Gap Between Evidence and Patient Access: Policy Implications for Bariatric and Metabolic Surgery in the Treatment of Obesity and its Complications

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Abstract Despite consistently supportive evidence of clinical effectiveness and economic advantages compared with currently available non-surgical obesity treatments, patient access to bariatric and metabolic surgery (BMS) is impeded. To address this gap and better understand the relationship between value and access, the objectives of this study were twofold: (i) identify the multidimensional barriers to adoption of BMS created by clinical guidelines, public policies, and health technology assessments; and, most importantly, (ii) develop recommendations for stakeholders to improve patient access to BMS. Updated public policies focused on treatment and clinical guidelines that reflect the demonstrated advantages of BMS, patient education on safety and effectiveness, updated reimbursement policies, and additional data on long-term BMS effectiveness are needed to improve patient access.

Key Points for Decision Makers

Obesity and its associated comorbidities have a significant economic and humanistic burden on healthcare systems.

Notwithstanding recent guidelines that recognize obesity as a disease, current policies for reimbursement and coverage of anti-obesity therapies, in addition to other barriers such as complex referral care paths, may potentially limit patient access.

As a result, bariatric and metabolic surgery (BMS), an intervention with demonstrated evidence of clinical and economic value, particularly for type 2 diabetes, continues to face access challenges.

In addition to other stakeholder interventions, access to BMS can be improved by updated clinical guidelines and coverage policies reflecting the advantages of BMS.

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1 Introduction

Obesity and its associated comorbidities have become a global health pandemic, placing an unsustainable burden on patients and healthcare systems. To curb the development or exacerbation of obesity, government guidance and policies from most industrialized countries have largely focused on population-oriented preventive approaches, potentially at the expense of screening and treatment [1–7]. Preventative measures notwithstanding, there has been a

rising trend in obesity prevalence [8–10]. Numerous comorbidities, including type 2 diabetes (T2DM), cardiovascular disease, and cancer attributable to being overweight or obese result in increased mortality and healthcare costs [11–16]. For those who are already obese, prevention strategies are already too late. As such, in 2013 the American Medical Association recognized obesity as a disease requiring a range of medical interventions [16].

In addition to health consequences, obesity results in a significant economic burden. According to the World Health Organization (WHO) Europe, obesity is responsible for 2–8 % of health costs and 10–13 % of deaths in different parts of that region [17]. Worldwide, there are significant direct and indirect costs associated with obesity [18–22]. Healthcare expenditures attributable to diabetes accounted for 11 % of global healthcare expenditures in 2014, and are projected to increase by 30–34 % by 2030 [23]. The overall economic burden of T2DM would be significantly reduced if obesity was prevented and treated.

1.1 Treatment of Obesity Comorbidities with Bariatric and Metabolic Surgery (BMS)

To treat obesity-associated comorbidities, including T2DM, a multifaceted approach, including non-surgical and surgical interventions such as bariatric and metabolic surgery (BMS), is recommended. There are several types of BMS; common procedures include adjustable gastric banding (AGB), Roux-en-Y gastric bypass (RYGB), and sleeve gastrectomy (SG). Bariatric surgical procedures are either restrictive (reducing the amount of food eaten), malabsorptive (reducing nutrient absorption by bypassing parts of the gut), or a combination of these.

Greater effectiveness has consistently been demonstrated with BMS compared with nonsurgical treatment [24–31]. Originally conceived as an acute weight-reduction therapy only, BMS has been demonstrated to effectively control metabolic syndrome components such as hyperlipidemia and, notably, hyperglycemia even before significant weight loss [32]. As a result, BMS can be employed as an effective treatment for T2DM, allowing many patients to reach and maintain therapeutic targets of glycemic and metabolic control that otherwise would not be achievable through intensive medical therapy [33–39]. In recognition of this, in 2013 BMS was deemed Cleveland Clinic's top medical innovation for diabetes [40].

