

Appendix 1: General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine whether: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for patients. An improved net health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

CMS divides the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits.

The issues presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematic assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological

strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens, and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease, and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing, and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation), and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations because one of the goals of our determination process is to assess net health outcomes. We are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

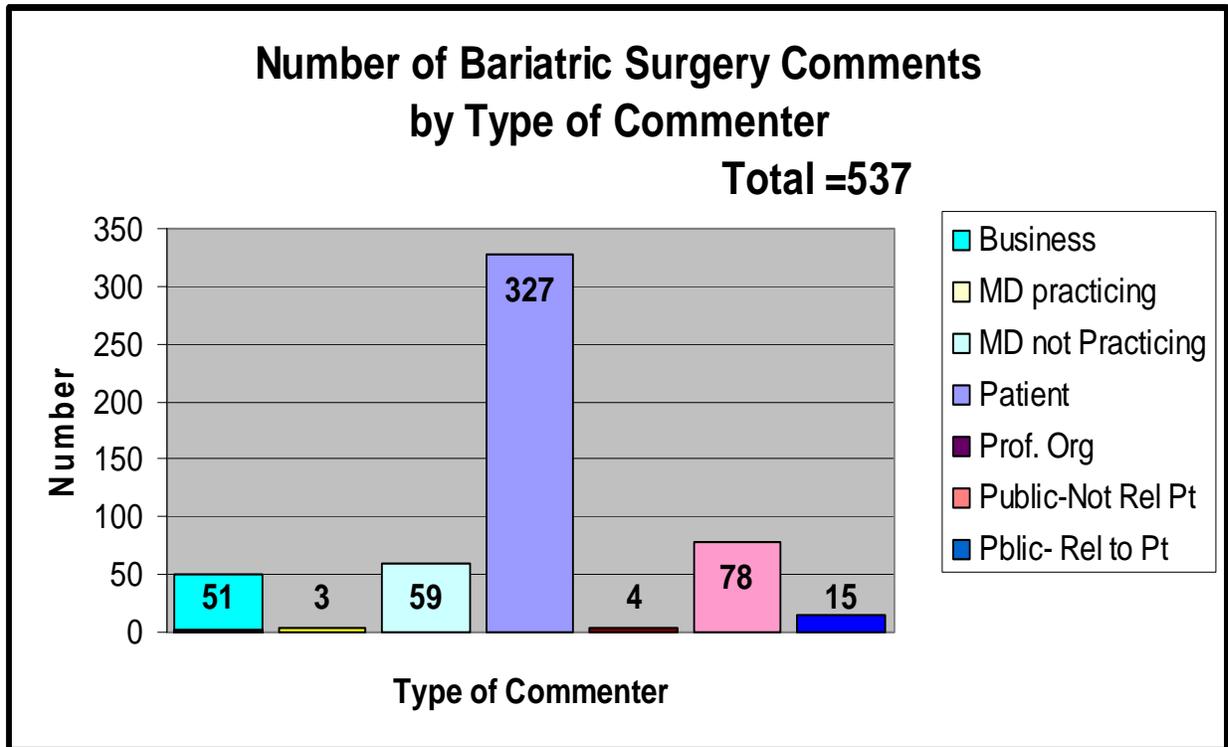
If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Net health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. For most determinations, CMS evaluates whether reported benefits translate into improved net health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses.

The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare

APPENDIX 2



Appendix 3
CMS Review Table for Bariatric Surgery

Author, Year and Title	Study Design	Demographics	Interventions (I) and Outcome Measures (O)	Results	Control Group
				Intervention Group	
Anthone G et al. The duodenal switch operation for the treatment of morbid obesity Ann Surg 2003 Oct; 238 (4): 618-627	Retrospective cohort	70 pts average BMI 52.	I-BPD O = Short-term mortality	Short-term mortality 1.4%	NA
Buchwald H 2004. Bariatric surgery: A systematic review and meta-analysis	review and meta-analysis N = 22,094	bariatric surgery patients; mean age = 39 female = 72.6%	I = bariatric surgery, O = weight loss, operative mortality	Excess weight loss averaged 61.2% overall, 47.5% for gastric banding, 61.2% for gastric bypass, 68.2% gastroplasty, and 70.1% for BPD or DS. Rates of operative mortality were 0.1% for purely restrictive procedures, 0.5 % for gastric bypass, and 1.1% for BPD ± DS. Diabetes completely resolved in 78.6%, & improved or resolved in 86%; hypertension completely resolved in 61.7% and improved or resolved in 78%; hyperlipidemia was improved in 70%; and OSA was resolved in 86%.	NA
Chau et al.2005. Pt characteristics impacting EWL after LAGB	Retrospective cohort	200 consecutive cases. LAGB. Median age = 44, BMI=45, 20%:80% M:F	I=LAGB O=Factors affecting %EWL	Logistic Regression –($\alpha=0.05$) that having DM (1.87), COPD (4.50) and age (1.02) were significantly assoc with >50% EWL& increasing BMI (0.92), HTN (0.64), Asthma (0.60) and being female (0.29) assoc with <50% EWL	NA

Author, Year and Title	Study Design	Demographics	Interventions (I) and Outcome Measures (O)	Results	Control Group
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Courcoulas A et al. The relationship between surgeon and hospital volume to outcome after gastric bypass surgery in Pennsylvania: a 3-year summary. Surgery 2003; 134:613-621	Retrospective cohort	Pennsylvania Hospital Discharge database 1999-2001. 4685 gastric bypass surgical procedures.	I= GBP O= mortality, complications respective rates for low and higher volume surgeons and facilities	Mortality = 0.6% Surgeons who performed fewer than 10 procedures per year had a 28% risk of adverse outcome and a 5% risk of death, compared with 14% (P < .05) and 0.3% (P = .06), respectively, for high volume surgeons. Hospital volume did not reach significance, but there was a striking interaction between surgeon and hospital volume; surgeons who performed 10 to 50 cases per year operating in low-volume hospitals had a 55% risk of adverse outcome	NA
Dindo D 2003. Obesity in General Elective Surgery	Retrospective cohort N = 239	Zurich Switzerland mean age = 49 female = 72%	O = many surgical procedures, I= rate of complications	Obesity not a risk factor for complications with the exception of wound infection in open surgery (non-obese = 3%, obese = 4%)	NA
Dolan K 2004. A comparison of laparoscopic adjustable gastric banding and biliopancreatic diversion in super obesity	prospective case-control; matched to 23 BPD patients to 1319 LAGB patients	mean age = 39, female = 69.6%; all super obese patients matched on sex, BMI and age	I = open and lap BPD vs. LAGB O= EWL, complication rate, re-operation rate, LOS, resolution of OSA, DM, HTN	BPD EWL at 24 months = 64.4%; complications = 56.6%; re-operations = 30.4%; OSA = 75%; HTN = 66%; diabetes = 100%	lap: EWL at 24 months = 48.4%; complications = 8.7%; OSA = 66%; HTN = 66%; DM =75%
Felix E 2003. Conversion of laparoscopic Roux-en-Y gastric bypass	retrospective cohort N = 1236	non-converted group: mean age = 40; female = 87% converted group: mean age = 48; female = 63%	I= LRYGB O = conversion rate	conversion rate: 3 reasons for conversion: 25% technical difficulty, 10% bleeding, 10% massive liver, males and older age increase chance for conversion	NA

