Australian Government

Department of Health

MSAC Application

Aspiration therapy via the insertion of a customised percutaneous endoscopic gastrostomy tube into the stomach for weight loss management in obese patients with a BMI ≥ 35

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): Australasian Medical & Scientific Ltd
Corporation name: Australasian Medical & Scientific Ltd
ABN: 28 051 991 372
Business trading name: Australasian Medical & Scientific Ltd

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 lobbyist acting on behalf of an Applicant?

☐ Yes
☒ No

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

☐ Yes
☐ No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Aspiration therapy via the insertion of a customised percutaneous endoscopic gastrostomy tube into the stomach for weight loss management in obese patients with a BMI ≥ 35

4. 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*)

Overweight and obesity is measured at the population level for adults using the Body Mass Index (BMI) which is calculated by dividing weight in kilograms by height in metres squared. Overweight is measured at a BMI of 25 or more with obesity determined at a BMI of 30 or more. These cut-off points are based on associations between and chronic disease and mortality.

Obesity rates in Australia present one of the greatest population health challenges. Epidemiological data on prevalence and demographic data from the Australian Bureau of Statistics indicate that, in 2008, 3.71 million Australians (17.5% of the population) were obese, and by 2025 this is projected to increase to 4.6 million Australians (18.3% of the population).

Downstream effects of obesity (from associated diabetes, cardiovascular disease, cancers and osteoarthritis) impacts on the MBS, health system expenditures, productivity and other impacts, with the financial costs of obesity totalling around $8.3 billion in 2008.

There is no single product or procedure that is suitable for all patients.

5. 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 proposed medical service is an endoscopic weight loss therapy utilising a customised percutaneous endoscopic gastrostomy tube (Aspire A-Tube) and an external device.

The procedure involves the doctor performing a gastroscopy, passing a gastroscope through the patient's mouth and looking into the stomach. The vision is seen on a screen. A small 1cm incision is then made in the patient's stomach. A 26Fr silicone tube (AspireAssist A-Tube) is then passed through the mouth, into the stomach and out the incision. A Skin-Port is attached to the external part of the tube on the abdominal wall.

The procedure takes around 15-minutes and is performed in a day surgery. The procedure is typically performed under "twilight sedation" (also called conscious sedation). The procedure itself is almost identical to the placement of PEG (percutaneous endoscopic gastrostomy) feeding tubes.

The procedure is fully reversible and causes no anatomical changes.

Patients can usually return home within a few hours, and many return to work in a few days.

6. (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: N/A

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

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):

(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)

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

☐ Yes
☒ No

(g) If yes, please advise: N/A

7. 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

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

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

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

☐ Pharmaceutical / Biological
☒ Prosthesis or device
☐ No

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

☐ Yes
☐ No

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

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

☐ 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? N/A

Trade name:
Generic name:

11. (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):
Trade name of prostheses:
Clinical name of prostheses:
Other device components delivered as part of the service:

(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

The application to obtain Prostheses Listing has been put 'on hold' whilst awaiting a new MBS item number.

(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): N/A

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

Single use consumables:

- IV hydration fluid, an intravenous cannula to deliver the twilight sedation.
- A syringe and needle
- A gauze dressing secured by an adhesive is applied to the abdomen post procedure
- Adhesive
- A "Pull" PEG kit is required.
- A guidewire
- A snare
- Products used in the sedation including bite guard, oxygen mask/nasal cannula, surgical drapes, betadine.

Multi-use consumables:

- Nil

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (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: Intra-gastric silicone tubing system.
Manufacturer's name: Aspire Bariatrics, Inc.
Sponsor's name: Australasian Medical & Scientific Ltd

(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

14. (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

(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: 279030 and 278644
TGA approved indication(s), if applicable: N/A (not on the ARTG certificate)
TGA approved purpose(s), if applicable:
279030: Gastronomy aspiration system intended for gastric drainage using a percutaneous endoscopic gastrostomy tube (stomach tube)
278644: External portion of a gastrostomy aspiration system intended for gastric drainage

15. 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? N/A

☐ Yes (please provide details below)
☐ No
Date of submission to TGA:
Estimated date by which TGA approval can be expected:
TGA Application ID:
TGA approved indication(s), if applicable:
TGA approved purpose(s), if applicable:

16. 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? N/A

☐ Yes (please provide details below)
☐ No

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

PART 4 – SUMMARY OF EVIDENCE

17. **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.***

	Type of study design*	**Title of journal article or research project (including any trial identifier or study lead if relevant)**	**Short description of research (max 50 words)****	**Website link to journal article or research (if available)**	**Date of publication*** **
1.	Randomised, controlled, open-label 52 week clinical trial.	Percutaneous Gastrostomy Device for the Treatment of Class II and Class III Obesity: Results of a Randomized Controlled Trial Christopher C. Thompson , MD, MSc, FASGE, FACG 1 , Barham K. Abu Dayyeh , MD, MPH 2 , Robert Kushner , MD, MS 3 , Shelby Sullivan, MD 4 , et al	This was a 10-centre 52-week clinical trial involving 207 participants with BMI's 35–55 kg/m². One group used AspireAssist plus Lifestyle Counselling. The other group had Lifestyle Counselling alone. Results demonstrated AspireAssist weight loss was greater than Lifestyle counselling.	https://www.aspirebariatrics.com/healthcare-professionals/ section 3/Clinical Trials	6 December 2016
2.	A prospective observational study Trial registration number: ISRCTN 49958132	Aspiration therapy for obesity; a safe and effective treatment Noren, E and Forssell, H	25 obese subjects, mean age 48 years had the Aspire A-tube inserted under conscious sedation. Aspiration of stomach contents was performed 3 times daily, 20 min after each meal, for 1–2 years. Results demonstrated substantial weight loss with few complications.	https://www.aspirebariatrics.com/healthcare-professionals/ section 3/Clinical Trials https://link.springer.com/content/pdf/10.1186%2Fs40608-016-0134-0.pdf	28 December 2016
3.	Pilot study Trial registration: Clinical Trials.gov NCT00773903	Aspiration therapy leads to weight loss in obese subjects: a pilot study Sullivan S[1], Stein R, Jonnalagadda S, Mullady D, Edmundowicz S.	18 obese subjects with a mean BMI of 42 underwent a pilot study comparing aspiration therapy plus lifestyle changes with lifestyle changes alone. The conclusion was that weight loss with aspiration therapy was far greater showing it to be a safe and effective long-term weight loss therapy.	https://www.aspirebariatrics.com/healthcare-professionals/ In section 3/Clinical Trials	December 2013

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
4.	Observational study Trial Register ISRCTN 49958132	A novel endoscopic weight loss therapy using gastric aspiration: results after 6 months Forssell H[1], Norén E[1].	25 obese patients had the AspireAssist tube inserted. They aspirated 3 times a day 20 minutes after meals. The results at 6 months showed that substantial weight loss was achieved with few complications using the AspireAssist system, suggesting its potential as an attractive therapeutic device for obese patients	https://www.ncbi.nlm.nih.gov/pubmed/25268305 https://www.aspirebariatrics.com/healthcare-professionals/section3 /Clinical Trials	30 September 2014
5.	Pilot trial CONTROL ID: 1896925	Aspiration Therapy in super obese patients Machytka,Evzen1 Buzga, Marek1; Kupka, Tomas1; Bojkova, Martina	Bariatric surgery for super obese patients has higher rate of mortality. 6 subjects: mean MBI of 63.6, average weight 184kgs had AspireAssist inserted. Mean weight loss: 24.6kgs at 6 months; 42kgs at 12 months. Results: AspireAssist is feasible, safe, few complications, effective in super-obese, either as long-term therapy or bridge to bariatric surgery.	Mo1944 Aspiration Therapy in Super Obese Patients - Pilot Trial. http://www.giejournal.org/article/S0016-5107(14)01656-3/fulltext	May 2014.

