

ASMBS Guidelines/Statements

ASMBS updated position statement on insurance mandated preoperative weight loss requirements

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Preamble

In 2011, the American Society for Metabolic and Bariatric Surgery (ASMBS) published a position statement on preoperative weight loss requirements [1]. This statement was developed in response to inquiries made to the ASMBS by patients, physicians, hospitals, health insurance payors, the media, and others regarding the need for and efficacy of insurance mandated preoperative weight loss requirements before undergoing bariatric surgery. In the evolving field of bariatric surgery, it is periodically necessary to provide updated position statements based on a growing or changing body of evidence. The Clinical Issues Committee and Executive Council of ASMBS have determined that since the 2011 position statement on preoperative weight loss requirements was issued, additional evidence is available to challenge the ongoing practice of insurance mandated preoperative weight loss as arbitrary, potentially harmful, unethical, and not supported by scientific data. The recommendations made within are made based on peer-reviewed, scientific, evidence-based literature and expert opinion.

The issue

The purpose of this position statement is to provide an evidence-based review of the medical literature from 2011 to the present regarding insurance mandated preoperative weight loss, in contrast to physician-, program-, or patient-initiated weight loss (as previously described and differentiated in the 2011 statement), which purports to improve surgical risk or assess patient adherence to programmatic requirements.

Obesity is epidemic in the United States and worldwide. The adverse effects of obesity on health and longevity were formally recognized and established by the National Institutes of Health (NIH) in 1985 [2]. Class II and III obesity (clinically severe obesity) alone are associated with an increase in all-cause mortality; over 300,000 deaths annually in the U.S. are attributed to obesity [3,4]. In addition to the health consequences of obesity, the yearly economic impact of adult obesity in the U.S. has been estimated at over \$315 billion in direct medical costs alone [5]. Metabolic and bariatric surgery have been shown to be safe and remain the most effective and durable treatments for clinically severe obesity with a documented reduction in all-cause mortality and long-term survival benefit [6]. Metabolic and bariatric surgery are cost-effective, particularly when type 2 diabetes is present, providing a return on investment in as little as 25 months to 5 years [7–11].

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Despite the overwhelming high quality data demonstrating the safety and benefits of metabolic and bariatric surgery, universal insurance coverage for treatment of clinically severe obesity has not been established, unlike for other potentially life-threatening diseases such as cancer, heart disease, and diabetes (for which obesity is a powerful risk factor). Furthermore, unlike coverage for patients with other life-threatening diseases, those with clinically severe obesity often face myriad arbitrarily imposed criteria to obtain insurance authorization for metabolic and bariatric surgery, which includes documentation of supervised diet attempts of various lengths of time (e.g., typically 3–18 months), with specified providers and formats; visits that must be continuous or consecutive in nature and occur within a specified time period (e.g., 12–24 months) before surgery and, in certain cases, must also meet a specified percentage of preoperative weight loss of 5%–15%; or failure to achieve a certain percentage of weight loss (5%–10%; insurance-mandated preoperative weight loss requirements). Insurance-mandated preoperative weight loss requirements are strictly enforced without consideration of the severity of obesity present; the status of other life-threatening co-morbid conditions or life circumstances that may force a patient to miss a required visit; or whether the patient can afford the additional costs of the adjunct dietary and exercise programs, medications, and visits to providers to comply with the requirements [1]. The outcome of insurance-mandated preoperative weight loss requirements is patient attrition, delay in obesity treatment, progression of obesity and associated life-threatening co-morbid conditions, and increased direct and indirect healthcare costs [1,12–17].

Background

Obesity is a chronic and complex disease and despite the lack of controversy in the health implications or risks of obesity, the management of obesity has historically been less standardized. The 1991 NIH consensus statement on the treatment for severe obesity suggested a standardized approach for patients seeking surgical therapy and provided selection criteria that included body mass index (BMI), previous weight loss attempts, and completion of a multidisciplinary evaluation in a clinical setting with resources to provide such management and life-long support [18]. The NIH consensus statement, however, did not recommend weight loss before surgery, given the understanding that the majority of individuals with clinically severe obesity have suffered a lifelong battle with obesity and have almost uniformly failed multiple prior efforts without long-term efficacy before seeking surgical treatment. The provider was felt to be best able to determine what constituted failed efforts for each patient [18–20].

Medicare requires that patients have been unsuccessful with medical treatment for obesity, but similar to the NIH

consensus recommendations, it does not require successful weight loss or mandate a specified type of diet or length of time, relying on providers to detail such efforts [21]. Although modest weight loss (5%–10% of initial weight) is associated with an improvement in established risk factors for cardiovascular disease related to obesity, these positive effects will not endure unless weight loss is achieved and maintained [22,23]. The majority of dietary weight loss clinical trials show that maximal weight loss will have generally occurred and begun to plateau by 6 months, with roughly one third of patients regaining lost weight within a year, and gaining more thereafter [23,24]. Except for those insurance companies that require a preset mandated percentage weight loss of 5%–15% of initial weight, the majority of insurance companies require the stringent adherence to a certain number of arbitrary months of consecutive visits, regardless of whether any actual weight is lost or gained. Conversely, some insurance companies require that a patient “fail” a 6- or 12-month supervised diet and achieve or maintain <10% weight loss during the mandated time period. Patients who met eligibility criteria at the time of initial presentation for surgical treatment who lose >10% of their initial weight are penalized with denial of coverage for surgery, despite persistent clinically severe obesity; others may be penalized because their BMI may have fallen below the threshold. The majority of patients denied insurance coverage for bariatric surgery will have progression of their obesity and obesity related co-morbid conditions, particularly diabetes, as well as a higher incidence of new-onset diabetes, hypertension, and sleep apnea while awaiting insurance approval [15–17], though it is well understood that the likelihood of achieving healthy weight without surgery is exceedingly low. A recent published longitudinal study of 76,704 obese men and 99,791 obese women from the United Kingdom’s Clinical Practice Research Datalink, followed for up to 9 years (and excluding patients who had undergone bariatric surgery), found that the annual probability of attaining normal weight was 1 in 1290 for men and 1 in 677 for women with morbid obesity [25]. Patients seeking surgical treatment for clinically severe obesity should therefore be evaluated for eligibility based on their initial presenting BMI and not be penalized or denied care for weight lost as part of insurance-mandated preoperative weight loss.

Data

The summary and recommendations from the 2011 statement concluded that there were no Level I studies or evidence-based reports that documented any benefit or need for a 3–18 month insurance-mandated preoperative dietary weight loss program before bariatric surgery. Insurance-mandated preoperative weight loss was found to be unsupported by any degree of medical evidence and

therefore inappropriate, counterproductive, and potentially harmful as it resulted in unnecessary delay and interference with potentially life-saving treatment. Individual surgeons and programs may recommend preoperative weight loss according to the specific needs and circumstances of the patient [1].

A MEDLINE search of the published data from the past 5 years was performed using key words “preoperative weight loss” AND “bariatric” or “obesity” for the present updated statement. Previously reviewed studies, small case studies, and studies lacking outcomes data or 30-day follow-up were excluded. Included in this review were 3 randomized clinical trials (RCTs), 1 prospective cohort study, 3 retrospective reviews, and 3 systematic reviews [26–35]. Only 1 RCT and retrospective review, however, were specifically related to insurance-mandated preoperative weight loss [34,35].

Although numerous preoperative weight loss strategies have been proposed, most of the available studies did not define or detail the specific diet utilized. Based on medical weight loss data, very-low-calorie diets (VLCD), defined as 800 kcal/d, and low-calorie diets, defined as 800–1200 kcal/d, were generally associated with the greatest absolute losses in the shortest periods of time, but were also associated with lower rates of long-term compliance and weight loss maintenance. Preoperative weight loss can only be considered important if there are related outcomes benefits, such as reduced complications, improvement in co-morbid disease status, better long-term weight loss, etc.