Author, Year and Title	Study Design	Demographics	Interventions (I) and Outcome Measures (O)	Results	Control Group
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Fernandez AZ 2003. Experience with over 3,000 open and Laparoscopic Bariatric procedures: multivariate analysis of factors related to leak and resultant mortality	Retrospective cohort N= 3073	Patients at VA Commonwealth University mean age=40.4 female= 81%	I=RYGB O=short-term mortality	Mortality = 1.5% Leak = 3.2%	NA
Fernandez AZ 2004. Multivariate risk factors for death following gastric bypass for treatment of morbid obesity	retrospective cohort N = 2011	open group: mean age = 40.7, female = 7% lap group: mean age = 41.8, female = 86.4%	I = open or lap bypass O = death rate, SBO, leak, pulmonary embolism	lap: mortality = .7% ; leak = 4.1%; SBO = 3.3%; pulmonary embolism = 1% open: mortality = 1.9%; leak = 2.5%; SBO = 3.3%; pulmonary embolism = 1.2% leak, pulmonary embolism and pre-operative weight are risk factors for death	NA
Flum D 2004. Impact of gastric bypass on operation survival: A population based analysis	retrospective cohort N = 3328	Washington state patients unoperated: mean age = 47, female = 63% operated: mean age = 43, female = 80%	I = bariatric surgery O = short-term mortality, long-term survival	overall short-term mortality = 1.9%; surgeon inexperience leads to 4.7 times higher short-term mortality. mortality at 15 years: non-operated = 16.3% operated = 11.8%	NA
Flum D.R. et al. Early mortality among Medicare beneficiaries undergoing bariatric procedures. JAMA 2005; 294: 1903-1908	Retrospective cohort	All Medicare patients having had bariatric surgery in a 5-year period	I = bariatric surgery O = short-term mortality, long-term survival overall and by surgeon experience	Mortality rates were greater for those aged 65 years or older compared with younger patients (4.8% vs. 1.7% at 30 days, 6.9% vs. 2.3% at 90 days, and 11.1% vs. 3.9% at 1 year; $P<.001$). Surgeons in the highest quartile of bariatric procedure volume had similar rates of early mortality in both younger and older patients (1.8% 90-day mortality in patients <65 years and 1.1% mortality in patients >65 years; $P=.40$)	NA

Author, Year and Title	Study Design	Demographics	Interventions (I) and Outcome Measures (O)	Results	Control Group
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Fontaine K 2003. Years of life lost due to obesity	retrospective cohort	U.S. population 18-85 years old NHANES	I = none O = years of life lost (YLL)	obese males have more YLL than obese females, especially at younger ages	NA
Gonzalez R 2003. Gastric bypass for morbid obesity patients 50 years or older: Is laparoscopic technique safer?	retrospective cohort N = 52	mean age = 55 female = 87%	I = LRYGB vs. ORYGB O = EWL, co-morbidities: HTN, hyperglycemia, LOS, mortality, morbidity	overall: decrease in HTN, hyperglycemia, EWL at 3 months = 68%. lap: LOS = 3.4; morbidity = 18%; mortality = 2.6%; ICU stay = 5% open: LOS = 5.9; morbidity = 26%; mortality = 0%; ICU stay = 36%	NA
Herron D 2004. The surgical management of severe obesity	review	U.S. population	I = bariatric surgery, medication O = weight loss	long-term weight loss less than 10% with diet and medication	NA
Hess DS et al. Biliopancreatic diversion with duodenal switch: results beyond 10 years Obese Surge 2005 Mar. 15(3) 408-416	Retrospective cohort	Population in one area of US having BPD over 15-year period	I = bariatric surgery O = short-term mortality, long-term survival overall and by surgeon experience	Overall short-term mortality = 0.58%	NA
Lee WJ 2003. Clinical significance of central obesity in laparoscopic bariatric surgery	retrospective cohort	national Taiwan hospital catchment area mean age = 30.9 female=74.8%	I = laparoscopic bariatric surgery O = co-morbidities: hyperglycemia, triglyceride levels, EWL, major complications, hospital stay	central group: hospital stay = 4.3 (male), 4 (female); EWL at 3 years = 55% (male), 57.5% (female) peripheral group: hospital stay = 4.1 (male), 3.8 (female); major complications =3.06% (male), 0.44% (female); EWL at 3 years = 59% (male), 56% (female)	NA

Author, Year and Title	Study Design	Demographics	Interventions (I) and Outcome Measures (O)	Results	Control Group
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Livingston EH 2002. Male gender is a predictor of morbidity and age a predictor of mortality for patients undergoing gastric bypass surgery	retrospective cohort N = 1067	female = 78% mean age = 42.3	I = gastric bypass O = mortality	renal failure = 2.2% (male), 0.5% (female); mortality = 3% (male), 0.8% (female); leak = 3.5% (male), 0.8% (female)	NA
Livingston EH 2004. Socioeconomic characteristics of the population eligible for obesity surgery	retrospective cohort	U.S. population National Health Information Survey (NHIS) 84% < 60 years old female = 64%	I = bariatric surgery, O= eligibles for surgery	2.8% of U.S. population eligible for bariatric surgery eligibles more likely to be impoverished, less-educated and African-American	NA
Livingston EH2004. Procedure incidence and in-hospital complication rates of bariatric surgery	retrospective cohort	U.S. population National Hospital Discharge Survey (NHDS)	I = none O = national incidence and complication rates; LOS; intestinal complications; cardiac and respiratory failure	in-hospital complication rate = 9.6%; procedure incidence = 125.2 per 100,000 discharges; LOS = 4.6; intestinal complications = 2.3%; cardiac and respiratory failure = .9%	NA

Author, Year and Title	Study Design	Demographics	Interventions (I) and Outcome Measures (O)	Results	Control Group
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Nguyen NT et al. The relationship between hospital volume and outcome in bariatric surgery at academic medical centers. Ann Surg 2004; 240:586-593.	Retrospective cohort	Data from the University HealthSystem Consortium Clinical Data Base (UCLA Irvine) for all patients who underwent Roux-en-Y gastric bypass for the treatment of morbid obesity between 1999 and 2002 (n = 24,166).	I= bariatric surgery Outcomes of bariatric surgery, including length of hospital stay, 30-day readmission, morbidity, observed and expected (risk-adjusted) mortality, and costs were compared between high-volume (>100 cases/year), medium-volume (50–100 cases/year), and low-volume hospitals (<50 cases/year)	Compared with low-volume hospitals, patients who underwent gastric bypass at high-volume hospitals had a shorter length of hospital stay (3.8 versus 5.1 days, $P < 0.01$), lower overall complications (10.2% versus 14.5%, $P < 0.01$), lower complications of medical care (7.8% versus 10.8%, $P < 0.01$), and lower costs (\$10,292 versus \$13,908, $P < 0.01$). Observed mortality was significantly lower at high-volume hospitals (0.3% versus 1.2%, $P < 0.01$). In a subset of patients older than 55 years, the observed mortality was 0.9% at high-volume centers compared with 3.1% at low-volume centers ($P < 0.01$).	NA
Pope GD 2002. National trends in utilization and in-hospital outcomes of bariatric surgery	National Inpatient Survey(NIS) N= 12203	US population having had bariatric surgery mean age = 40.2 female = 83.6%	I = none O= rates of bariatric surgery, co-morbidities, mortality, re-operation rate, LOS, pulmonary embolism	rate of bariatric surgery increased from 2.7 to 6.3/100,000 , co-morbidities ranged from 20.9% in 1990 to 31.6% in 1997; bypass comprised 86.1% of bariatric surgeries in 1997; In-hospital mortality = 0.37%; LOS = 4; pulmonary embolism = .07%; re-operations = 1.4%	NA
Residori L 2003. Prevalence of co-morbidities in obese patients before bariatric surgery: Effect of race	retrospective cohort N = 300	mean age = 37.5 female = 86.8 40% Hispanic; 34% Caucasian; 25% African American ; 1% Asian	I = none O = pre-operative co-morbidity prevalence rates	57% of patients had at least one metabolic complication; diabetes prevalence = 30%; hyperlipidemia = 71.4%; hypertension = 68.8%	NA

