17 of explanatory notes to this Category) Fee: $551.85 Benefit: 75% = $413.90
30475	ENDOSCOPY with balloon dilatation of gastric or gastroduodenal stricture (Aneas.) (See para T8.17 of explanatory notes to this Category) Fee: $320.25 Benefit: 75% = $240.20 85% = $272.25
30473	OESOPHAGOSCOPY (not being a service to which item 41816 or 41822 applies), GASTROSCOPY, DUODENOSCOPY or PANENDOSCOPY (1 or more such procedures), with or without biopsy, not being a service associated with a service to which item 30476 or 30478 applies (Anais.)(See para T8.17 of explanatory notes to this Category) Fee: $177.10 Benefit: 75% = $132.85 85% = $150.55
30478	ESOPHAGOSCOPY (not being a service to which item 41816, 41822 or 41825 applies), gastroscopy, duodenoscopy or panendoscopy (1 or more such procedures), with 1 or more of the following endoscopic procedures - polypectomy, removal of foreign body, diathermy, heater probe or laser coagulation, or sclerosing injection of bleeding upper gastrointestinal lesions, not being a service associated with a service to which item 30473 or 30476 applies Multiple Services Rule (Anaes.) Fee: $245.55 Benefit: 75% = $184.20 85% = $208.75 (See para TN.8.17 of explanatory notes to this Category)
30485	ENDOSCOPIC SPHINCTEROTOMY with or without extraction of stones from common bile duct (Aneas.) (See para T8.17 of explanatory notes to this Category) Fee: $563.30 Benefit: 75% = $422.50 85% = $483
30491	BILE DUCT, ENDOSCOPIC STENTING OF (including endoscopy and dilatation) (Anaes.) (See para T8.17 of explanatory notes to this Category) Fee: $555.35 Benefit: 75% = $416.55 85% = $475.85

MBS Code	Description
30494	ENDOSCOPIC BILIARY DILATATION (Anaes.) (See para T8.17 of explanatory notes to this Category) Fee: $420.50 Benefit: 75% = $315.40
31456	GASTROSCOPY and insertion of nasogastric or nasoenteral feeding tube, where blind insertion of the feeding tube has failed or is inappropriate due to the patient's medical condition (Anaes.)Fee: $245.55 Benefit: 75% = $184.2
41819	DILATATION OF STRICTURE OF UPPER GASTRO-INTESTINAL TRACT using bougie or balloon over endoscopically inserted guidewire, including endoscopy with flexible or rigid endoscope (Anaes.)Fee: $348.95 Benefit: 75% = $261.75 85% = $296.65
41831	OESOPHAGUS, endoscopic pneumatic dilatation of (Anaes.) (Assist.)Fee: $357.00 Benefit: 75% = $267.75 85% = $303.45

PART 9 – FEEDBACK

The Department is interested in your feedback.

55. How long did it take to complete the Application Form?

Approximately 120 hours (including research and preparation).

56. (a) Was the Application Form clear and easy to complete?

☒ Yes
☐ No

(b) If no, provide areas of concern:

57. (a) Are the associated Guidelines to the Application Form useful?

☒ Yes
☐ No

(b) If no, what areas did you find not to be useful?

58. (a) Is there any information that the Department should consider in the future relating to the questions within the Application Form that is not contained in the Application Form?

☐ Yes
☒ No

(b) If yes, please advise: