

## Private Healthcare Australia Better Cover. Better Access. Better Care.



**MSAC Consultation Survey – Application 1555.1** 

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#### About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have 21 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for over 14.4 million Australians.

### 1. What is your organisation's experience with the proposed health service or technology. Or with the related health condition?

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31578, 31581, 31572 and 31569). This figure has declined in recent years from an average of 25,000 three years ago. With surgical costs of approximately \$20,000 per bariatrics surgical intervention, direct expenditure is around \$440,000,000 per year. PHI funds also cover a number of the other health interventions flagged in the PICO for members triggered by BMIs in excess of 35-40. These include increased rates of hernias, joint replacements and cardiac conditions. Health funds also support prevention interventions, including healthy lifestyle programs aimed at reducing the onset of morbid obesity.

### 2. Is the proposed population(s) for the health service or technology appropriate?

PHA support the comments from the Medical Services Advisory Committee (MSAC) in review of application 1551.1 and those of PICO Advisory Subcommittee (PASC) that inclusion of Class I and Class II BMI categories without comorbidities would only result in bracket creep of surgery. In the data provided, Class I represents 19.71% of Australians compared to only 4.0% in Class III. The majority of Class II, representing 7.7% of all Australians, would also include a lot of Australians otherwise not eligible for stapled gastrectomy or bypass. PHA does not support the need for this bracket creep, with new technologies – including GLP1- Antagonists – that were not available as an early line treatment when this procedure was last considered by MSAC. While we note ESG is somewhat less invasive than traditional stapled bariatric surgery, it remains significantly more invasive than medications and exercise, and comes with some risks related to perforation, particularly with clinicians inexperienced with the device and treatment.

### 3. Is the proposed approach to delivery of the health service or technology appropriate?

PHA agrees the broad scope sought by Apollo Surgical with a seven-fold increase in "eligible" PHI members is completely inappropriate. Although value in bariatric surgery for patients with a BMI over 40% and with those above 35% with comorbidities is well supported, it does not appear justified for those with lower risk and a BMI below 40%.

The most effective bariatrics practices 'centres of excellence' for surgical stapling procedures have invested substantially in adding dieticians and other allied providers to their practice. Patients also have pre and post engagement with psychologists and psychiatrists to help them through the journey associated with such an invasive procedure, and to ensure they embed lifestyle changes in addition to the having the operation. There is no evidence that the gastroenterologists who are most likely to engage in this care are appropriately resourced in these areas to achieve similar success.

Bariatric surgeons who have performed this surgery, first with gastric bands, then later with stapling options, recognised the substantive difference in long-term success that came from recognising that the actual surgery is only one part of the long-term success of sustained weight loss. PHA support the notion that ESG may be an effective operation for patient cohorts that fit the same definition as current bariatrics surgery interventions. This includes Class III and Class II with comorbidities, where the patient is unwilling to consider a sleeve gastrectomy due to a variety of factors, such as fears regarding the lack of reversibility, or general concerns around the level of such invasive surgery. PHA also recognises that since the February 2019 MSAC submission 1555, GLP-1 antagonists have entered the market. While their focus (due to supply shortages) remains for diabetic patients, evidence is growing that suggests these provide far closer weight loss than traditional GLP-1 Inhibitors and pharmacological options in augmenting VLED and other first level interventions around diet and exercise. There are also emerging signs that Ozempic and next generation antagonists are showing positive results regarding cardiac risk. It is highly unlikely patients would elect to have an endoscopic sleeve gastroplasty with such promising evidence, in particular, regarding the clear crossover of Class I and Class II (noncomorbidity) patients being referred by GPs to these medications.

We also support PASC in claiming the three-month window of "failure" as the trigger to go to an invasive surgical procedure is inappropriate. The 12-month hurdle recommended by PASC remains optimal. PHA does support the appropriateness of this treatment as an alternative for patients who do not wish to proceed with direct permanent removal of stomach tissue associated with a bypass or sleeve. How this is addressed with an MBS, however, is not clear. But if it is a case of this generating a new MBS for sleeve gastroplasty for patient with BMI over 40, or over 35 with comorbidities, then we could support this. Our concerns remain regarding the lack of allied professionals to support patients to maintain weight loss after the first three months. We also have concerns about the frequency with which this option would be elected by patients and doctors when aligned to the same preconditions for surgery.

### 4. Does the comparator(s) set out in the application accurately reflect Australian clinical practice?

The current practice and triage for overweight, obese and morbidly obese patients are well established. Early interventions focusing on lifestyle and diet should be attempted before moving to traditional pharmacopeia and VLED. For those having tried and failed these methods for more than 12 months, and with a BMI over 40 or over 35 with comorbidities, then surgical intervention should be considered.

The part that is yet to be fully encapsulated in clinical practice, which is more related to access and prescribing pathways, is the role of the new class of GLP-1 antagonists and other emerging weight loss drugs. While data remains limited, including on optimal methods to sustain weight loss through this method, this class of drug would appear to be the best solution for the category of patients ESG is targeting – those with significant weight issues but without comorbidities or with high risks associated with their condition.

While these medications are not cheap, they represent a simpler pathway between current treatments and stapled surgical intervention than ESG, reducing the burden of treatment for patients. They also come with all the positives of a simpler access path (prescribers), no surgical intervention risk, no need for surgical training compared to ESG, and ultimately a reduced cost per patient to the health system. The benefits for reducing cardiovascular disease are further positives. With a circa 10% effective weight loss at six months, these medications are likely to push a number of patients indicated for this surgery out of the at-risk class and into a BMI below 30-35%.