Author, Year and Title	Study Design	Demographics	Interventions (I) and Outcome Measures (O)	Results	Control Group												
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Shen R. 2004. Impact of patient follow-up on weight loss after	retrospective cohort N = 355	mean age = 40.4	I = LAGB, RYGB, patient follow-up O = EWL	LAGB patients had increased EWL on average if they had 7 or more post-op visits; no difference in RYGB group; > 7 visits = 50.4% EWL, < 6 visits = 41.9% EWL	NA												
Sjostrom C 2000. Differentiated long-term effects of intentional weight loss on diabetes and hypertension	Case-control N = 692	Swedish morbid obese patients mean age = 47 (control), 46 (surgery) female = 65.9%	I= bypass and restrictive surgery (VBG) O = long-term weight loss, co-morbidities	surgical group lost an average of 20.1kg at 8 years; OR for diabetes, for cases compared to controls = 0.16; OR for HTN, for cases compared to controls = 1.01	control group lost no weight over 8 years; diabetes 7.8 -24.9 at 8 years												
Steinbrook R 2004. Surgery for severe obesity	Expert Opinion	U.S. Population	I = none O = projected bariatric procedure rates	100,000 expected from 2003	NA												
Sugerman H 2004. Effects of bariatric surgery in older patients	retrospective cohort N = 80	age ≥ 60 at time of bariatric surgery. mean age = 63 female = 78%	I = banding, RYGB O = EWL, weight loss, mortality, complications, co-morbidity	EWL 49% after surgery; long-term mortality unclear, diabetes decreased 30% at 5 years; HTN decreased 30%, GERD decreased 51% wound infection in 4/88; leak in 2/88; pulmonary embolus in 1/88	NA												
Shikora SA, et al. Laparoscopic roux-en-y gastric bypass results and learning curve of a high-volume academic program.	Retrospective cohort	750 morbidly obese pts. 85%:15% F:M. BMI 47	I= LRYGB – O= Complications/Mortality by experience	<table border="0"> <tr> <td></td> <td>1st hundred cases</td> <td>next 650</td> </tr> <tr> <td>Complication rate</td> <td>26%</td> <td>13%</td> </tr> <tr> <td>Mortality rate</td> <td>1%</td> <td>0%</td> </tr> <tr> <td>Operating time</td> <td>212 min.</td> <td>132 min</td> </tr> </table>		1st hundred cases	next 650	Complication rate	26%	13%	Mortality rate	1%	0%	Operating time	212 min.	132 min	NA
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Author, Year and Title	Study Design	Demographics	Interventions (I) and Outcome Measures (O)	Results	Control Group
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Suter et al. Laparoscopic Gastric Banding: A prospective randomized study comparing the Lapband and the SAGB: early results	RCT	180 Morbidly obese pts	I= LAGB vs. SAGB O= EWL, Co-morbidity Rx, QOL, Complications,	50% of the patients lost 50% of EWL in both groups. There was no difference between the groups for co-morbidity Rx, complication rates or QOL measure.	NA
Szold A 2001. Laparoscopic adjustable silicone gastric banding for morbid obesity: results and complications in 715 patients	retrospective cohort N=715	mean age=34.6 female= 76%	I= LAGB O= Complications	complications= 1.7% re-operation rate= 7.9%	NA
Zizza C 2003. Bariatric surgeries in North Carolina, 1990-2001: A gender comparison	retrospective cohort	North Carolina Hospital Discharge Data Base ≥18 years of age, 78-79% were state residents of NC female = 86%	I= bariatric procedures O =odds ratio of women to men having surgery	OR female: male of having bariatric surgery was 4.96 (4.39, 5.59), controlling for age and year of procedure, and residence in NC; mortality = 1.1% (female), 1.95% (male)	NA