Although effective, BMS remains a relatively uncommon treatment for patients with obesity and, in particular, diabetes. While approximately 11 % of people with a body mass index (BMI) $>35 \text{ kg/m}^2$ [9, 41]—almost 18 million in the US alone—may be clinically eligible for BMS, only 1 % of those eligible have undergone surgery [42]. That gap between the eligible population and those who actually

undergo BMS suggests barriers to access likely resulting in inferior care and higher overall costs. As emphasized in a recent editorial [43], surgery should be available as an option whenever appropriate, rather than as a treatment of last resort once all other options have been exhausted.

The high global prevalence of obesity and T2DM, combined with the consequent rising economic burden, indicates a critical need to revisit the current approach to prevention and to adopt a more direct approach based on treatment. Above all, the growing recognition of obesity as a disease accentuates the need to shift healthcare resource support toward interventions that treat obesity and related complications [44, 45].

1.2 Brief Overview of Economic Evidence of BMS

Although the average cost of BMS is in the US\$11,500 to US\$26,000 range, that cost is offset by reductions in subsequent overall healthcare costs related to obesity comorbidities [46]. Direct cost savings following BMS result from the reduced prevalence and severity of comorbid conditions which, in turn, translate into reduced comorbid condition medication costs, and reduced healthcare resource utilization. Surgical intervention has been associated with net cost savings compared with nonsurgical obesity care due to improved resolution of obesity-related comorbid conditions [47–50]. Significant reductions in both short- and long-term medication costs have also been shown [37, 51–56]. Long-term, BMS has been shown to be less costly (1.5-fold lower) and more clinically effective than standard care over a 10-year span [47], and more cost-saving over a 5-year period than standard medical management of diabetes (diet, exercise, and pharmaceutical therapy) [56].

Importantly, health technology assessments (HTAs) have demonstrated the cost effectiveness of bariatric surgery in Argentina, Canada, and Germany [24, 27, 28]. In patients with a BMI $>40 \text{ kg/m}^2$ or T2DM and BMI $>35 \text{ kg/m}^2$, surgical treatment has shown to be cost effective versus nonsurgical treatment [25–31, 47–49, 57–71]. Thus, compared with nonsurgical interventions, BMS appears to have a positive economic impact in the management of obesity in terms of both cost savings and cost effectiveness.

Notwithstanding evidence of significant positive economic impact, current evidence has limitations. First, although approximately 20 % of patients regain weight after surgery, this weight regain has not yet been accounted for in many economic analyses [72]. Second, variations in treatments and costs across payer types (private vs. public) and countries have resulted in differing return on investment timelines [37, 55, 56, 68–71]. Lastly, many studies examine an arbitrary sample of patients receiving BMS or

Table 1 Access and coverage of BMS by country

Country	Current coverage highlights	Barriers to access
Australia/ New Zealand	RYGB is covered [73, 74]	Wait lists and limited capacity effectively restrict BMS only to patients with severe obesity and comorbidities and those who can afford high out-of-pocket costs Lack of reimbursement for all surgical costs and nutritional supplements potentially limits access to patients who can afford high out-of-pocket costs
Brazil	Procedures have to be performed at accredited centers [75]	There is only one reference center for BMS for every 4 million inhabitants, leading to long waiting lists [76] Insufficient investment in hospital infrastructure Little financial incentive for doctors to perform surgery, as well as low referral rates from specialists and endocrinologists
Canada	Only RYGB is publically insured nationwide [28, 77] With exceptions, LAGB and LSG are largely covered in all provinces [28, 77]	Coverage for AGB in some Canadian provinces lags behind HTA and professional guideline recommendations [28, 77] Patient wait times for surgery may be as high as 5–10 years [78] Number of patients waiting may be underreported due to discrepancy in the referral network between general practitioners and specialists [79] BMS is elective procedure often performed in only a few specialized hospitals, leading to substantial out-of-pocket costs for travel and accommodation [80]
European Union	Varies by country	Heterogeneity in endpoints and regional policies because of differences in surgery populations and cost structures; inconsistency in coverage policies across individual hospitals, regions, and provinces; and different financial metrics which are not geographically transferrable Lack of funding for non-surgical treatment requirements preceding BMS disqualifies patients from receiving surgery Lack of reimbursement completeness for all surgical costs and nutritional supplements increases out-of-pocket costs Lack of awareness about BMS among patients, with the exception of France where awareness is high among both patients and providers [81]
France	RYGB is covered under French National Health Insurance [82]	Some postoperative nutritional supplements and follow-up operations are not covered [82]
Germany	RYGB is covered [83]	Although recent guidelines have defined quality standards for bariatric surgeons, bariatric surgery is not recognized as a subspecialty of surgery, potentially creating an expertise gap [84] Statutory health insurance makes decisions on a case-by-case basis since bariatric and metabolic surgery is indicated only after the failing of multimodal weight loss programs [84]
Spain	Preferences for specific surgery types are unspecified [85]	Children and adolescents are only covered in exceptional circumstances [85]
Taiwan	Procedures have to be performed at accredited centers [86]	Access to BMS may be limited due to relatively low procedure volumes as well as the limited availability of qualified surgeons in the country [87]