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

**** If the publication is a follow-up to an initial publication, please advise.*

18. 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)****	**Website link to research (if available)**	**Date*****
1.	A comparative study	A comparative 100-participant 5-year study of aspiration therapy versus Roux-en-Y- gastric bypass Aspiration Therapy (AT) Roux-en-Y gastric bypass (RYGB)	In the first trial of its kind this study compares AT with RYGB with respect to weight loss, quality of life health benefits and safety. One-year results show AT provides approximately ⅔ of the weight loss of RYGB but with fewer and less severe side effects	Not available	First year results of the 5-year comparative study have been published. The final results of the 5-year study are expected to be published in May 2019
2.	Multi-Center Post-Market European Registry Study.	Aspiration Therapy as a Tool to Treat Obesity: One to Four Year Results in a 160-Patient Multi-Center Post-Market Registry Study	The objective of the study was to evaluate long-term safety and efficacy of AspireAssist in a clinical setting. The conclusion was that the AspireAssist is a safe, durable, effective weight management therapy for people with Class 11 and Class 111 obesity plus those with "super obesity" (BMI > 55kg/m²)	Not available	This has been submitted to Obesity Surgery. Trial Register ISRCTN 49958132 Retrospectively registered

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

****Date of when results will be made available (to the best of your knowledge).*

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

19. 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):

Gastroenterologists and the Gastroenterological Society of Australia (GESA) - www.gesa.org.au

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

Australian and New Zealand Metabolic & Obesity Surgical Society (ANZMOSS) – www.anzmoss.org.au

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

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

There are no direct weight loss competitors for this medical service.

23. 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: Gastroenterologist

Name of expert 2: redacted
Telephone number(s): redacted
Email address: redacted
Justification of expertise: Gastroenterologist

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

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

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. 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:

Overweight and obesity is measured at the population level for adults using the Body Mass Index (BMI) which is calculated by dividing weight in kilograms by height in metres squared. Overweight is measured at a BMI of 25 or more with obesity determined at a BMI of 30 or more. These cut-off points are based on associations between and chronic disease and mortality.

Classification	BMI	Risk of co-morbidities
Underweight	<18.50	Low (but risk of other clinical problems increased)
Normal range	18.50 - 24.99	Average
Overweight:	>25.00	
Pre-obese	25.00 - 29.99	Increased
Obese class 1	30.00 - 34.99	Moderate
Obese class 2	35.00 - 39.99	Severe
Obese class 3	>40.00	Very severe

The prevalence of overweight and obesity among Australians has been steadily increasing for the past 30 years. In 2011–12, around 60% of Australian adults were classified as overweight or obese, and more than 25% of these fell into the obese category (ABS 2012). In 2007, around 25% of children aged 2–16 were overweight or obese, with 6% classified as obese (DoHA 2008).

Health problems related to excess weight impose substantial economic burdens on individuals, families and communities. Data from the Australian Diabetes, Obesity and Lifestyle (AusDiab) study indicate that the total direct cost for overweight and obesity in 2005 was $21 billion ($6.5 billion for overweight and $14.5 billion for obesity). The same study estimated indirect costs of $35.6 billion per year, resulting in an overall total annual cost of $56.6 billion (Colagiuri et al. 2010).

The causes, prevention and management of obesity are complex. They include social and cultural issues, the local environment, food industry practices and public policies, personal attitudes, behaviours, and human biology.

National surveys have identified factors contributing to the increasing prevalence of overweight and obesity among adults:

- Comparison of the results of the 1995 National Nutrition Survey (McLennan & Podger 1998) with those of the 1983 National Dietary Survey of Adults showed a significant increase in energy intake (equivalent to 3–4%, 350 kilojoules or one slice of bread extra per day) (Cook et al. 2001).
- The 2007–08 National Health Survey showed that 37% of adults exercised sufficiently to obtain benefits to their health (AIHW 2010a). A further 8% exercised for sufficient time, but not for enough sessions, and another 10% had a sufficient number of sessions but not enough accumulated time. Slightly more males (39%) than females (36%) exercised at sufficient levels.

This application is for a treatment for the severe and very severe obese.

25. 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:

The AspireAssist procedure is for patient over 18 years of age who are obese and have a BMI of between 35 and 65 who have failed to achieve and maintain weight loss with non-surgical weight loss therapy. The AspireAssist is intended for patients who require long-term therapy and is used in conjunction with lifestyle therapy and continuous medical monitoring.

The patients are usually initially assessed by their General Practitioner (GP) in regards to their clinical need to lose weight. The GP refers the patient to a Gastroenterologist or a Bariatric Surgeon. The specialist will assess the patient and discuss which product/procedure would be most suitable for them.

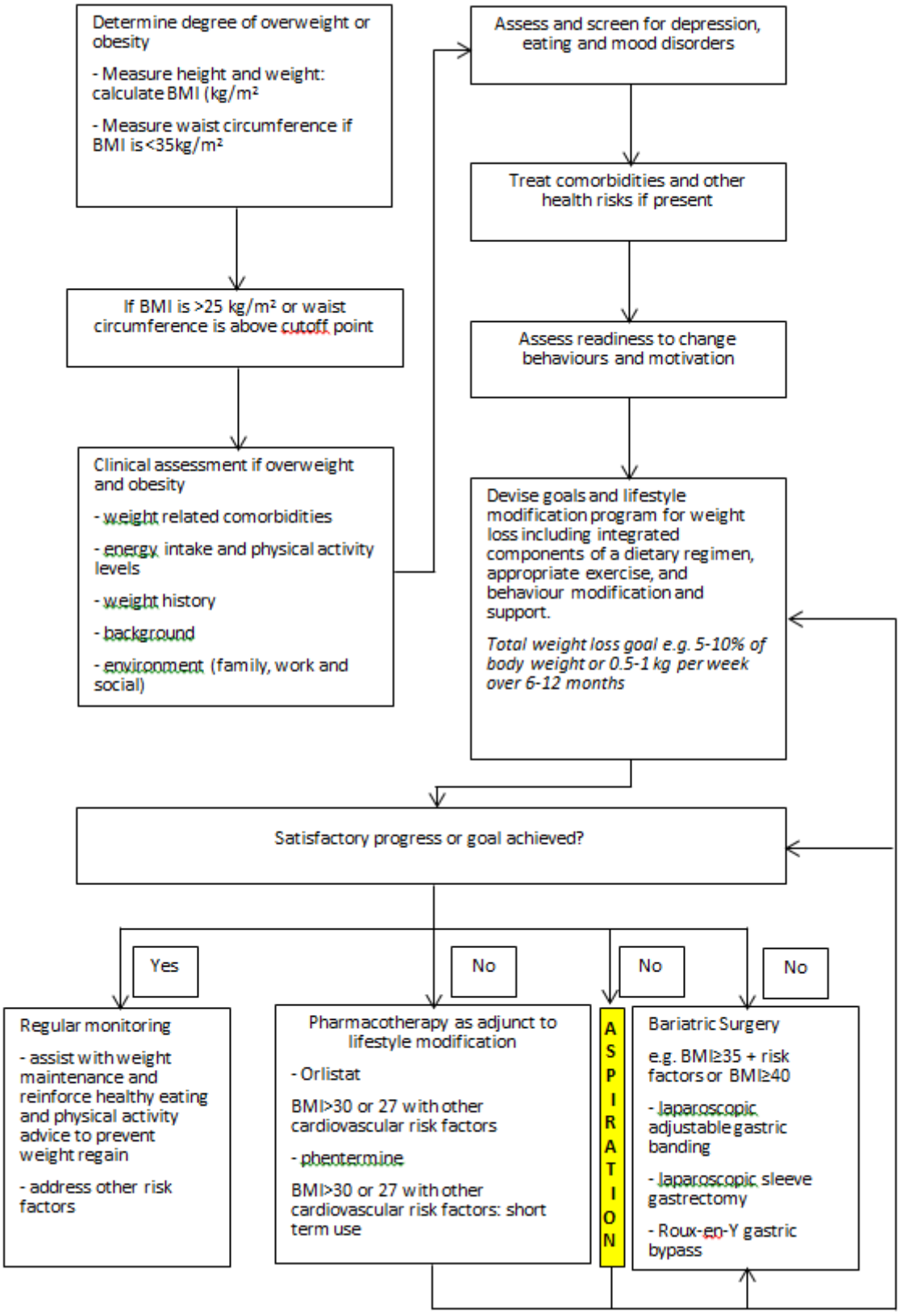
AspireAssist and the associated procedure is ideal for patients who need a procedure that does not alter their anatomy, is safe and simple, does not require a general anaesthetic. It is intended for patients who want a healthier lifestyle and need assistance to not only lose weight but to maintain their weight loss.

Although the clinical trial evidence has evaluated the safety and effectiveness of the AspireAssist procedure for the group of patient over 18 years of age who are obese (BMI of between 35 and 65) and have failed more conservative treatment, it may be that in practice there are two possible sub-groups that could most benefit.

- Morbidly obese patients who want bariatric surgery but who are too obese and high-risk for a general anaesthetic. The AspireAssist procedure could be used to help these patients lose enough weight to be eligible for bariatric surgery.
- Obese patients who cannot have an active lifestyle, for example wheelchair bound, and need to match their net food intake to their very low activity level.

26. 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):

Flowchart A: Current clinical management pathway



Obesity is a worldwide health problem associated with substantial morbidity and cost. Lifestyle modification and pharmacotherapy for obesity have limited benefit. Bariatric surgery is effective but with substantial risks, considerable cost and limited patient applicability. Aspiration therapy has evolved as a result of an attempt to replicate some of the anatomical manipulations and the physiological effects of the traditional weight loss surgery in a minimally invasive manner. This endoscopic procedure has the potential to be more cost-effective compared with current surgical approaches. Depicted in the flowchart is a possible 'location' for Aspiration therapy, that is, after Pharmacotherapy and before Bariatric Surgery.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

The key components required for the medical service/procedure to insert the tube used for the AspireAssist tube are:

- Intravenous cannula, line and saline bag
- An endoscope
- A "Pull" Percutaneous Endoscopic Gastrostomy (PEG) Kit
- Local anaesthetic using a syringe and needle.
- A scalpel
- A snare
- A guidewire needle and guidewire
- A dressing
- Betadine to clean the skin

The medical service to insert the tube used for the AspireAssist product involves the following steps.

- The patient is admitted to the day surgery and asked to change into a gown and paper cap.
- The patient is moved in to theatre where the anaesthetist then inserts an intravenous line.
- Sedation is administered.
- The procedure usually takes 15 minutes.
- Using an endoscope the doctor performs a complete examination of the upper gastrointestinal
- The stomach is distended with air.
- The doctor then looks at where on the abdominal wall to place the tube
- The abdomen is prepared with antiseptic solution and sterile drapes.
- Local anaesthetic is injected in the skin and subcutaneous tissue.
- A scalpel is used to make a 1cm cut in the abdomen.
- A snare is inserted through the endoscope
- A guide wire needle (trocar) is inserted through the skin incision into the stomach and visualize the tip of the needle inside the stomach.
- The guide wire is inserted through the guide wire needle (trocar),
- The wire is grasped with a snare and the endoscope with the guide wire is removed through the mouth.
- The A-Tube is attached to the tip of the wire exiting the mouth.
- The A-Tube is then attached by inserting the guide wire through the loop on the A-Tube and pulling the tail of the A-Tube through the guide wire.
- The A-Tube is pulled through the abdominal wall
- The endoscope is then reintroduce the endoscope and the proper A-Tube position is checked by taking a photograph of the site along the gastric wall.
- The endoscope is then removed
- Antibiotic ointment is applied to the gastrostomy site.
- Gauze is applied to the skin with tape.

- The patient is then woken up and moved to the post-operative area where they stay until well enough to go home, usually after a few hours.

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

Yes, the AspireAssist A-Tube Kit used in the procedure has a registered trademark.

29. 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?

Yes. The proposed medical procedure involves the use of an AspireAssist A-Tube. This is the only weight loss product that has a tube and a Skin-Port for drainage. Other weight loss procedures are completely different being either intra-gastric balloons or surgery (gastric banding, sleeve gastrectomy or to removal of part of the stomach). Simply put, surgical treatments for obesity reduce the capacity of the stomach. The AspireAssist procedure removes excess food from an unaltered stomach.

30. 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):

Yes. The proposed medical procedure required for the AspireAssist does have limitations. The patients must be over the age of 18 with a BMI of 35 – 65.

The contra-indications to having this procedure are:

- Previous abdominal surgery that significantly increases the medical risks of gastrostomy tube placement
- Oesophageal stricture, pseudo-obstruction, severe gastroparesis or gastric outlet obstruction, inflammatory bowel disease
- History of refractory gastric ulcers
- Ulcers, bleeding lesions, or tumours discovered during endoscopic examination
- Uncontrolled hypertension (blood pressure>160/100)
- History or evidence of serious pulmonary or cardiovascular disease,
- Anaemia
- Pregnant or lactating
- Eating disorders
- Physical or mental illness that could interfere with compliance with the therapy
- Poor general health or severe organ dysfunction such as liver of kidney dysfunction

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

N/A

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

Gastroenterologists

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

N/A

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

Part of the qualifications to become a Gastroenterologist involves training on inserting PEG tubes. Any doctor wanting to use AspireAssist needs to have performed and be familiar with inserting PEG (Percutaneous Endoscopic Gastrostomy) tubes.

35. 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 only qualification required to perform the procedure required to insert the AspireAssist tube is being a doctor who is qualified to insert a PEG tube.

36. (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

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

N/A

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

- ☒ Yes
- ☐ No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

38. 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):

If the comparator is defined as the procedure replaced, the proposed medical procedure, aspiration therapy via the insertion of a customised percutaneous endoscopic gastrostomy tube (AspireAssist) into the stomach for weight loss management in obese patients with a BMI ≥ 35, has no direct comparator currently listed on the MBS. The actual procedure is the same as a percutaneous endoscopic gastrostomy - PEG (MBS Item 30481) but the intent is the reverse. It is believe that there is currently a patient sub-group that is not serviced by any of the currently funded procedures.

In terms of defining the comparator in terms of how the proposed procedure (Aspiration therapy) works, the main option in weight loss medications in Australia is Xenical (orlistat). Xenical (orlistat) works in the stomach and intestine by preventing the body from absorbing some of the fat, helping to lose weight. The proposed procedure removes excess food via a gastrostomy tube.

In terms of defining the comparator based on the main intended patient population, the proposed procedures falls somewhere between pharmaceutical therapy and laparoscopic adjustable gastric

banding (LAGB). As is the case with LAGB, the proposed procedure is long term but reversible in contrast to other bariatric surgery procedures. As is not the case with LAGB, the proposed procedure does not alter the anatomy.

39. 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)
☐ No

Comparator	MBS item number	Fee
Laparoscopic adjustable gastric banding (LAGB)	31569 – placement 31584 – removal 31587 - adjustment	$849.55 $1539.10 $97.95

Note: This is the only possible comparator. However, the Applicant believes that there is no true comparator currently funded.

40. 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):

	Laparoscopic adjustable gastric banding	Aspiration therapy
Usual stay in hospital	1-4 days	2-4 hours
Post-operative care – see detail in attached algorithm	Management of pain, nausea, vomiting Naso-gastric tube Intravenous therapy Blood tests Weight checked regularly Day 2 start on clear liquid diet Day 4 full liquid diet Day 14-21 start on soft food diet Solid diet after 21 days On-going multivitamin and micronutrients given	Management of pain. Doctor visit 7-10 days after procedure to shorten A-Tube, attach Skin-Port and teach patient how to aspirate. A-Tube shortened as patient loses weight. Additional nutritional supplementation not required.

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

☒ Yes
☐ No

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

The proposed procedure, Aspiration therapy, would fill the gap for patients who have been unsuccessful on Xenical (orlistat) and who are not suitable for bariatric surgery (LAGB).

As outlined in Question 25, there are two possible sub-groups of patient not serviced by the currently funded procedures.

1. Morbidly obese patients who want bariatric surgery but who are too obese and high-risk for a general anaesthetic. The AspireAssist procedure could be used to help these patients lose enough weight to be eligible for bariatric surgery.
2. Obese patients who cannot have an active lifestyle, for example wheelchair bound, and need to match their net food intake to their very low activity level.

42. 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 Applicant believes that there is a gap in the current clinical management pathway. This gap falls between conservative weight-loss programmes including pharmaceutical therapy and bariatric surgery. The current clinical management pathway for patients who have failed to lose weight (and maintain the loss) whilst on conservative weight loss programmes (including pharmaceutical therapy), is to have bariatric surgery. However, for patients unsuitable for bariatric surgery, the current pathway terminates after failure to lose weight (and maintain the loss) whilst on conservative weight loss programmes (including pharmaceutical therapy).

The Applicant believes that Aspiration therapy fills this gap.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

43. 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):

Proposed – Aspiration therapy

In the pivotal randomised clinical trial, PATHWAY (Thompson et al 2016), at 52 weeks, participants in the AspireAssist group, on a modified intent-to-treat basis, had lost a mean (±s.d.) of 31.5±26.7% of their excess body weight (12.1±9.6% total body weight), whereas those in the Lifestyle Counselling group had lost a mean of 9.8±15.5% of their excess body weight (3.5±6.0% total body weight) (P <0.001). A total of 58.6% of participants in the AspireAssist group and 15.3% of participants in the Lifestyle Counselling group lost at least 25% of their excess body weight (P <0.001). The most frequently reported adverse events were abdominal pain and discomfort in the perioperative period and peristomal granulation tissue and peristomal irritation in the postoperative period. Serious adverse events were reported in 3.6% of participants in the AspireAssist group.

In a post-marketing study (Nyström et al 2018) the mean percent total weight loss at 1, 2, 3, and 4 years, respectively, was 18.2% ± 9.4% (n/N = 155/173), 19.8%± 11.3%(n/N = 82/114), 21.3% ± 9.6% (n/N = 24/43), and 19.2% ± 13.1% (n/N= 12/30), where n is the number of measured participants and N is the number of participants in the absence of withdrawals or lost to follow-up. Clinically significant reductions in glycated haemoglobin (HbA1C), triglycerides, and blood pressure were observed. For participants with diabetes, HbA1C decreased by 1% (P < 0.0001) from 7.8% at baseline to 6.8% at 1 year. The only serious complications were buried bumpers, experienced by seven participants and resolved by removal/replacement of the A-Tube, and a single case of peritonitis, resolved with a 2-day course of intravenous antibiotics.

In a prospective observational study (Noren et al 2016) after 1 year mean (SD) BMI was 32.1 kg/m2 (5.4), $p < 0.01$, and excess weight loss was 54.4% (28.8), $p < 0.01$. Quality of life, as measured with EQ-5D, improved from 0.73 (0.27) to 0.88 (0.13), $p < 0.01$. After 2 years BMI was 31.0 kg/m2 (5.1), $p < 0.01$, and excess weight loss was 61.5% (28.5), $p < 0.01$. There were no serious adverse events or electrolyte disorders. Compliance was 80% after 1 year and 60% after 2 years.

Comparator - Laparoscopic adjustable gastric banding

In a randomised trial (Courcoulas et al 2015) at three years the use of diabetes medications was reduced more in the surgical groups than the lifestyle intervention-alone group, with 65% of RYGB, 33% of LAGB, and none of the intensive lifestyle weight loss intervention participants going from using insulin or oral

medication at baseline to no medication at year 3 (P < .001). Mean (SE) reductions in percentage of body weight at 3 years were the greatest after RYGB at 25.0% (2.0%), followed by LAGB at 15.0% (2.0%) and lifestyle treatment at 5.7% (2.4%) (P < .01).

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

☒ Superiority over **Lifestyle Counselling**
☐ Non-inferiority

45. 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:

Health outcomes:

- Clinically significant reductions in HbA1c, triglycerides and blood pressure

- 27.6 – 31.5% loss of excess body weight

- Improvement in quality of life (The quality of life increased significantly, with the EQ-5D increasing from 0.73 to0.83 (P=0.003) at 6 months. Forssell.H_Endoscopy_2015).