APPENDIX 4

Table of papers referred by commenters

	Arterburn, J et al. The coming epidemic of obesity in elderly Americans. <i>Am Geriatr Soc</i> 2004; 52: 1907-912.
*	Anthone G, Lord RV, DeMeester TR, Crooks PF “ The duodenal switch operation for the treatment of morbid obesity” <i>Ann Surg</i> 2003 Oct; 238 (4): 618-627
	Anthone GJ, “the duodenal switch operation for morbid obesity” <i>Surg Clin North Am.</i> 2005 Aug;85 (4):819-833.
	Christou NV, Sampalis JS, Liberman M, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. <i>Ann Surg</i> 2004; 240(3):416-23; discussion 423-424.
*	Courcoulas A, Schuchert M, Gatti G, Luketich J. The relationship between surgeon and hospital volume to outcome after gastric bypass surgery in Pennsylvania: a 3-year summary. <i>Surgery</i> 2003; 134:613-621.
*	Fernandez AZ, DeMaria EJ, Tichansky DS, Kellum JM, Wolfe LG, Meador J, Sugerma HJ. Multivariate analysis of risk factors for death following gastric bypass for treatment of morbid obesity. <i>Ann Surg</i> 2004; 239(5): 698-702.
	Finkelstein E.A. et al. National medical spending attributable to overweight and obesity: How much, and who’s paying?, <i>Health Affairs Web Exclusive</i> , May 14, 2003.
*	Flum D.R. et al. Early mortality among Medicare beneficiaries undergoing bariatric procedures. <i>JAMA</i> 2005; 294: 1903-1908.
	Flum et al. Impact of gastric bypass operation on survival: a population-based analysis. <i>J Am Coll Surg</i> 2004;199:543–551,
	Goodney PP, Siewers AE, Stukel TA, et al. Is surgery getting safer? National trends in operative mortality. <i>J Am Coll Surg</i> 2002; 195 (2):219-227.
	Grant J. Duke procedure for super obesity: preliminary report with 3.5 year follow-up. <i>Surgery</i> 1994;115:718-726.
	Health, United States, 2004; Table 6.
	Hess DS, Hess DW, “Biliopancreatic diversion with duodenal switch” <i>Obesity Surg</i> 1998. 8:267-282.
*	Hess DS, Hess DW, Oakley RS: “Biliopancreatic diversion with duodenal switch: results beyond 10 years” <i>Obese Surge</i> 2005 Mar. 15(3) 408-416 .
	Jamal MK, DeMaria EJ, Carmody BJ, et al. The impact of major co-morbidities on mortality and complications after gastric bypass. <i>Surgery for Obesity and Related Disorders</i> , 2005 (in press)
	Jan J et al. Safety of laparoscopic gastric bypass and laparoscopic adjustable gastric banding in older patients. Presented at the 22 nd annual meeting of the American Society for Bariatric Surgery 2005, Orlando, FL (Plenary Session)
	Kral JG, Thung SN, Biron S, et al. Effects of surgical treatment of the metabolic syndrome on liver fibrosis and cirrhosis. <i>Surgery</i> 2004; 135:48-58.
	Li,R et al, Kaiser Perm abstract submitted to ASBS. Sidney, Stiles, Kaiser Permanente outcomes. in preparation for submission, 2000-2004.
	Marceau P, Biron S., et al “Biliopancreatic diversion with a new type of gastrectomy” <i>Obesity Surg</i> 1993. 3:29-35.
	Marceau P, Hould FS, Simard S, et al. Biliopancreatic diversion with duodenal switch” <i>World J Surg</i> 1998. 22: 947-954.
	Nguyen NT, Longoria M, Gelfand DV, Sabio A, Wilson SE. Staged laparoscopic Roux-en-Y: a novel two-stage bariatric operation as an alternative in the super-obese with massively enlarged liver. <i>Obes Surg</i> 2005; 15:1077-1081.
*	Nguyen NT, Paya M, Stevens CM, Mavandadi S, Zainabadi K, Wilson SE. The relationship between hospital volume and outcome in bariatric surgery at academic medical centers. <i>Ann Surg</i> 2004; 240:586-593.
	O’Brien PE, Dixon JB. Weight loss and early and late complications—the international experience. <i>Am J Surg</i> 2002; 184(6B):42S-45S.
	Quebbemann B, Engstrom D, Siegfried T, Garner K, Dallal R. Bariatric surgery in patients older than 65 years is safe and effective. <i>Surg Obes Relat Dis</i> 2005; 1:389-392.
	Rabkin RA, Rabkin JM, Metcalf B, Lazo M, et al “Nutritional markers following duodenal switch for morbid obesity” <i>Obes Surg.</i> 2004 Jan; 14(1): 84-90
	Regan JP, Inabnet WB, Gagner M, Pomp A. Early experience with two-stage laparoscopic Roux-en-Y gastric bypass as an alternative in the super obese patient. <i>Obes Surg</i> 2003; 13:861-864.
	Rhoads J.A. Overweight and obese elderly and near elderly in the United States, 2002. MEPS- AHRQ Statistical Brief #68, 2005.
	Schauer PR, Ikramuddin S, Gourash W, et al. Outcomes after laparoscopic Roux-en-Y gastric bypass for morbid obesity. <i>Ann Surg</i> 2000; 232 (4):515-529.
*	Sugerma HJ, DeMaria EJ, Kellum JM, Sugerma EL, Meador JG, Wolfe LG. Effects of bariatric surgery in older patients. <i>Ann Surg</i> 2004; 240:243-247.
	Wittgrove AC, Clark GW. Laparoscopic gastric bypass, Roux-en-Y- 500 patients: technique and results, with 3-60 month follow-up. <i>Obes Surg</i> 2000; 10(3):233-239
	* Commenter Referenced Papers utilized by CMS

APPENDIX 5
5A - ACS Guidelines

5B – ASBS Guidelines
ASBS BARIATRIC SURGERY CENTERS OF EXCELLENCE

ASBS BARIATRIC SURGERY COE REGULATIONS

ELIGIBILITY

Institutions will qualify for designation as an American Society for Bariatric Surgery (ASBS) Bariatric Surgery Center of Excellence (BSCOE) when they can document to the Surgical Review Corporation (SRC) that 1) they have the resources to perform safe bariatric surgery, and 2) they have excellent short and long-term outcomes. These indices, therefore, not only document process, i.e. equipment, supplies, training of surgeons, and the availability of consultant services, but emphasize results.

Application for designation as an ASBS Bariatric Surgery Center of Excellence is voluntary. The process begins with centers applying first for Provisional Status when they can demonstrate to the SRC that they have the resources to provide safe and effective bariatric surgery. These 10 requirements are listed under the Provisional Status tab.

Provisional Status applications are reviewed by the Bariatric Surgery Review Committee (BSRC) and depending upon the information provided by the applicant, centers and surgeons may receive the following designation:

- **Approved – Provisional Status.** These applicants may apply for Full Approval within two years.
- **Denied – Provisional Status.** Denied applicants have six months to correct their deficiencies. They may request that their application be reviewed again, or they can appeal the decision to the Board of Directors.
- **Monitoring Status.** This designation is assigned by the BSRC when the surgery case volumes provided by an applicant appear to be insufficient to reach the required 125 cases per year (institution) or 50 cases per year/125 cases lifetime experience (surgeon) within the two-year Provisional Status period unless there is a significant increase in volume. Applicants are neither approved nor denied but instead are asked to report their volumes in six months to be re-evaluated.
- **Pending Status.** Applications can be placed in Pending Status when additional information is requested by the BSRC in order to make an accurate evaluation.

Provisional Status participants may apply for Full Approval when they can show that they have the experience necessary to provide safe and effective bariatric surgery based upon a review of their outcomes. Once the Full Approval application is received, a site inspection is conducted. The information collected during the site inspection and the Full Approval application are evaluated by the BSRC. The Committee may then recommend:

- **Full Approval.** This recommendation is forwarded to the ASBS Executive Council for

final consideration and vote.

- Denied. Applicants may request (1) that the application be reviewed again, (2) a second site inspection be conducted, and/or (3) an appeal to the Board of Directors. If denied, the institution will be placed back on Provisional Status.
- Pending Status. Reviewers may request additional information or a second site inspection.

Institutions that receive Provisional Status or Full Approval may lose that designation and be placed on Probationary Status when they no longer are able to meet the requirements. Failure to meet the standards after being reduced to Probationary Status within an acceptable period of time may result in a withdrawal of accreditation. If the deficiencies are rectified within six months, Provisional Status or Full Approval will be reinstated.

Excellent bariatric surgery requires competent surgeons and well-prepared facilities. Eligible applications require three "portfolios" to comprise a single application: one portfolio submitted by each surgeon, one portfolio submitted by the surgical practice or group, and the remaining portfolio by the institution (hospital). Solo practitioners and surgeons employed directly by hospitals or academic institutions must complete individual surgeon portfolios and a surgical practice portfolio.

Applications missing any one of these three important elements may experience a delay in processing the application.

Successful applicants are designated as a BSCOE for specified term of one, two or three years. The determination of the appropriate term shall be made by the BSRC according to the following guidelines:

Appropriate Term:

Three Years: Designation as a BSCOE for a term of three years is reserved for those applicants who not only meet all requirements but exceed the requirements for Full Approval in most or all respects. There are no issues with respect to any requirement for any of the constituent co-applicants: the institution, surgical group or individual surgeon. The applications and site inspection indicate no conditions which would prevent the applicant and its constituent members from being able to continue to meet or exceed all requirements for the entire three year term of the designation.