Table 1 continued

Country	Current coverage highlights	Barriers to access
UK	RYGB is covered [88]	Wait lists and limited capacity effectively restrict BMS only to patients with severe obesity and comorbidities, and those who can afford high out-of-pocket costs
US	Medicare covers BMS for BMI ≥ 35 with at least one co-morbidity and previously unsuccessful medical treatment, and no longer requires COE [89] BMS covered by Medicaid in 45 states [90] RYGB and LSG are covered	Some private insurers cover on a limited basis, although individual plans have discretion over whether or not BMS is covered [90] The elimination of COE requirements by Medicare has improved patient access without increasing complication or reoperation rates [91] The lift on COE restrictions by Medicare may boost surgical volumes Complex network of referral care paths, potentially resulting in patients falling through the cracks In the US, payer focus on short-term ROI may impede coverage and may be accentuated by the recent ACO-based healthcare reforms Coverage for SG lags behind HTA and professional guideline recommendations [92]

ACO accountable care organization, AGB adjustable gastric band, BMI body mass index, BMS bariatric and metabolic surgery, COE center of excellence, HTA health technology assessment, LAGB laparoscopic adjustable gastric band, LSG laparoscopic sleeve gastrectomy, ROI return on investment, RYGB Roux-en-Y gastric bypass, SG sleeve gastrectomy

focus on patients with specific comorbidities (e.g. diabetes) or higher BMIs, thereby leaving some uncertainty about the cost effectiveness or savings of BMS for obese patients with lower BMIs or fewer comorbidities.

2 Barriers to BMS Access

Despite economic and clinical benefits, globally there are significant barriers to patient access to BMS (detailed in Table 1) that may be categorized broadly as (i) obesity bias, (ii) patient-related factors, (iii) current BMI-based selection criteria, (iv) access to centers of excellence or qualified surgeons, (v) infrequent clinical guideline updates and data gaps, and (vi) restrictive third-party payer coverage.

2.1 Obesity Bias

Obesity has been characterized as a self-inflicted condition, implying that any treatment for obesity should be a personal and financial responsibility of the patient, and that resources from third-parties should not be allocated towards the treatment of obesity [93–96]. Many conditions that can be ameliorated through healthy choices, such as hyperlipidemia and smoking-related cancer, represent significant shares of total healthcare costs. Obese patients have been uniquely targeted as lacking will power and ignoring healthy choices, resulting in a disproportionate

focus on changes in patient behavior as a prerequisite to treatment [96].

Possibly as a result of slowly and differentially evolving attitudes regarding obesity, coverage standards for BMS have been inconsistent compared with other surgeries. This is illustrated by consistent reimbursement for drug-eluting cardiac stents, even though more than 10 % of patients fail to continue antiplatelet therapy beyond the first month, increasing stent thrombosis and increasing mortality by a factor of 10 [97]. Similarly, solid organ transplants are routinely offered with full reimbursement coverage, even though up to 38 % of patients fail to take their anti-rejection medication [98]. Thus, it is crucial to raise stakeholders' awareness about the limitations of patients' willpower to prevent and reverse obesity, and thus the importance of treating obesity as a disease with appropriate treatment. Indeed, education of healthcare providers about overweight and obesity has been shown to change negative attitudes [96, 99].

