

Medicare Coverage Advisory Committee – Evaluative Questions

Obesity Patients With One or More Co-morbidities

1. How well does the evidence address the effectiveness of Bariatric Surgery in the treatment of obesity in patients with one or more co-morbidities compared to non-surgical medical management? * 1 – Poorly * 2 * 3 – Reasonably Well * 4 * 5 – Very Well											
12345											
	2. How confident are you in the validity of the scientific data on the following outcomes? 1 - No confidence 2 3 - Moderate Confidence 4 5 - High Confidence					3. How likely is it that Bariatric Surgery, including RYGBP, banding, and BPD, will positively affect the following outcomes in obese patients with one or more co-morbidities compared to non-surgical medical management? 1 – Not Likely 2 3 – Reasonable Likely 4 5 – Very likely					
Wt Loss (sustained)	1 2 3 4 5					1 2 3 4 5					
Long-term Survival	1 2 3 4 5					1 2 3 4 5					
Short-Term Mortality	1 2 3 4 5					1 2 3 4 5					
Co-morbidities	1 2 3 4 5					1 2 3 4 5					
4. How confident are you that the following bariatric surgeries will produce a clinically important net health benefit in the treatment of obese patients with one or more co-morbidities? * 1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence											
RYGBP – open	1 2 3 4 5					RYGBP – lap	1 2 3 4 5				
BPD - open	1 2 3 4 5					BPD - lap	1 2 3 4 5				
Banding - open	1 2 3 4 5					Banding - lap	1 2 3 4 5				
5. Based on the scientific evidence presented, how likely is it that the results of Bariatric Surgery in obese patients with one or more co-morbidities can be generalized to: * 1 – Not Likely * 2 * 3 – Reasonably Likely * 4 * 5 – Very Likely											
a. The Medicare population (aged 65+):					1	2	3	4	5		
b. Providers (facilities/ physicians) in community practice:					1	2	3	4	5		

Glossary:

Obesity refers to “Class II Obesity” and “Class III Extreme Obesity.” NIH defines “Class II Obesity” as BMI = 35.0 to 39.9 and Class III Extreme Obesity as BMI ≥ 40. **Co-morbidity.** Includes but is not limited to high risk factors such as MI, type 2 diabetes, hypertension and sleep apnea, etc. A treatment will “positively affect” co-morbidities if it reverses and/or prevents them.

Validity. CMS uses “validity” here as defined by Meinert, “Validity, in the context of a treatment difference, refers to the extent to which that difference can be reasonably attributed to a treatment assignment.” (Meinert CL. Clinical Trials, Overview. In: Redmond CK, Colton T, eds. Biostatistics in clinical trials. Wiley and Sons, 2001. pp. 37-51). This encompasses all issues of methodologic framework, study design, observed results, biological rationale, etc.

Net health benefit. Balance between risks and benefits including complications of surgery

RYGBP = Roux-en-Y Gastric Bypass, open and laparoscopic

Banding = Laparoscopic & open gastric banding

BPD = Biliopancreatic Diversion with or without Duodenal Switch, open and laparoscopic

Medicare Coverage Advisory Committee – Evaluative Questions

Obesity Patients Without Co-morbidities

1. How well does the evidence address the effectiveness of Bariatric Surgery in the treatment of obesity in patients without co-morbidities compared to non-surgical medical management?											
* 1 – Poorly * 2 * 3 – Reasonably Well * 4 * 5 – Very Well											
1 2 3 4 5											
	2. How confident are you in the validity of the scientific data on the following outcomes?					3. How likely is it that Bariatric Surgery, including RYGBP, banding, and BPD, will positively affect the following outcomes in obese patients without co-morbidities compared to non-surgical medical management?					
	1 - No confidence					1 – Not Likely					
	2					2					
	3 - Moderate Confidence					3 – Reasonable Likely					
	4					4					
	5 - High Confidence					5 – Very likely					
Wt Loss (sustained)	1 2 3 4 5					1 2 3 4 5					
Long-term Survival	1 2 3 4 5					1 2 3 4 5					
Short-Term Mortality	1 2 3 4 5					1 2 3 4 5					
Co-morbidities	1 2 3 4 5					1 2 3 4 5					
4. How confident are you that the following bariatric surgeries will produce a clinically important net health benefit in the treatment of obese patients without co-morbidities?											
* 1 – No Confidence * 2 * 3 – Moderate Confidence * 4 * 5 – High Confidence											
RYGBP – open	1 2 3 4 5					RYGBP – lap	1 2 3 4 5				
BPD - open	1 2 3 4 5					BPD - lap	1 2 3 4 5				
Banding - open	1 2 3 4 5					Banding - lap	1 2 3 4 5				
5. Based on the scientific evidence presented, how likely is it that the results of Bariatric Surgery in obese patients without co-morbidities can be generalized to:											
* 1 – Not Likely * 2 * 3 – Reasonably Likely * 4 * 5 – Very Likely											
c. The Medicare population (aged 65+):											
	1 2 3 4 5										
d. Providers (facilities/ physicians) in community practice:											
	1 2 3 4 5										

Glossary:

Obesity refers to “Class II Obesity” and “Class III Extreme Obesity.” NIH defines “Class II Obesity” as BMI = 35.0 to 39.9 and Class III Extreme Obesity as BMI ≥ 40.

Co-morbidity. Includes but is not limited to high risk factors such as MI, type 2 diabetes, hypertension and sleep apnea, etc. A treatment will “positively affect” co-morbidities if it prevents them.

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