Safety Outcomes:

- Adverse events associated with percutaneous endoscopic gastrostomy tubes

- Abdominal pain

Clinical Effectiveness Outcomes:

- Successful endoscopic placement of the A-tube

- Mean percent body weight loss at 52 weeks

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

It is extremely difficult to estimate what percentage of the obese population would qualify for the proposed procedure. In 2016/17 there were 22,335 claims for the Initiation of the management of anaesthesia for bariatric surgery in a patient with clinically severe obesity (MBS Item 20791). However, this figure only gives an indication of the number of patients willing / able / desperate enough to have anatomy altering surgery.

The Applicant believes that the population willing to have Aspiration therapy, because it involves the patient having to aspirate food from the stomach, is relatively small and would be measured in the hundreds rather than thousands.

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

Single procedure – once only.

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

The proposed medical procedure is usually required once only. The tube that is to be inserted, and not the actual medical procedure, may last several years.

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

If the application for a new MBS item number of the medical service/procedure is successful and if the product is successfully listed on the Prostheses List the estimated number of patients having the proposed medical service/procedure in the first full year may be up to fifty.

49. 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:

If the application for a new MBS item number is successful and if the product is successfully listed on the Prostheses List the estimated number of patients having the proposed medical service/procedure could grow by 100% each year, that is, up to two hundred in the third year. Again, due to the patient having to aspirate food from the stomach, it is not anticipated that there will be much leakage.

PART 8 – COST INFORMATION

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

The proposed medical service is to be conducted with the patient under light sedation. The setting and sedation for the proposed procedure is similar to that used for the currently listed MBS Item for percutaneous gastrostomy.

• MBS Fee – Gastroenterologist:	$357.00	85% MBS / 15% Private Health
• MBS Fee – Anaesthetist:	$99.00	85% MBS / 15% Private Health
• Day Clinic facility charge:	$736.00	100% Private Health
• A-tube prosthesis:	$2,300.00	100% Private Health
• First year kit:	$3,300.00	100% Private Health
Total	$6,792.00	

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

The insertion of the tube takes about 15 minutes. It is usually done in a day clinic under twilight sedation, not a general anaesthetic. The whole procedure lasts approximately 30 minutes.

52. 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 (03) – (Therapeutic procedures)

MBS Item 30xxx
PERCUTANEOUS GASTROSTOMY (initial procedure):
(a) including any associated imaging services; and
(b) including the insertion of a device for the purpose of facilitating weight loss for patients with a BMI ≥ 35.
Multiple Services Rule
(Anaes.)
Fee: $357.00 **Benefit:** 75% = $267.75 85% = $303.45
(See para TN.8.17 of explanatory notes to this Category)

PART 9 – FEEDBACK

The Department is interested in your feedback.

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

14 days.

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

☐ Yes
☒ No

(b) If no, provide areas of concern:

On the website the Application Form was version 2.4 and the Guidelines was version 1.4. Because of this the numbers (from 2) were incorrect. There is also an incorrect number in the Guidelines (15a then 16b instead of 15a and 15b)

Question 42(a) asked if "**the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?"** Does this mean it is used in addition to **OR** instead of? This is confusing as this relates to two possible answers.

There is a telephone number on the application forms but when calling one is asked to send an email and cannot speak to anyone. It takes a while for someone to respond to any email sent requesting assistance.

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

☒ Yes But could be more informative especially for first time applicants. If the questions asked had the relevant page in the therapeutic guidelines this would be very helpful

☐ No

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

Some explanations in the Guidelines were very different from the actual question that was asked. I found several questions confusing and difficult to understand what was actually being sought.

56. (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:

Ensure that the questions numbers in the application form match those given in the Guidelines.

On the website the versions are different so the question numbers are also different. The application form is version 2.4 and the Guidelines is version 1.4.

The Guidelines ask one to refer to the Technical Guidelines but don't mention whether to find the information in the 230 pages Technical Guidelines: Investigative of the 203 pages of the Technical Guidelines: Therapeutic. It would be helpful if mention is also made about where in each Technical Guideline the sought information could be located as the index does not use the same terminology as what appears in the Application Form.