

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, Inc.

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WellCare Health Insurance of Arizona, Inc.*



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WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

~~Bariatric Surgery to Improve Health Outcomes in Members with Type 2 Diabetes Mellitus~~

RETIRED: NO LONGER IN USE

Guideline Number: HS-100

Original Effective Date: 4/16/2009

Revision Date: RETIRED

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Bariatric Surgery performed to improve health outcomes in members with type 2 diabetes mellitus and a Body Mass Index < 35 is considered experimental and investigational and NOT a covered benefit.

BACKGROUND

Overall, the prevalence of diabetes in the United States is 7.9 %; 6.8% in men and 8.9% in women. The prevalence of diabetes increases with increasing age; approximately 11-15% over age 50 as compared to 6.6% or less in lower age groups. It is highest in blacks (11.2%) and lowest in whites (7.2%). Data from the Behavioral Risk Factor Surveillance System (BRFSS) in 2001 show that obesity is significantly associated with a higher rate of diabetes. Compared with adults with normal weight, adults with a BMI of 35-39.9 are 3.44 times more likely to have diabetes and adults with a BMI of 40 or higher are 7.37 times more likely of having diagnosed diabetes. The prevalence of diabetes in persons with BMIs from 35 to 39.9 is 14.9% and 25.6% in persons with BMI \geq 40.

Diabetes mellitus is commonly managed with dietary modification and medications. With the exception of pancreatic transplant, there are no common surgical procedures that are intended to treat diabetes. In addition, Medicare will pay for the routine costs, as well as transplantation and appropriate related items and services, for Medicare beneficiaries participating in a National Institutes of Health (NIH)-sponsored clinical trial of islet cells transplantation (NCD 260.3.1). However, surgical procedures used for weight loss in morbidly obese persons have been noted to reduce medication use and in some cases eliminate diabetes altogether. The same procedures have been proposed to treat diabetes mellitus in persons who are not morbidly obese.

Centers for Medicare and Medicaid Decision Memo (February 12, 2009)

The Centers for Medicare & Medicaid Services (CMS) has determined the following:

1) The evidence is not adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) improve health outcomes in Medicare beneficiaries who have type 2 diabetes mellitus (T2DM) and a body-mass index (BMI) < 35. Therefore, these procedures are not reasonable and necessary for patients with type 2 diabetes and BMI < 35 under section 1862(a)(1)(A) of the Social Security Act.

2) The evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass (RYGBP), laparoscopic adjustable gastric banding (LAGB), and open and laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS) improve health outcomes in Medicare beneficiaries who have T2DM and a BMI \geq 35. Type 2 diabetes mellitus is a comorbid condition related to obesity as defined in NCD Manual 100.1 (Bariatric Surgery for Treatment of Morbid Obesity).

This decision makes no changes to National Coverage Determination (NCD) Manual section 100.8 (Intestinal Bypass Surgery) and section 100.11 (Gastric Balloon for Treatment of Obesity). Treatments for obesity alone remain non-covered.

CMS does not believe that the current evidence demonstrates improved health outcomes for diabetic Medicare patients undergoing bariatric surgery with a BMI < 35. Therefore, we have determined that bariatric surgery is not reasonable and necessary for Medicare beneficiaries with a BMI < 35 as a treatment for diabetes and we are issuing a noncoverage decision.

We would ideally like to see an adequately powered RCT (multi-center if possible) with a control arm of medical treatment, with the ability to evaluate outcomes in subgroups of BMI above and below 35. Furthermore, we desire the ability to draw conclusions about conventional bariatric surgery types such as RYGBP, LAGB, and BPD.

CMS currently provides coverage for certain bariatric surgery procedures for Medicare beneficiaries with a BMI \geq 35 who have at least one comorbidity. We do not define or list those comorbidities. The data reviewed clearly indicate that diabetes is improved following bariatric surgery in the obese population with a BMI \geq 35. Thus, this coverage determination finds that it is reasonable and necessary to list diabetes as a comorbidity in NCD 100.1 and we are modifying that NCD to reflect this decision.

Bariatric Surgery Techniques

Several modifications of bariatric surgery have developed over the last several years. Two major types of surgery are now being employed. One type diverts food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and adsorption of nutrients cannot occur – a malabsorptive procedure. The other type restricts the size of the stomach and decreases intake – a restrictive procedure. Other surgeries combine both types of procedures. Initially, bariatric surgery was developed as an open procedure, but in recent years, successful attempts have been made to convert some of the procedures to laparoscopic procedures, while new ones have been developed solely as laparoscopic procedures. The following are descriptions of bariatric surgery procedures:

Roux-en-Y Gastric Bypass (RYGBP) (Open/Lap)

RYGBP achieves weight loss through both gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption. The RYGBP procedure has been performed regularly since the early 1980s and was first performed laparoscopically in the early 1990s. RYGBP is one of the most common types of weight loss procedures in current use, with approximately 50,000

cases performed in 2001.