2.2 Patient-Related Barriers

In addition to healthcare-provider barriers, there are also barriers attributable to patients themselves. Cost, perceived risks associated with BMS, perception of one's own weight, and a lack of understanding of the impact of excess weight on life expectancy and morbidity, among others, prevent patients from seeking BMS [100–105].

One survey of 2784 patients with BMIs between 34.3 and 43.4 kg/m² and up to eight comorbidities found that

patients had never tried surgery, primarily due to cost and safety perceptions [101]. The main cost barriers identified by participants were affordability, uncertainty about insurance coverage, and time away from work. The major safety issues cited included concern about experiencing major complications, unknown risks of surgery, fear of surgery, and not knowing the predictability of the outcome [101].

Another patient-related barrier to effective obesity treatment is the widespread prevalence of excess weight, which results in a perception of morbidity-inducing levels of BMIs as acceptable [104, 105]. Many patients may also understate the health consequences of obesity. In one study with female candidates for bariatric surgery, the majority rated themselves as being in good health despite frequent comorbidities, did not accurately perceive their level of obesity, nor understand their risk of developing weight-related disease [104]. In another study, only 55 % of those overweight, and 87 % of those obese, correctly perceived their weight [105].

Furthermore, there are socioeconomic disparities between the general morbidly obese ($\text{BMI} > 40 \text{ kg/m}^2$) population and the subset that have access to and/or receive bariatric surgical procedures, suggesting that poorer patients, particularly in rural areas, have more limited access to BMS than more affluent patients [100, 106–109]. Compared with the general population, individuals who are candidates for bariatric surgery are often older, come from racial or ethnic minorities, are economically disadvantaged, and have low levels of education [107, 109]; however, in some countries it is this subset of the population that is least likely to have access to bariatric surgery [109].

2.3 Current Body Mass Index-Based Selection Criteria

An important barrier to BMS access is BMI-based selection criteria. Currently, HTAs and clinical guidelines recommend BMS for weight loss and comorbidity management for select patient populations. These populations are defined by BMI and the presence of weight-related comorbidities, including hypertension, T2DM, hyperlipidemia, heart failure, and sleep apnea. Except in Asia, bariatric surgery has been consistently advocated as a later line of treatment in patients with a $\text{BMI} \geq 40 \text{ kg/m}^2$ and for those with a BMI in the $35\text{--}40 \text{ kg/m}^2$ range with one or more weight-related comorbidities. The recommendations for BMS based on BMI cutpoints are detailed in Fig. 1 [44, 77, 80, 81, 83, 85, 86, 110–121]. BMS HTAs are fairly consistent in using the same criteria as clinical guidelines for recommending BMS (Fig. 2) [24–26, 28–31, 53, 73, 75, 122–131].

The widespread use of a uniform BMI-centric criterion for patient selection across the world may result in additional barriers to BMS access. Specifically, mounting evidence suggests that the currently used BMI thresholds for BMS eligibility may be inappropriate for Asian populations, who may experience more adverse health risks at lower BMIs than other populations [86, 118]. Taiwanese guidelines recommend lower BMI thresholds ($\text{BMI} \geq 32.5 \text{ kg/m}^2$ with comorbidities or $\text{BMI} \geq 37.5 \text{ kg/m}^2$) due to these population-specific considerations [86]. More recently, BMI thresholds in certain guidelines from this region have been further reduced to include patients with a $\text{BMI} > 27.5 \text{ kg/m}^2$ [118].

In the US, the Blue Cross Blue Shield Technology Evaluation Center, and the Agency for Healthcare Research and Quality, have explored the use of BMS in patients with a $\text{BMI} \leq 35 \text{ kg/m}^2$, especially among those with T2DM [125–127]. A growing consensus among US governmental and non-governmental organizations, such as the National Institutes of Health (NIH), the American Association of Clinical Endocrinologists, the Obesity Society, and the American Association of Metabolic and Bariatric Surgery, as well as the Cochrane Collaboration (UK), support the intervention's benefits in populations with a BMI between 30 and 35 kg/m^2 with comorbidities [44, 123, 131].