Two RCTs were reviewed. Neither of these studies specifically assessed insurance mandated preoperative weight loss. In 1 study, 294 patients were randomly allocated to a 2-week preoperative VLCD regimen ($n = 137$) or no specific diet ($n = 136$) to assess impact on perioperative outcomes after laparoscopic Roux-en-Y gastric bypass (LRYGB). There was a significant weight loss seen in the VLCD group versus control (4.9 ± 3.6 kg compared with $.4 \pm 3.2$ kg; $P < .001$) with good reported compliance, but there was no significant difference in mean operative time, estimated blood loss, visual scale of difficulty, or intraoperative complications. Long-term weight loss outcomes were not reported [26].

Behavioral lifestyle interventions (BI) for individuals with clinically severe obesity have been extensively studied in medical weight loss trials and found to be more effective than standard diet alone with 5%–10% weight loss achieved in 6 to 12 months [33,34]. A second RCT compared BI defined as dietary education, physical activity, and behavioral strategies with 24 weekly contacts of which 12 were face to face and 12 via telephone for 6 months with 3 monthly telephone contacts postoperatively, compared with usual care (UC), which consisted of any 6-month physician-supervised weight loss in patients undergoing laparoscopic adjustable gastric band (LAGB) and LRYGB. There were 121 patients randomized to the BI group and 119 patients

randomized to the UC group. Of the 240 patients, 71 patients in the BI group and 72 patients in the UC group underwent surgery. Although the patients in the BI group had greater preoperative weight loss (5.7% versus 2.6% mean excess weight loss [EWL] $P < .001$), there was no difference in postoperative complications or EWL at 6 and 12 months, with slightly less weight loss seen in the BI group compared with the UC group at 24 months (26.5% versus 29.5% mean EWL%; $P = .02$). Aggressive behavioral lifestyle intervention, with over 80% group completion of weekly contacts, failed to show any overall postoperative outcomes benefit despite greater preoperative weight loss [27]. A third RCT identified 55 patients who met NIH consensus guidelines for bariatric surgery and randomized them into a mandatory 6-month medically supervised weight management program or 6 months of UC and then followed them postoperatively after undergoing LAGB (initial and at 6 months) looking at patient behaviors and weight loss outcomes. Mandatory participation in medically supervised weight management was not found to have any difference in postoperative weight loss or behavior outcomes [34].

Three recently published interval systematic reviews also failed to find any evidence that mandated preoperative weight loss was effective in achieving preoperative weight loss or associated with any improved outcomes benefit [31–33]. One systematic review included a recent large prospective population based cohort study from the Scandinavian Obese Patients Registry that analyzed data on 22,327 patients, of whom 96.5% underwent LRYGB and were divided into percentiles based on the amount of preoperative weight loss. Preoperative weight change in the 25th, 50th, and 75th percentile were .5%, -4.7% , and -9.5% , respectively. In multivariate analysis, comparing patients in the 75th percentile with the 25th percentile preoperative weight loss groups, risk of any complication was reduced by 13% (odds ratio .87, 95% CI .33–.64). Long-term outcomes data and weight loss outcomes, however, were not provided [29]. Two additional uncontrolled case series have shown no difference in weight loss outcomes. The only study that involved laparoscopic sleeve gastrectomy (LSG) looked at 141 consecutive patients who underwent LSG without any specified or mandated preoperative diet. Of the 141 patients, 72 patients lost weight before surgery, 64 patients gained weight, and 6 patients were unchanged. There was no difference found in operative time or postoperative weight lost at 1 year [27]. In another series, 548 consecutive patients underwent LRYGB with no specified preoperative diet and were analyzed based on the percentage of preoperative weight loss achieved, $<5\%$, 5%–10%, and $>10\%$ with 166, 239, and 143 patients, respectively. Mean operative time and length of stay was greater for the $<5\%$ weight loss group compared with the 2 other groups ($P = .001$), but there was no difference in weight loss between the 3 groups at 6 months and at 2 years. A