Two Years: Designation as a BSCOE for a term of two years is appropriate for applicants who meet all requirements and perhaps exceed the requirements in some respects but not in all. There are no obvious issues with respect to any requirement as to any of the constituent members. Designation for a two year period, as opposed to three years, would be appropriate if the applications or site inspection indicates that one or more of the constituent members may have an issue in continuing to meet all requirements.

One Year: Designation as a BSCOE for a term of one year is appropriate for applicants who meet the minimal requirements for Full Approval but do not exceed the requirements to any substantial degree. If there are actual or potential deficiencies with one or more of the constituent members which are apparent from the applications or site inspection which are of concern to the reviewers, designation for a one year term is appropriate. In such cases the applicant should be informed of the deficiency so that it can be addressed prior to renewal of the designation. The length of time the program has existed at the applicant center may also be a factor requiring a one year approval period.

PROVISIONAL STATUS

The initial application is for designation as a Provisional Center of Excellence. The questionnaire for this initial status focuses on:

- Resources of the applicant institution.
- Training and experience of the surgeons and surgical group.
- Whether the criteria for Provisional Status are met.

The Bariatric Surgery Review Committee (BSRC) reviews the information, determines whether the guidelines are met, and grants or denies the designation. Information in the application is accepted on an honor system; site inspections will be required only on the rare occasions when the BSRC is not comfortable with the information in the application. If the application is denied, the applicant institution and the surgeon(s) are advised of the reason for denial and invited to reapply when the deficit is corrected.

Provisional Status shall not exceed two years. Before that deadline, hospitals are encouraged to submit an application for Full Approval recognition as an American Society for Bariatric Surgery (ASBS) Bariatric Surgery Center of Excellence.

In order to expedite the development of the centers, Surgical Review Corporation (SRC) is prepared to designate an institution as a Provisional Center of Excellence if it meets the following conditions as determined by the BSRC:

1. **a. An institutional commitment at the highest levels of the applicant medical staff and the institution's administration to excellence in the care of bariatric surgical patients as documented with an ongoing, regularly scheduled, in-service education program in bariatric surgery.**
b. An institutional commitment that is also demonstrated by employing credentialing guidelines for bariatric surgery.

This requirement refers to a culture in which the staff is prepared to manage morbidly obese patients, to manage these individuals with understanding and compassion, and to appreciate the burdens of the co-morbidities of the disease. The staff should be aware of the basic concepts of bariatric surgery through in-service programs. Those directly caring for these patients should be able to recognize the early signs of the common complications including pulmonary embolus, anastomotic leak, infection,

and bowel obstruction so that these can be managed promptly.

2. **a. The reasonable expectation that the applicant institution will perform at least 125 bariatric surgical cases per year.**

b. The reasonable expectation that each applicant surgeon will have performed at least 125 total bariatric cases lifetime with at least 50 cases performed in the preceding 12 month period.

"Bariatric surgical cases" are defined as primary operations and/or revisions. Endoscopies, placement of feeding jejunostomies, hernia repairs, and plastic surgical reconstructions are not included in this classification.

"Performed" is defined as conducting a significant part of the operation as primary surgeon. Applicants may not include cases where they served as the assisting surgeon.

Applicants may include up to 75 operations performed during their fellowship in their total lifetime count.

3. **The applicant maintains a designated physician Medical Director for bariatric surgery who participates in the relevant decision-making administrative meetings of the institution.**

The position of Bariatric Surgery Medical Director shall be filled by a qualified bariatric surgeon who is appointed through the administrative/medical staff process with hospital minutes documenting his or her participation in the bariatric program decisions. Regularly scheduled meetings to address the bariatric program in the institution that involve medical staff, nursing, administration, central supply, operating room personnel, and the business office are required.

4. **The applicant hospital maintains, within 30 minutes of request, a full complement on staff of the various consultative services required for the care of bariatric surgical patients including the immediate availability of an ACLS-qualified physician on site who can perform patient resuscitations.**

The facility must have a full-time staff with experience managing critically ill, morbidly obese patients with ventilators and invasive hemodynamic

monitoring technologies that can support the management of a critically ill patient until he or she is sufficiently stable to leave the facility.

- 5. The applicant maintains a full line of equipment and instruments for the care of bariatric surgical patients including furniture, wheel chairs, operating room tables, beds, radiologic capabilities, surgical instruments and other facilities suitable for morbidly obese patients.**

Furniture, beds, scales, wheel chairs, operating room tables and litters, strong enough and extra wide to accommodate the severely obese according to the weight limits established by the institution, must be available for those patients who need this specialized equipment. Patient movement/transfer systems for morbidly obese patients must be in place throughout the institution wherever the morbidly obese receive care. Ambulances serving the institution should also be equipped to manage these large patients with appropriate stretchers, straps, and transfer devices. Finally, and perhaps most important, the staff must be trained to use the equipment and be capable of moving these large individuals without injury either to the patients or the staff.

- 6. The applicant has a bariatric surgeon who spends a significant portion of his or her efforts in the field of bariatric surgery and who has qualified coverage and support for patient care.**

The surgeon must be certified by the American Board of Surgery (ABS) or the American Osteopathic Board of Surgery (AOBS), and/or Royal College of Physicians and Surgeons of Canada (RCPSC). In addition, the surgeon must show evidence of bariatric surgical expertise in accordance with the guidelines of the American Society of Bariatric Surgery (ASBS).

Qualified coverage is defined as the coverage required for the full care of a bariatric patient in the absence of the primary surgeon. The covering surgeon should be certified by the ABS, AOBS, and/or RCPSC, have significant experience in the care of bariatric surgical patients, and be capable of managing the full range of complications associated with surgery of the morbidly obese. In order for the on call surgeon to demonstrate significant experience in managing bariatric patients and their complications, they must be Board certified or eligible, have at least eight hours of Continuing Medical Education (CME) in bariatric surgery and have assisted on at least five non-stapling gastric procedures and/or 10 gastric stapling and/or anastomotic procedures, depending upon the covering arrangement. The covering surgeon must have completed these

requirements by the time the applicant Center reapplies for Full Approval status. However, there is a grace period under Provisional Status during which a Center can be granted Full Approval without meeting the standard. Once Full Approval status is granted, the standard must be met before reapplying. This requirement only applies to general surgeons who cover bariatric cases and does not apply to coverage by bariatric surgeons.

- 7. The applicant utilizes clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure. In addition, all bariatric surgical procedures are standardized for each surgeon.**

It is the surgeon's responsibility and duty to select which primary operation(s) he or she will perform and it is the expectation of SRC that the procedure(s), no matter what the choice, will be done in a standardized manner. Similarly, the surgeon should determine the details of the planned perioperative care. These details will be documented so that each member of the surgeon's team is aware of the care plan and is prepared to follow the process as outlined by the surgeon. Unless such a process is followed, outcomes cannot be evaluated.

The clinical pathway protocols, i.e. a sequence of orders and therapies describing the routine care of the uncomplicated patient, must be available for review during the site inspection.

- 8. The applicant utilizes designated nurse or physician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients.**

The hospital should have a subset of nurses who routinely care for the bariatric patients and receive regular in-service education on their care, preferably assigned to a designated bariatric floor or wing. There should be a bariatric coordinator designated to supervise the bariatric program.

