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
1   2   3   4   5

	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

Obesity Patients Without Co-morbidities

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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?
	
	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 without 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 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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