The expansion of the range of acceptable BMIs for BMS should be explored and potentially include those with moderate obesity ($30\text{--}35 \text{ kg/m}^2$). Alternatively, the guidelines and coverage policies should adopt a comorbidity-centric model for the medical management of obesity rather than a BMI-centric model [132, 133]. A comorbidity-centric model would place the focus on complications rather than weight itself. This would include BMS as a therapeutic alternative for a wider population and add an innovative and effective treatment for diabetes.

2.4 Access to Centers of Excellence or Qualified Surgeons

Generally, guidelines around the world recommend that BMS procedures be performed at high-volume centers with deep multidisciplinary expertise [14–115, 117, 118]. However, in 2013, the US Centers for Medicare and Medicaid Services (CMS) made a decision in disagreement with this consensus, eliminating its requirement for performing BMS at centers of excellence (COE) as a condition of reimbursement [89], based on studies reporting no differences in BMS success/efficacy and complication rates before and after implementation of the COE requirement. However, the limited availability of qualified surgeons still remains a barrier in some parts of the world (Table 1).

Fig. 1 Recommended BMI cutpoints for BMS from obesity clinical guidelines [44, 77, 80, 81, 83, 85, 86, 110–121]. BMI body mass index, BMS bariatric and metabolic surgery, NIH National Institutes of Health, AGA American Gastroenterological Association, ADSS Asian Diabetic Surgery Summit, SSAT Society for Surgery of the Alimentary Tract, ACP American College of Physicians, NHS National Health Service, VA/DOD Department of Veterans Affairs/Department of Defense, CADTH Canadian Agency for Drugs and Technologies in Health, SAGES Society for American Gastrointestinal and Endoscopic Surgeons, HAS Haute Autorite De Sante, MHSP Ministry of Health and Social Policy, SIGN Scottish Intercollegiate

Guidelines Network, IDF International Diabetes Federation, IFSO-APC International Federation for the Surgery of Obesity and Metabolic Disorders–Asia Pacific Chapter, IQWiG Institute for Quality and Efficiency in Health Care, AACE/TOS/ASMBS American Association of Clinical Endocrinologists/The Obesity Society/American Society of Metabolic and Bariatric Surgery, CIHI Canadian Health Institute for Health Information, NICE National Institute for Health and Care Excellence

2.5 Infrequent Clinical Guideline Updates and Data Gaps

Recently available economic and clinical evidence on BMS has not been incorporated in clinical guidelines, in part because of infrequent revision (Fig. 1) [44, 77, 80, 81, 83, 85, 86, 110–121]. Since 2012, only three guidelines have been published [44, 80, 119]. Approximately one-half of the guidelines (8/19) are largely based on the first US NIH guideline, dating from 1998, which proposed BMS as a later line of treatment for patients with a BMI ≥ 35 kg/m² at a time when the procedure was a relatively new intervention. Guideline recommendations have not significantly changed in 16 years despite significant safety and efficacy data in a wide range of patient populations.

Notwithstanding mounting evidence of the clinical and economic effectiveness of bariatric surgery, obesity clinical guidelines and BMS HTAs have identified several data gaps. In general, those data gaps may be grouped into six categories: (a) lack of head-to-head comparisons among BMS procedures; (b) defining the lower limit of BMI where BMS is recommended; (c) long-term outcomes;

(d) optimal criteria for surgical selection; (e) line of therapy (early vs. late utilization); and (f) indications for BMS. Table 2 contrasts those data gaps with the available evidence. Updated clinical guidelines would significantly improve patient access to BMS and ensure that systematic criteria are applied to identify patients for whom BMS has been shown to be safe and effective based on scientific research.

2.6 Restrictive Third-Party-Payer Coverage

Although BMS is both clinically effective and cost effective for managing diabetes and other comorbidities due to sustained weight loss, BMS coverage continues to remain restrictive throughout the world, thus limiting patient access. Several access barriers related to third-party-payer coverage policies are consistent across the globe, including the following.

- The recommendation of BMS as third-line or later therapy deters access if the first and second lines of treatment are also not accessible [92, 110, 114, 153].