The physician's practice should also have nursing and physician extenders who provide continuing education and care to the bariatric patients in the practice. This should be outlined in the practice portfolio if it is a split practice that still performs significant general surgery.

- 9. The applicant makes available organized and supervised support groups for all patients who have undergone bariatric surgery at the**

institution.

The activities of the support group should be documented including group locations, meeting times, supervisor, curriculum, and attendance. For example, such activities as on-line chat rooms, web-based support groups, exercise, instruction, and clothing sales should be noted.

- 10. The applicant provides documentation of a program dedicated to a goal of long-term patient follow-up of at least 75% for bariatric procedures at five years with a monitoring and tracking system for outcomes, and agreement to provide annual outcome summaries to SRC in a manner consistent with Health Insurance Portability and Accountability Act (HIPAA) regulations.**

This requirement is based on the observation that a significant number of patients develop nutritional deficiencies, internal and external hernias, return of previous emotional disorders, as well as other late complications. There is no requirement that the surgeon provide the follow-up personally, only that he or she is aware of the long-term status of the patient. Accordingly, the follow-up data can be gathered during group sessions, reunions, or through inspections at other physicians' offices. The applicant agrees to enter all patients who undergo surgery in the group's or individual practice; no patients will be excluded.

FULL APPROVAL

Prior to applying for Full Approval status, the Center must first have been granted Provisional Status. While Provisional Status is based on the adequacy of resources, Full Approval is based on the achievement of acceptable outcomes.

SRC anticipates developing additional guidelines and criteria for Full Approval based on outcomes data reported by program participants and by other databases. Future applications for Full Approval as well as renewal applications will be required to meet any outcomes data requirements and guidelines which may be in place at the time of application or renewal.

The application for Full Approval as an American Society for Bariatric Surgery (ASBS) Bariatric Surgery Center of Excellence requests:

- Information to assure that the requirements for Provisional Status remain satisfied.
- Information regarding the patient populations, the operations performed, and their outcomes.

Full Approval requires a site inspection. The process is initiated once the application for Full Approval has been received by SRC. Site inspections are conducted by a two person team that follows a prescribed protocol that includes:

- A tour of the facilities.
- Evaluation of the center and its quality of care.
- Interviews.
- Random chart reviews.

The purpose of the site inspection is to gather data, not to make judgments. The information collected during the site inspection is then submitted to the Bariatric Surgery Review Committee (BSRC) for review with the Full Approval application. If the application warrants it, approval is granted for one to three years.

Programs that fail to maintain standards may be placed on a Probationary Status. If the deficits are not corrected or if there are egregious findings, the BSRC may also recommend to the ASBS that the designation as a Center of Excellence be revoked.

If a program disagrees with the decisions of the BSRC, it can appeal the matter to the Board of Directors, which will review the data at its next scheduled meeting.

The Full Approval application process to become an ASBS Bariatric Surgery Center of

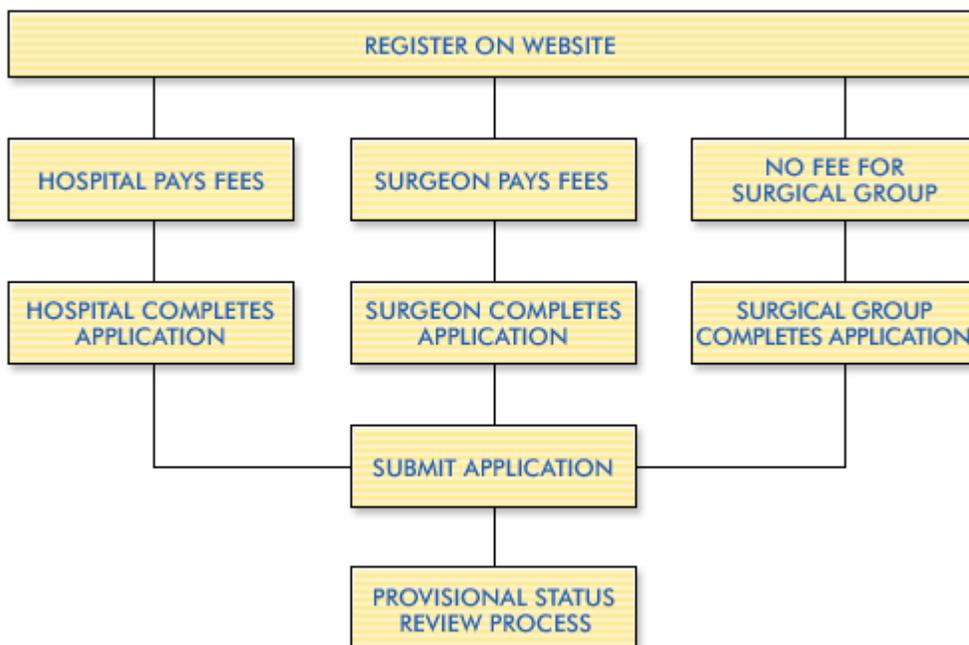
Excellence involves the following steps:

1. **The center and its surgeons continue to meet the criteria required for Provisional Status and fully comply with the 10 requirements for Provisional Approval.**
2. **Any deficiencies noted during Provisional Status review have been corrected.**
3. **A complete and accurate description of changes in the institution or the staff (since the Provisional Status application) has been submitted to the BSRC.**
4. **A list of the academic activities of the surgeons including grants obtained, papers published, presentations, participation in courses, etc. has been provided.**
5. **Outcomes data for bariatric surgery are reported in an anonymous fashion in accordance with HIPAA regulations. Outcomes data must include a list of all bariatric surgical operations performed within the previous 12 month period including the following information (partial list):**
 - Age
 - Gender
 - Weight
 - Height
 - BMI
 - Co-morbidities
 - Procedure
 - Length of Stay
 - Complications including mortality, re-admissions within 30 days of discharge, re-operations within 30 days after the initial operation