recent retrospective study looked specifically at the effect of insurance-mandated medical weight management programs on weight loss outcomes and included patients who underwent LSG, LRYGB, and LAGB. A total of 1432 patients were reviewed and stratified by payor mix based on whether their insurance mandated preoperative weight loss and resulted in 500 patients for analysis after bucket matching algorithm. The regression model found no significant difference in weight loss outcomes between the mandated weight management group and the comparison group at 1 and 2 years [32].

Overall, there is no evidence of any kind that insurance-mandated preoperative weight loss or preoperative weight loss in general has any clear impact on postoperative outcomes or weight loss. No published RCT, systematic review, or retrospective review has identified any postoperative outcomes benefit after insurance mandated preoperative weight loss. Nor is there any precedent for requiring weight loss or proof of lifestyle compliance before authorization of any other elective surgical procedure.

In conclusion, it is the position of the ASMBS that insurance-mandated preoperative weight loss is not supported by medical evidence and has not been shown to be effective for preoperative weight loss before bariatric surgery or to provide any benefit for bariatric outcomes.

Recommendations

1. There are no data from any randomized controlled trial, large prospective study, or meta-analysis to support the practice of insurance mandated preoperative weight loss. The discriminatory, arbitrary, and scientifically unfounded practice of insurance-mandated preoperative weight loss contributes to patient attrition, causes unnecessary delay of lifesaving treatment, leads to the progression of life-threatening co-morbid conditions, is unethical, and should be abandoned.
2. There is no Level I data in the surgical literature or consensus in the medical literature (based on over 40 published RCTs) that has clearly identified any 1 dietary regimen, duration, or type of weight loss program that is optimal for patients with clinically severe obesity.
3. Patients seeking surgical treatment for clinically severe obesity should be evaluated based on their initial BMI and co-morbid conditions. The provider is best able to determine what constitutes failed weight loss efforts for their patient.

Disclaimer

This Position Statement is not intended to provide inflexible rules or requirements of practice and is not intended, nor should it be used to state or establish a local,

regional, or national legal standard of care. Ultimately, choice of treatment should be individualized for each patient; surgeons must use their judgment in selecting from among the different feasible treatment options.

The ASMBS cautions against the use of this Position Statement in litigation in which the clinical decisions of a physician have been called into question. The ultimate judgment regarding the appropriateness of any treatment must be made by the individual physician, taking into consideration the available evidence and circumstances presented. Thus, an approach that differs from the Position Statement, standing alone, does not necessarily imply that the approach was below the standard of care. A conscientious physician could responsibly adopt a course of action different from that set forth in the Position Statement when, in the reasonable judgment of the physician, such a course of action is indicated by the condition of the patient, the limitations of available resources, or advances in knowledge or technology. All that should be expected is that the physician will follow a reasonable course of action on the basis of current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this Position Statement is to assist practitioners in achieving this objective.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