Fig. 2 HTA-recommended BMI cutpoints for BMS [24–26, 28–31, 53, 73, 75, 122–131]. *BMI* body mass index, *BMS* bariatric and metabolic surgery, *HTA* health technology assessment, *OHTAC* Ontario Health Technology Advisory Committee, *BRATS* Boletim Brasileiro de Avaliação Tecnologias em Saúde, *IECS* Institute for Clinical Effectiveness and Health Policy, *DIMDI* German Institute for Medical Documentation and Information, *CTAF* California Technology Assessment Forum, *NICE QIS* National Institute for Health and

Care Excellence Quality Improvement Scotland, *CADTH* Canadian Agency for Drugs and Technologies in Health, *AHRQ* Agency for Healthcare Research and Quality, *MSAC* Medical Services Advisory Committee, *BCBSTEC* Blue Cross Blue Shield Technology Evaluation Center, *LBI* Ludwig Boltzmann Institute for Health Technology Assessment

- The requirement that all appropriate non-surgical measures be tried for at least 6 months prevents many eligible patients from qualifying to receive BMS since they are unable to follow through the prerequisite requirements of dieting and exercise [92, 110, 114, 153].
- The recommendation of BMS only for a small subset of the obese population, specifically for patients with a BMI ≥ 35 kg/m² with comorbidities or BMI ≥ 40 kg/m², is based on outdated clinical guidelines.
- Payer prejudicial attitudes towards obesity as a self-inflicted condition likely impacts coverage, and thus access.
- The perception of BMS as only a weight loss intervention rather than an intervention to treat comorbidities (BMI-centric vs. comorbidity-centric).

Access to BMS is contingent on a matrix of multivariable pillars (Fig. 3). With increasing worldwide emphasis on the demonstration of value from medical interventions, reimbursement and access hinge on multiple factors, including continued development of long-term health benefit evidence in obese and diabetic populations in

various weight ranges, head-to-head comparisons between technologies, and alignment of evidence needs and levels of evidence awareness among different stakeholders.

3 Recommendations for Stakeholders

To the end of improving access to BMS for the eligible population, various actions by stakeholders could and should be undertaken.

- Expand government policy focus from predominately emphasizing obesity prevention to include comorbidity treatment.
- Update clinical guidelines to incorporate the clinical and financial advantages of BMS as a comorbidity treatment so patient selection becomes more comorbidity-centric.
- Update reimbursement policies to reflect the current demonstrated value of surgery in the mildly obese (BMI 30–35 kg/m²) populations to resolve comorbidities, allowing earlier appropriate use of BMS in a wider range of patients.