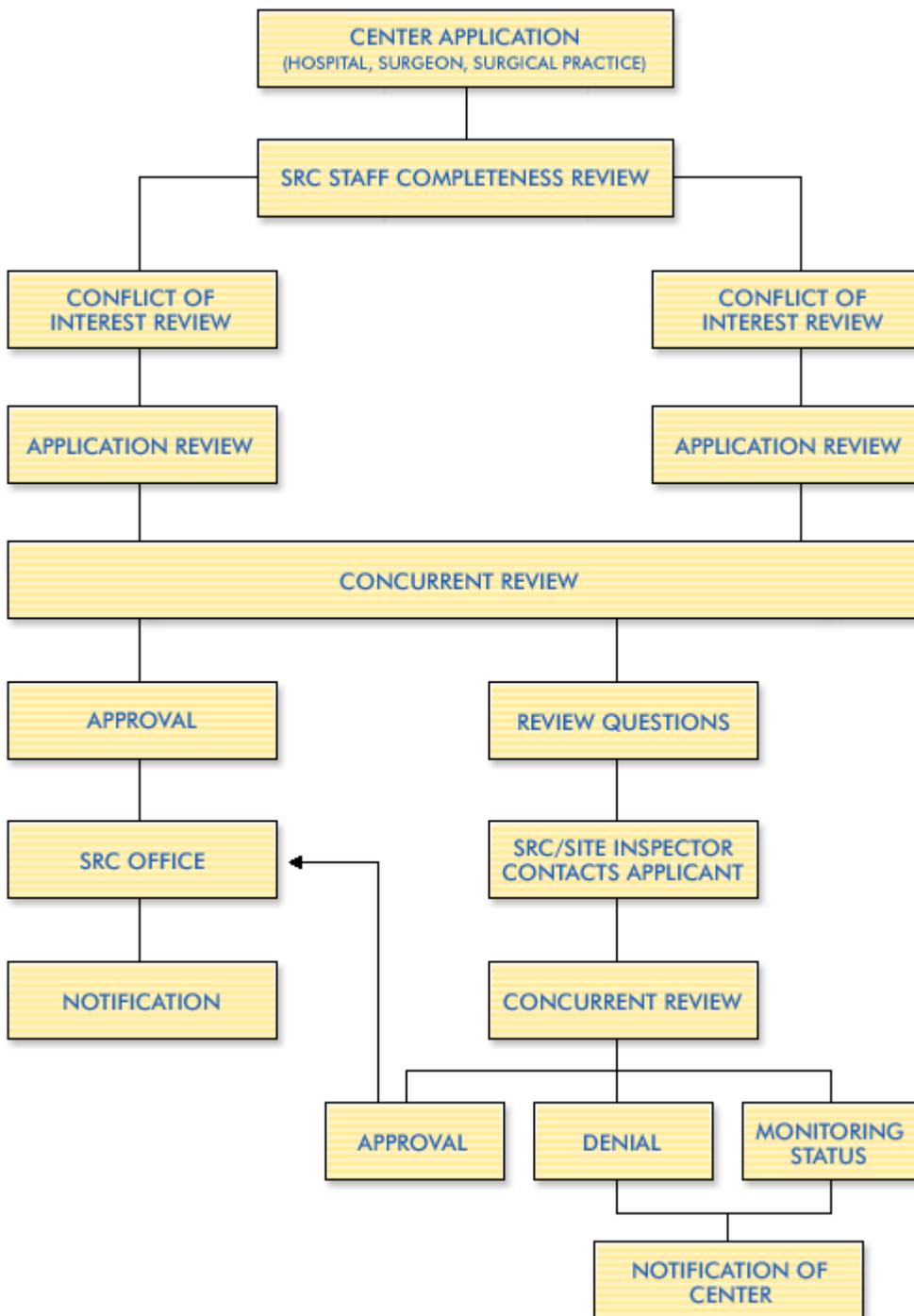
PROVISIONAL STATUS

The American Society for Bariatric Surgery Centers of Excellence program is a rigorous process designed to adequately determine those hospitals, surgeons and surgery centers that meet the standards set by the ASBS for providing excellent bariatric surgery care. The charts below details each step of the application process to become a Bariatric Surgery Center of Excellence.