References

- [1] Brethauer S. ASMBS position statement on preoperative supervised weight loss requirements. *Surg Obes Relat Dis* 2011;7(3):257–60.
- [2] Health implications of obesity. National Institutes of Health Consensus Development Conference Statement. *Ann Intern Med* 1985;103(1):147–51.
- [3] Flegal KM, Kit BK, Orpana H, Graubard BI. Association of all-cause mortality with overweight and obesity using standard body mass index categories: a systematic review and meta-analysis. *JAMA* 2013;309(1):71–82.
- [4] U.S. Department of Health and Human Services. The Surgeon General's vision for a healthy and fit nation fact sheet [monograph on the Internet]. Washington, D.C.: U.S. Department of Health & Human Services [cited 2016 June 7]. Available from: http://www.surgeongeneral.gov/priorities/healthy-fit-nation/obesityvision_fact_sheet.html.
- [5] Finkelstein EA. How big of a problem is obesity? *Surg Obes Relat Dis* 2014;10(4):569–70.
- [6] Kim J, Eisenberg D, Azagury D, Campos GM. American Society for Metabolic and Bariatric Surgery position statement on long-term survival benefit after bariatric surgery. *Surg Obes Relat Dis*. Epub 2015 Nov 27.
- [7] Gallagher SF, Banasiak M, Gonzalvo JP, et al. The impact of bariatric surgery on the Veterans Administration healthcare system: a cost analysis. *Obes Surg* 2003;13(2):245–8.
- [8] Sampalis JS, Liberman M, Auger S, Christou NV. The impact of weight reduction surgery on health-care costs in morbidly obese patients. *Obes Surg* 2004;14(7):939–47.