Biliopancreatic Diversion (BPD) with and without Duodenal Switch (DS) (Open/Lap)

BPD/DS, like RYGBP, combines both restrictive and malabsorptive mechanisms. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with the RYGBP. As such, patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantial malabsorption occurs. Although this procedure is less commonly performed than either banding procedures or RYGBP, the approach is strongly favored by some bariatric surgeons because this procedure appears to yield higher Excess Weight Loss (EWL). The partial biliopancreatic diversion with duodenal switch is a variant of the BPD procedure. Recently, a number of centers in the United States and Canada have begun to perform this procedure, which involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis.

Laparoscopic Adjustable Gastric Banding (LAGB) (Lap)

Gastric banding achieves weight loss by gastric restriction, not malabsorption. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands used today are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. Today, essentially all of the banding procedures are performed laparoscopically. The open version of adjustable gastric banding (AGB) is not performed at present.

Sleeve Gastrectomy (Open/Lap)

Sleeve gastrectomy is a 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. It may be the first step in a two-stage procedure when performing RYGBP.

Vertical Gastric Banding (VGB) (Lap)

VGB uses mechanical restriction to cause weight loss, a similar mechanism to that used in LAGB, with no malabsorption component. However, the upper part of the stomach is stapled, creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less. VGB was one of the more common surgical procedures for weight loss in the late 1980s and early 1990s but has been largely supplanted by LAGB since 1995. Now its role in the treatment of patients with severe obesity is limited. VGB is essentially no longer performed.

On May 19, 2008, CMS initiated a national coverage analysis regarding the use of gastric bypass and other types of surgery for treatment of diabetes. Our goal is to assess the evidence for the ability of various gastric and intestinal bariatric surgery procedures to improve diabetes status among obese, overweight, and non-overweight diabetics. We are not reconsidering current coverage determinations for types of surgery for morbid obesity in the NCD Manual section 100.8 (Intestinal Bypass Surgery) and section 100.11 (Gastric Balloon for Treatment of Obesity).

CODING

Non-Covered CPT® Codes

- 43644** Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
- 43645** Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
- 43770** Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components)
- 43771** Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric band component only
- 43772** Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band component only
- 43773** Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric band

- component only
- 43774** Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric band and subcutaneous port components
 - 43842** Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
 - 43843** Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
 - 43845** Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 c, common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
 - 43846** Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (less than 100 cm) Roux-en-Y gastroenterostomy
 - 43847** Gastric restrictive procedure, without gastric bypass, for morbid obesity; with small bowel reconstruction to limit absorption
 - 43848** Revision of gastric restrictive procedure for morbid obesity, other than adjustable gastric band (separate procedure)
 - 43886** Gastric restrictive procedure, open; revision of subcutaneous port component only
 - 43887** Gastric restrictive procedure, open; removal of subcutaneous port component only
 - 43888** Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only

Non-Covered ICD-9© Procedure Codes

- 44.31** Other operations on stomach; gastroenterostomy without gastrectomy; high gastric bypass
- 44.38** Other operations on stomach; gastroenterostomy without gastrectomy; laparoscopic gastroenterostomy (Roux-en-Y)
- 44.39** Other operations on stomach; gastroenterostomy without gastrectomy; other gastroenterostomy (Open Roux-en-Y)
- 44.68** Other operations on stomach; other repair of stomach; laparoscopic gastroplasty; (Vertical banded gastroplasty VBG)
- 44.93** Other operations on stomach; insertion of gastric bubble (balloon)
- 44.94** Other operations on stomach; removal of gastric bubble (balloon)
- 44.95** Other operations on stomach; laparoscopic gastric restrictive procedure
- 44.96** Other operations on stomach; laparoscopic revision of gastric restrictive procedure
- 44.97** Other operations on stomach; laparoscopic removal of gastric restrictive device(s)
- 44.98** Other operations on stomach; (laparoscopic) adjustment of size of adjustable gastric restrictive device

Non-Covered HCPCS© Codes

- S2083** Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

Non-Covered ICD-9-CM Diagnosis Codes

- 250.02** Type II Diabetes mellitus
- V85.0** Body Mass Index less than 19, adult
- V85.1** Body Mass Index between 19-24, adult
- V85.21** Body Mass Index 25.0-25.9, adult
- V85.22** Body Mass Index 26.0-26.9, adult
- V85.23** Body Mass Index 27.0-27.9, adult
- V85.24** Body Mass Index 28.0-28.9, adult
- V85.25** Body Mass Index 29.0-29.9, adult
- V85.30** Body Mass Index 30.0-30.9, adult
- V85.31** Body Mass Index 31.0-31.9, adult
- V85.32** Body Mass Index 32.0-32.9, adult
- V85.33** Body Mass Index 33.0-33.9, adult
- V85.34** Body Mass Index 34.0-34.9, adult

REFERENCES

1) Centers for Medicare and Medicaid Services Decision Memo for Surgery for Diabetes (CAG-00397N). February 12, 2009.