#### 5. Does the organisation agree with the outcomes as set out in the PICO?

The outcomes are obvious in terms of the metrics to measure weight/BMI/safety/reintervention. The nuances referenced by PASC are further critical outcomes. These include the calculation of dehiscence, a known issue with sutures as they breakdown or stretch over time (a factor not relevant in the same way with a stapling procedure and stomach removal), although both do have considerations for short and long-term complications. Similarly, PASC has called out the critical factors of comparing short and long-term outcomes, given short-term weight loss is recognised to occur in almost all bariatrics/weight loss procedures. This is not always sustained, and ESG certainly appears likely to have a higher risk of mid to longer term decline of weight loss and subsequent surgeries than a sleeve procedure. This would result in additional funding for surgical intervention, once with the apollo device, then a gastrectomy, something not associated with a single definitive non-reversible stapling procedure. PHA also has concerns about the accuracy of the cost model when deployed in Australia, which will be explained in Q7.

### 6. Where the application is for an item on the Medicare Benefits Schedule, does the organisation want to comment on the proposed item descriptor(s)?

PHA would expect PASC and clinicians advising the MSAC to be the experts in describing the procedure, should it be listed. In accordance with comments from PASC from the previous application, PHA does not support starting at a BMI of 30 (Class I). While we are not clinical

experts in this category, it would appear PASC and MSAC would only consider listing this at a match of the current clinical rules associated with MBS 31572, 31575, 31578, 31581 and 31569, i.e:

'The term clinically severe obesity generally refers to a patient with a Body Mass Index (BMI) of 40kg/m2 or more, or a patient with a BMI of 35kg/m2 or more with other major medical co-morbidities (such as diabetes, cardiovascular disease, cancer). The BMI values in different population groups may vary due, in part, to different body proportions which affect the percentage of body fat and body fat distribution. Consequently, different ethnic groups may experience major health risks at a BMI that is below the 35-40 kg/m2 provided for in the definition.'

To implement a lower clinical hurdle would not only be inflationary in terms of surgeries performed, including potential later revisions, it would potentially replace a known and clinically efficacious option that does involve a number of support services previously referred around patient counselling, dieticians etc. Critically, and as listed in multiple occasions across the PICO and other documentation, there is little to no evidence to support performing this surgery on those below 35% BMI with low-risk patients.

Health systems impact the pathway to this surgery being selected. In the USA, this is based on a completely different (and often self-pay) model of ambulatory care centre treatment. While PHI funds may potentially save income long-term from patients electing ESG at a BMI of 30-35%, we do not see this as being consistent with a well determined approach consistent to the clinical rules outlined for the bariatric MBS codes above. When also viewed against other available treatments, including pharmaceutical, as well evidence suggesting low risk

# 7. Where the application is for an item on the Medicare Benefits Schedule (MBS), does the organisation support the proposed fee for the health service or technology?

Attracting the same fee for a similar outcome is not unreasonable, but we are unclear on the likely time taken for the procedure and how this may influence a benefit rate.

Likewise, the evidence does not support that the outcomes are equivalent. The actual cost incurred by patients in gap fees for bariatric surgery are often significant. As such, MSAC and the Department may want to gain a more accurate picture of the full cost of the operations to better assess its value. MSAC should consider the costs of hospitalisation, any devices used, and likely out of pocket costs for patients. Much of the evidence held by the sponsor will come from their US experience, where different forces impact the cost of surgery (including insurance status). The US model of care is clearly based around Ambulatory Surgery Centres (ASC) as day cases, whereas the PICO discusses the Australian model is more likely to involve an inpatient stay.

From our experience both across devices with PL listings and some MBS items, the approvals for funding made by MSAC may be based on a model of care that is not shown to be consistent with actual private hospital practices. We cite BPH treatment with Urolift as an example, where funding was approved on this being a day surgery case with a limited base of anchors compared

to the gold standard TURP, yet surgical practice shows many of these patients are treated as inpatient stays and significantly higher costs for patients for the procedure.

## 8. If MSAC supported the proposed health service or technology, would the organisation want to see it implemented? If yes, what would have to happen for this to occur? If no, why not?

PHA supports choice for patients who are eligible for bariatric surgery under the current conditions being able to access this treatment - provided the surgeon has experience with this treatment and has suitable allied support staff including dieticians, psychologists and psychiatrists etc. We would not want to see it offered at a lower BMI rate (in Class I patients), or with clinicians that did not have extensive experience and the allied supports in place.

#### 9. Does the organisation support public funding for the proposed health service or technology, as it is proposed to be delivered?

We would not support current submission given the increased number of patients it would attract, as well as the health services and the substantial additional costs that would subsequently need to be covered by PHIs.

New medications offer alternative choices for this cohort that were not available when it was last application was submitted for consideration, which was rejected. PHA also supports the current MBS guidelines for bariatric treatment.

Medicare statistics show a decline in demand for this type of surgery, with many patients benefiting from access now to GLP1-antagonists. Reducing the requirements for an invasive surgery seems counter intuitive. We recognise that the MERIT study suggests the treatment is safe and effective, but not in a way that is superior to less invasive medication and diet and exercise changes, or more aggressive but proven gastric sleeve procedures currently available.

The US models of care, where this study was based, make sense in that market where many insurers will not cover bariatric surgery, and the ambulatory care model works well in self-pay or limited co-pay segments. In Australia, we would expect the final cost to health funds with ESG including PL device costs and hospital stay to be comparable to gastric stapling (sleeve/bypass). There is no evidence to support a superior outcome with ESG, or substantively reduced patient risk.

It is also not clear that moving this surgery to a larger number of consultants including gastroenterologists, who may not be linked with allied health, will benefit patients. If existing clinicians believe this treatment is better for some patients who are already eligible for bariatric treatment due to anxiety or other reasons, then there is merit in supporting their clinical choice, but this should not come at supporting a considerable increase in the number of patients eligible.