- [9] Cremieux PY, Buchwald H, Shikora S, Ghosh A, Yang HE, Buessing M. A study on the economic impact of bariatric surgery. *Am J Manag Care* 2008;14(9):589–96.
- [10] Perryman MR, Gleghorn V. Obesity-related costs and the economic impact of laparoscopic adjustable gastric banding procedures: benefits in the Texas Employees Retirement System. *J Med Econ* 2010;13(2):339–50.
- [11] Klein S, Ghosh A, Cremieux PY, Eapen S, McGavock TJ. Economic impact of the clinical benefits of bariatric surgery in diabetes patients with BMI ≥ 35 kg/m². *Obesity (Silver Spring)* 2011;19(3):581–7.
- [12] Jamal MK, DeMaria EJ, Johnson JM, et al. Insurance-mandated preoperative dietary counseling does not improve outcome and increases dropout rates in patients considering gastric bypass surgery for morbid obesity. *Surg Obes Relat Dis* 2006;2(2):122–7.
- [13] Kuwada TS, Richardson S, El Chaar M, et al. Insurance-mandated medical programs before bariatric surgery: do good things come to those who wait? *Surg Obes Relat Dis* 2011;7(4):526–30.
- [14] Al Harakeh AB, Burkhamer KJ, Kallies KJ, Mathiason MA, Kothari SN. Natural history and metabolic consequences of morbid obesity for patients denied coverage for bariatric surgery. *Surg Obes Relat Dis* 2010;6(6):591–6.
- [15] Pories WJ, MacDonald KG Jr, Morgan EJ, et al. Surgical treatment of obesity and its effect on diabetes: 10-y follow-up. *Am J Clin Nutr* 1992;55(2 Suppl):582S–5S.
- [16] Hayes MT, Hunt LA, Foo J, Tychinskaya Y, Stubbs RS. A model for predicting the resolution of type 2 diabetes in severely obese subjects following Roux-en Y gastric bypass surgery. *Obes Surg* 2011;21(7):910–6.
- [17] Jurowich C, Thalheimer A, Hartmann D, et al. Improvement of type 2 diabetes mellitus (T2 DM) after bariatric surgery—who fails in the early postoperative course? *Obes Surg* 2012;22(10):1521–6.
- [18] NIH conference. Gastrointestinal surgery for severe obesity. Consensus Development Conference Panel. *Ann Intern Med* 1991;115(12):956–61.
- [19] Gibbons LM, Sarwer DB, Crerand CE, et al. Previous weight loss experiences of bariatric surgery candidates: how much have patients dieted prior to surgery? *Surg Obes Relat Dis* 2006;2(2):159–64.
- [20] Jantz EJ, Larson CJ, Mathiason MA, Kallies KJ, Kothari SN. Number of weight loss attempts and maximum weight loss before Roux-en-Y laparoscopic gastric bypass surgery are not predictive of postoperative weight loss. *Surg Obes Relat Dis* 2009;5(2):208–11.
- [21] Centers for Medicare and Medicaid Services. Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity (CAG-00250 R) [cited 2016 June 7]. Available at: [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=160&NcaName=Bariatric+Surgery+for+the+Treatment+of+Morbid+Obesity+\(1st+Recon\)&bc=ACAAAAAAEAAA&](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=160&NcaName=Bariatric+Surgery+for+the+Treatment+of+Morbid+Obesity+(1st+Recon)&bc=ACAAAAAAEAAA&).
- [22] Klein S, Burke LE, Bray GA, et al. American Heart Association Council on Nutrition, Physical Activity, and Metabolism. Clinical implications of obesity with specific focus on cardiovascular disease: a statement for professionals from the American Heart Association Council on Nutrition, Physical Activity, and Metabolism: endorsed by the American College of Cardiology Foundation. *Circulation* 2004;110(18):2952–67.
- [23] Turk MW, Yang K, Hravnak M, Sereika SM, Ewing LJ, Burke LE. Randomized clinical trials of weight-loss maintenance: a review. *J Cardiovasc Nurs* 2009;24(1):58–80.
- [24] Franz MJ, VanWormer JJ, Crain AL, et al. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. *J Am Diet Assoc* 2007;107(10):1755–67.
- [25] Fildes A, Charlton J, Rudisill C, Littlejohns P, Prevost AT, Gulliford MC. Probability of an obese person attaining normal body weight: cohort study using electronic health records. *Am J Public Health* 2015;105(9):e54–9.
- [26] Van Nieuwenhove Y, Dambrauskas Z, Campillo-Soto A, et al. Preoperative very low-calorie diet and operative outcome after laparoscopic gastric bypass: a randomized multicenter study. *Arch Surg* 2011;146(11):1300–5.
- [27] Sherman WE, Lane AE, Mangieri CW, Choi YU, Faler BJ. Does preoperative weight change predict postoperative weight loss after laparoscopic sleeve gastrectomy? *Bariatric Surg Pract Patient Care* 2015;10(3):126–9.
- [28] Giordano S, Victorzon M. The impact of preoperative weight loss before laparoscopic gastric bypass. *Obes Surg* 2014;24(5):669–74.
- [29] Anderin C, Gustafsson UO, Heijbel N, Thorell A. Weight loss before bariatric surgery and postoperative complications: data from the Scandinavian Obesity Registry (SOReg). *Ann Surg* 2015;261(5):909–13.
- [30] Kalarchian MA, Marcus MD, Courcoulas AP, Cheng Y, Levine MD. Preoperative lifestyle intervention in bariatric surgery: a randomized clinical trial. *Surg Obes Relat Dis* 2016;12(1):180–7.
- [31] Ochner CN, Dambkowski CL, Yeomans BL, Teixeira J, Xavier Pi-Sunyer F. Pre-bariatric surgery weight loss requirements and the effect of preoperative weight loss on postoperative outcome. *Int J Obes (Lond)* 2012;36(11):1380–7.
- [32] Cassie S, Menezes C, Birch DW, Shi X, Karmali S. Effect of preoperative weight loss in bariatric surgical patients: a systematic review. *Surg Obes Relat Dis* 2011;7(6):760–7.
- [33] Gerber P, Anderin C, Thorell A. Weight loss prior to bariatric surgery: an updated review of the literature. *Scand J Surg* 2015;104(1):33–9.
- [34] Parikh M, Dasari M, McMacken M, Ren C, Fielding G, Ogedegbe G. Does a preoperative medically supervised weight loss program improve bariatric surgery outcomes? A pilot randomized study. *Surg Endosc* 2012;26(3):853–61.
- [35] Horwitz D, Saunders JK, Ude-Welcome A, Parikh M. Insurance-mandated medical weight management before bariatric surgery. *Surg Obes Relat Dis*. Epub 2015 Sep 21.