Table 2 Evidence to be incorporated into clinical guidelines and HTAs

Identified data gaps in HTAs and clinical guidelines	Evidence to be incorporated
Optimum criteria for surgical selection: defining the lower limit of BMI where BMS is recommended	<p>Guidelines from the Asia-Pacific region are beginning to recommend surgery at lower levels of obesity based on ethnic/race specific data [86, 118]</p> <p>BMS safely and effectively ameliorated diabetes and associated comorbidities, reducing cardiovascular risk, including those with BMI 30–35 kg/m² [36, 53, 129–143]</p> <p>Additionally, LSG safely and effectively resulted in significant weight loss in patients with BMI 30–35 kg/m² who were resistant to medical treatment (36 % had at least one comorbidity) [140, 141]</p> <p>BMS was a cost effective alternative to nonsurgical interventions over a lifetime in patients with BMI 30–40 kg/m², and with BMI >30 kg/m² with diabetes in South Korea [62]</p> <p>Recent studies have suggested that preoperative fasting insulin or glucose concentrations may be a better predictor of the benefits of BMS [33–39, 142, 143]</p>
Optimum criteria for surgical selection: indications for BMS	<p>Diabetes is accepted as an indication for BMS in those with BMI >35 kg/m² [144]</p> <p>Indications for BMS should be expanded to include treatment of diabetes in those with lower BMIs based on data stated above</p> <p>As noted by the ADA, additional trials in those lower-weight populations may be necessary [144]</p>
Long-term outcomes	<p>Bariatric surgery can achieve substantial sustained weight loss in the majority of eligible obese patients as well as obesity-related condition resolution or improvement over time (T2DM, CVD, sleep apnea) [145–147]</p> <p>Sustained weight loss has been maintained out to 20 years [145]</p> <p>Surgery was more efficient than regular care for the prevention of T2DM in persons with obesity over 15 years [34]</p> <p>Surgery resolved or improved T2DM and other obesity-related CV comorbidities out to 5 and 20 years [70, 145]</p> <p>Surgery reduced medication use for T2DM and other CV comorbidities for up to 3 years [51, 70]</p> <p>BMS is associated with an 89 % reduction in risk of premature death over a 5-year period versus not having surgery [148]</p> <p>Establishing long-term effects may be confounded by variability in expenses among institutions and populations, as well as services and capital management</p> <p>Non-adherence rate to follow-up visits after surgery has been reported to be as high as 17.5 %, thus a substantial number of patients are lost to follow-up, leading to uncertainty regarding data on population-wide benefits of the intervention [149]</p>
Line of therapy (surgical interventions currently recommended for later intervention)	<p>Early intervention helped T2DM patients achieve glycemic control more effectively than intensive medical therapy within 1 year and at 3 years [33]</p> <p>People whose T2DM was most severe or in its later stages when they had surgery were more likely to have a relapse, regardless of whether they regained weight [150]</p> <p>Surgery is effective in managing the broad range of health problems experienced by severely obese individuals with T2DM [33, 151, 152]</p> <p>Many eligible patients may not qualify to receive BMS since they are unable to follow through the required steps</p>
Lack of head-to-head comparisons among BMS procedures	<p>2014 Cochrane review [123]</p> <p>Weight loss outcomes similar between RYGB and SG, and both of these procedures had better outcomes than adjustable gastric banding</p> <p>In those with very high BMI, biliopancreatic diversion with duodenal switch resulted in greater weight loss than RYGB</p> <p>Duodenojejunal bypass with sleeve gastrectomy and laparoscopic RYGB had similar outcomes (based on one small trial)</p> <p>Isolated SG led to better weight-loss outcomes than adjustable gastric banding after 3 years of follow-up</p> <p>It is likely more head-to-head comparisons with larger subject numbers are needed to determine best procedure for a given type of patient</p> <p>Organizations around the world have acknowledged the need for direct head-to-head trials between RYGB, LAGB, and SG [72, 121, 125, 139]</p>

ADA American Diabetes Association, *BMI* body mass index, *BMS* bariatric and metabolic surgery, *CV* cardiovascular, *CVD* cardiovascular disease, *HTA* health technology assessment, *LAGB* laparoscopic adjustable gastric band, *LSG* laparoscopic sleeve gastrectomy, *RYGB* Roux-en-Y gastric bypass, *SG* sleeve gastrectomy, *T2DM* type 2 diabetes mellitus

Fig. 3 Bariatric surgery reimbursement

- Educate stakeholders:
 - *payers*: on clinical and financial benefits of BMS, particularly as a treatment for T2DM and other comorbidities;
 - *patients*: on the benefits and risks associated with these procedures and the need for long-term adherence with lifestyle management following surgery;
 - *providers*: on updated efficacy, safety, and cost effectiveness information on BMS and the need for adherence assistance with post-surgery lifestyle requirements.
- Develop standards in research methodologies and endpoints applicable to multiple regions to eliminate inconsistencies in coverage policies across individual hospitals, regions, and provinces, particularly in the EU.
- Establish care pathways for optimal referral networks, to reduce the heterogeneity in endpoints and regional policies.
- Establish and leverage COEs in emerging markets, to build technical expertise and patient awareness before nationwide expansion in Taiwan and Brazil.
- Develop additional evidence on long-term BMS effectiveness, especially in the moderately obese.

4 Conclusions

Although BMS is clinically effective and cost effective for managing obesity-associated comorbidities, a gap persists between available evidence and actual uptake. Updated

public policies focused on treatment and clinical guidelines that reflect the demonstrated advantages of BMS, patient education on safety and effectiveness, updated reimbursement policies, and additional data on long-term BMS effectiveness are needed to improve patient access to bariatric surgery.

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