Rationale:

Patient Selection Criteria for Coverage

A requirement that a candidate for bariatric surgery complete a formal, medically supervised weight loss programs of specified duration has been a fixture of HCSC bariatric surgery medical policy for some time. The rationale for this requirement was founded on review and interpretation of available evidence in the scientific medical literature, primarily national consensus guidelines. However, HCSC has decided to modify this requirement based on a current review of the bariatric surgery scientific literature related to required pre-surgery weight loss programs, and including consideration of input from bariatric surgeons and their professional societies. The HCSC policy will no longer require documentation that a morbidly obese member must have completed a pre-surgery weight loss program of specified duration as one of the criteria for benefit coverage of bariatric surgery. This change does not mean, however, that HCSC no longer believes that successful bariatric surgery requires multi-disciplinary support from the member's bariatric surgery program and a life-long commitment to life-style changes.

Definition of Outcomes

Outcomes of bariatric surgeries are notoriously difficult to evaluate in part due to the constantly evolving nature of the surgery. Small modifications are commonly made to decrease the incidence of postoperative and long-term complications. In addition, few controlled studies have directly measured the weight loss and complications associated with the different surgical approaches, particularly comparing gastric restrictive procedures with malabsorptive procedures. Case series from individual institutions or individual surgeons with varying lengths of follow-up dominate the literature. The outcomes for specific surgeries may widely differ among institutions or surgeons, perhaps due to small variations in surgical technique, intensity of follow-up, or patient selection criteria. However, during the 1970s and 1980s, both vertical-banded gastroplasty (VBG) and gastric bypass became widely accepted types of bariatric surgery. These two procedures were the focus of the 1991 National Institutes of Health (NIH) Consensus Development Conference on gastrointestinal surgery for severe obesity, which also noted that limited data were available regarding biliopancreatic bypass (BPB). (5)

A 2003 Blue Cross Blue Shield Association (BCBSA) Technology Evaluation Center (TEC) Assessment (6) summarized studies comparing open gastric bypass and vertical-banded gastroplasty. These comparisons demonstrated that open gastric bypass resulted in a greater amount of weight loss than vertical-banded gastroplasty, with no definite differences in complication rates. Therefore, gastric bypass is considered the criterion for the purpose of this discussion, and this is supported by the increasing acceptance of gastric bypass by the surgical community, representing greater than 80% of all bariatric surgery procedures performed in 2002. (7) Therefore, the results of open gastric bypass will be compared to the newer procedures not addressed by the 1991 NIH conference; i.e., gastric banding and BPB with or without duodenal switch. The following outcomes are considered relevant for bariatric surgery.

Weight loss

There is no uniform standard for reporting results of weight loss and no uniform standard for describing a successful procedure. Common methods of reporting the amount of body weight loss are percent of ideal body weight achieved or percent of excess body weight (EBW) loss, with the latter most commonly reported. These 2 methods are generally preferred over the absolute amount of weight loss, since they reflect the ultimate goal of surgery: to reduce weight into a range that minimizes obesity-related morbidity. Obviously, an increasing degree of obesity will require a greater amount of weight loss to achieve these target goals. There are different definitions of successful outcomes, but a successful procedure is often considered one in which at least 50% of EBW is lost, or when the patient returns to within 30% of ideal body weight. The results may also be expressed as the percentage of patients losing at least 50% of EBW. The following table summarizes the variation in reporting weight loss outcomes.

Table 2. Weight Loss Outcomes

Outcome Measure	Definition	Clinical Significance
Decrease in weight	Absolute difference in weight pre- and post-treatment	Unclear relationship to outcomes, especially in morbidly obese
Decrease in body mass index (BMI)	Absolute difference in BMI pre- and post-treatment	May be clinically significant if change in BMI clearly leads to change in risk category
Percent of excess weight loss	Amount of weight loss divided by excess body weight	Has anchor to help frame clinical significance; unclear threshold for clinical significance
Percent patients losing >50% of EBW	No. pts. losing >50% EBW divided by total patients.	Additional advantage of framing on per patient basis. Threshold for significance (>50%) arbitrary

Percent ideal body weight	Final weight divided by ideal body weight	Has anchor to help frame clinical significance; unclear threshold for clinical significance

BMI: body mass index; EBW: excess body weight.

Durability of weight loss

Weight change (i.e., gain or loss) at yearly intervals is often reported. Weight loss at 1 year is considered the minimum length of time for evaluating these procedures; weight loss at 3–5 years is considered an intermediate time period for evaluating weight loss; and weight loss at 5–10 years or more is considered to represent long-term weight loss following bariatric surgery.

Short-term complications—Operative and perioperative complications that occur within 30 days

In general, the incidence of operative and perioperative complications is increased in obese patients, particularly in thromboembolism and problems with wound healing. Other perioperative complications include anastomotic leaks, bleeding, bowel obstruction, and cardiopulmonary complications such as pneumonia or myocardial infarction.