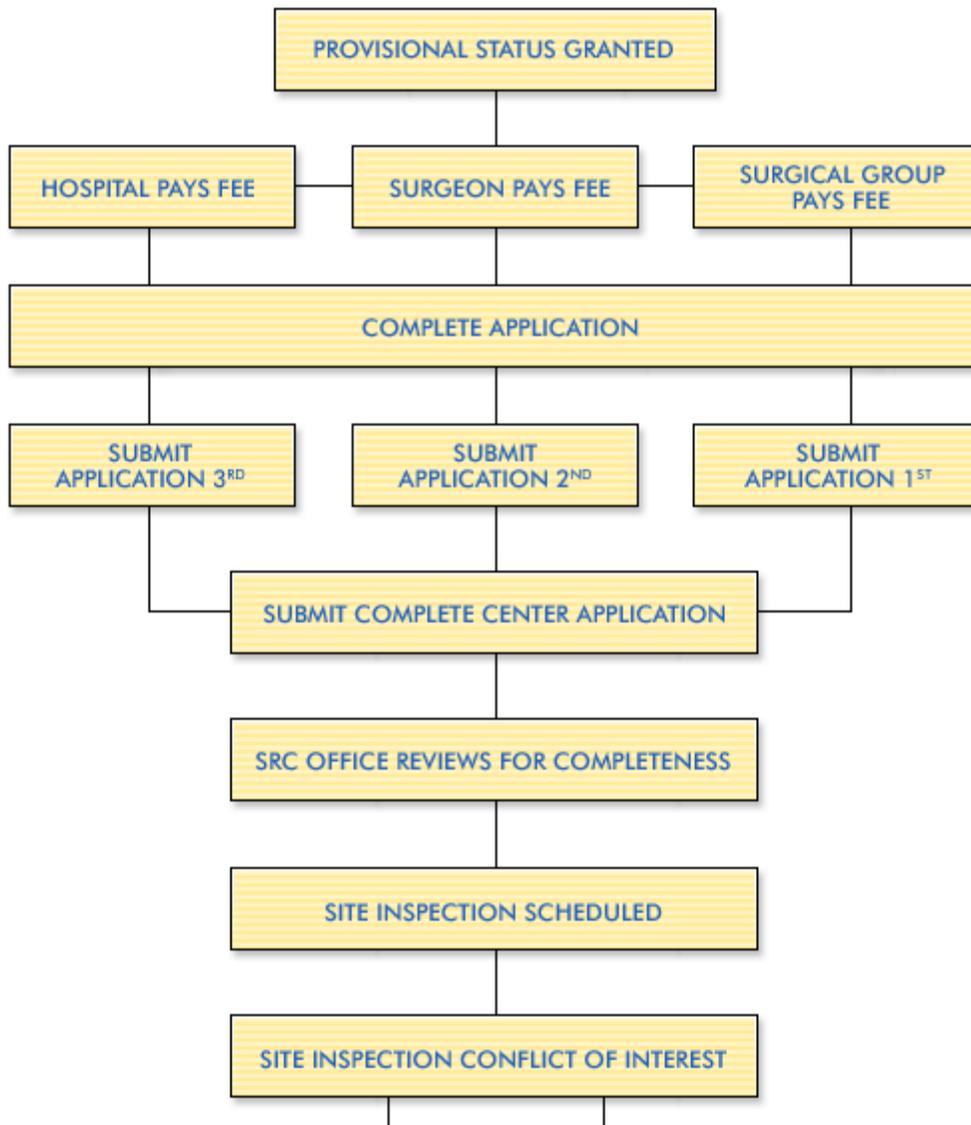
PROVISIONAL STATUS APPLICATION PROCESS

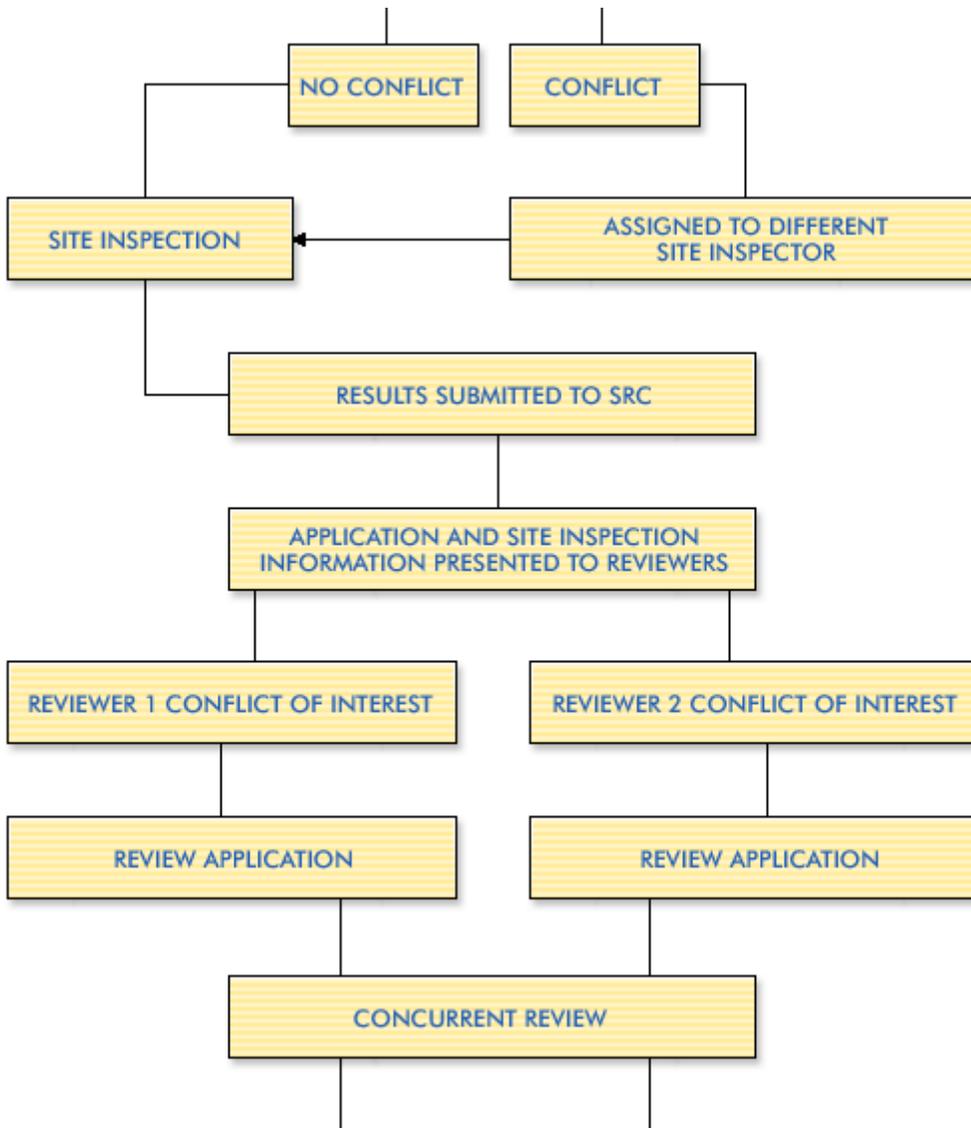


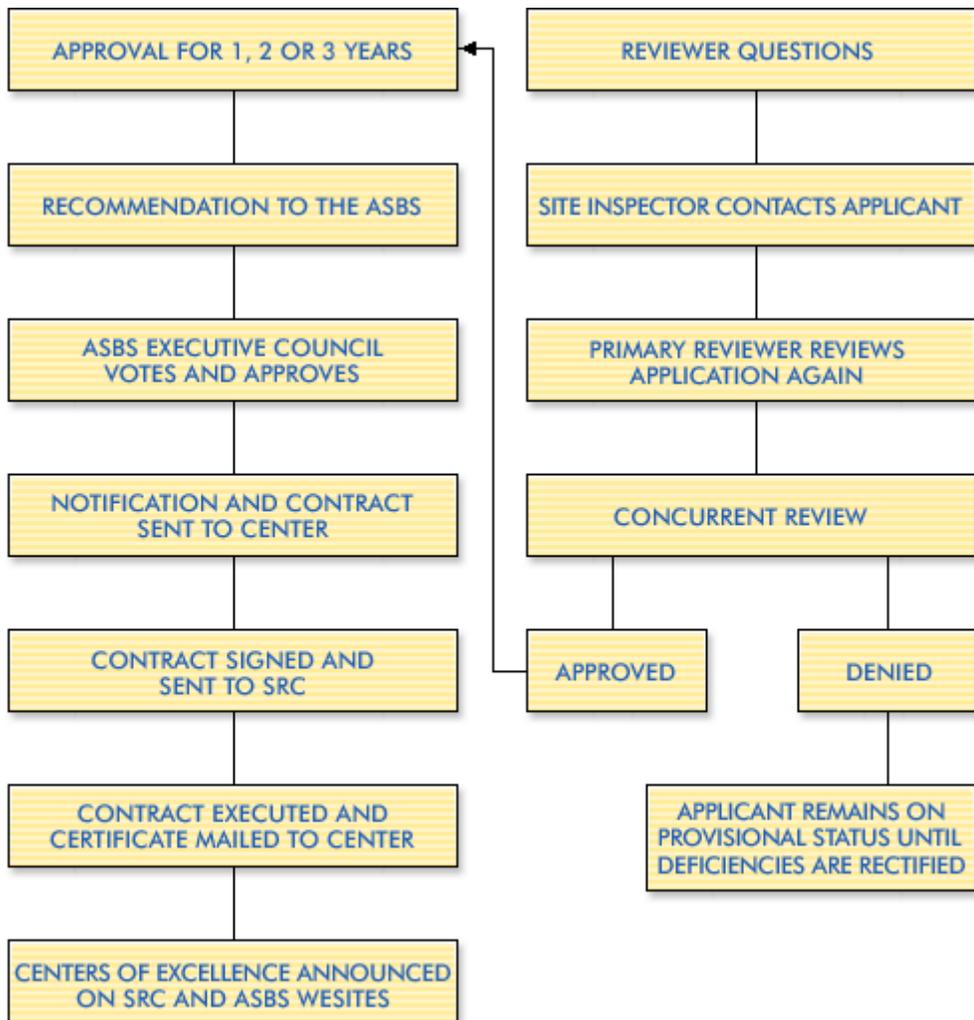
PROVISIONAL STATUS REVIEW PROCESS



FULL APPROVAL







SITE INSPECTION

The purpose of the site inspection is to verify that the information submitted in an application is correct, and to substantiate and confirm that the requirements for Full Approval as a Bariatric Surgery Center of Excellence have been met. At the time a site inspection is scheduled, a detailed instruction letter and a checklist will be sent to help with preparation for the inspection. The checklist will give details on the staff members and materials that will need to be assembled for the site inspectors.

Everything the site inspectors will need to see will be included on the list. This is not a surprise inspection. Gathering the necessary materials will facilitate a smoother inspection. Failure to provide the necessary materials could result in the termination of your inspection. For most Centers, site inspections will take approximately one day. However, if your center has multiple surgeons and practices as co-applicants, it may take a bit longer.

The site inspectors will not provide results during the inspection. Their purpose is to verify the information in the application, confirm that the center meets the necessary requirements and report this information to the Bariatric Surgery Review Committee (BSRC).

The information collected by the site inspectors will be submitted to the BSRC for evaluation. Based upon the site inspection findings and the information provided in your application, the BSRC will make recommendations to the American Society of Bariatric Surgery (ASBS). The ASBS will announce those centers that they recognize to be Centers of Excellence. A letter will be mailed informing Centers of their results.