MEDICA®
UTILIZATION MANAGEMENT POLICY

TITLE: GASTROINTESTINAL SURGERY FOR MORBID OBESITY

Origination Date: November, 2005
Subsequent Endorsement Dates: 12/2005, 11/2006, 11/2007, 11/2008, 11/2009

This policy was developed with input from specialists in general and vascular surgery, and endorsed by the Medical Policy Committee.

PRODUCT APPLICATION

This policy provides general information concerning Medica's administrative processes. It applies to all fully insured Medica Health Plans, Medica Insurance Company, and Medica Health Plans of Wisconsin products, unless a specific limitation or exception exists. For self-insured plans, consult individual plan sponsor benefit documents. If there is a discrepancy between a Utilization Management Policy and a self-insured benefit plan, the provisions of the benefit plan will govern. With respect to Medicare and Medicaid members, this policy will apply unless Medicare or Medicaid policies require different coverage.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

Medica updates its Utilization Management Policies regularly, and reserves the right to amend these policies without notice to Medica members. *Medica also reserves the right to amend these policies without notice to contracted health care providers unless the amendment materially alters the policy. If the amendment materially alters the policy, Medica will disclose the change to contracted health care providers not less than 45 days prior to implementation of the policy.* Medica's Utilization Management Policies contain general information only and do not guarantee coverage. Receipt of benefits is subject to all terms and conditions of the member's coverage document. Members should consult their Certificates of Coverage or Plan Documents/Summary Plan Descriptions to review the provisions relating to a specific coverage determination. If there is a conflict between a Utilization Management Policy and the applicable coverage document, the coverage document will govern. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Utilization Management Policy may call Medica's Provider Service Center toll free at 1-800-458-5512.

Medica's Utilization Management Policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of gastrointestinal surgery for morbid obesity. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions
   A. **Weight loss surgery** encompasses major operations with significant risks of complications. The risks are reduced if the operation and follow-up care are performed by a specialist in bariatric surgery.
   B. **Morbid obesity** is a condition in which excessive body fat compromises organ systems, psychosocial well-being, and overall quality of life. Co-morbidities associated with this condition are often exacerbated by weight gain and improved with sustained weight loss. While there is no uniform consensus on how to operationally define morbid obesity, the current convention is to calculate the person's Body Mass Index (BMI). Morbid obesity is defined as having a BMI of 40 or more, or having a BMI between 35 and 39.9 with additional co-morbidities. A BMI between 35 and 40 is roughly equivalent to 100 pounds overweight for an average adult, depending on height.

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C. **Body Mass Index (BMI)** is a formula that uses a person's body mass (height and weight) to estimate that person's risk for morbidity and premature mortality. *(See Appendix 1 – Body Mass Index [BMI] Conversion Table.)* A BMI between 35 and 39 is viewed as a very high health risk, while a BMI of 40 or more is viewed as an extremely high health risk. The BMI associated with the lowest mortality is between 20 and 25. **Note:** BMI is not to be used with certain groups of people (i.e., athletes, body builders, or pregnant women) who have high BMIs due to muscle mass, fetal tissue, etc.

D. **Restrictive surgical procedures** reduce the size of the stomach and limit the amount of food that can be ingested at one time. Surgical incision and resection of the intestine is not involved. Examples of purely restrictive operations for morbid obesity include vertical banded gastroplasty and adjustable silicone gastric banding (LapBand).

E. **Combined restrictive and malabsorptive surgical procedures** restrict meal size and may alter the digestion process, thus causing food to be incompletely absorbed. Examples of combined restrictive and malabsorptive procedures include Roux-en-Y gastric bypass and biliopancreatic diversion with duodenal switch.

F. **Bariatric surgical preparatory program** is a multi-disciplinary approach to preoperative care of the bariatric patient. It encompasses bariatric surgical procedure education; dietary, nutrition, and exercise counseling; management of comorbidities; nursing care; and psychological evaluation and counseling, as warranted.

II. Common surgical interventions

A. Purely Restrictive procedures:

1. **Vertical banded gastroplasty** consists of constructing a small pouch by placing a vertical staple line along the lesser curvature of the stomach. An opening (or stoma) is created at the distal end of the pouch to allow food to pass normally, but more slowly, from the pouch to the stomach and then to the small intestines. The pouch generally holds about one ounce of food. The person feels full quickly and experiences pain, nausea and/or vomiting when overeating. Both open and laparoscopic techniques are performed for this procedure.
2. **Adjustable silicone gastric banding** is similar in intent to the vertical banded gastroplasty except that an inflatable, adjustable silicone band is laparoscopically inserted around the upper stomach to create a small stomach pouch. An injection reservoir is enclosed under the skin's surface. The inflatable inner surface of the band is then injected with saline to a level suitable for food restriction and subsequent weight loss, as well as patient comfort. The degree of inflation can be adjusted by a clinician as needed. By removing the silicone band, the procedure can be reversed with minimal need for stomach reconstruction. Although most commonly inserted laparoscopically, this procedure can also be done using an open incision.

B. Combined Restrictive and Malabsorptive procedures:

1. **Roux-en-Y gastric bypass** and its variants consist of two basic steps: creating a small stomach pouch and re-routing the intestines to connect to the pouch. First, a small gastric pouch is constructed, thereby partitioning the pouch from the remaining stomach. The intestine is cut, and the distal end of the bowel is attached to the pouch where the stoma is created. The remaining intestinal limb is reattached farther down the intestinal tract, thereby creating a Y-shaped limb of varying lengths. Gastric bypass procedures work by restricting food intake and by limiting the absorption of calories and nutrients. A gastric bypass is both a gastric restrictive and a malabsorptive procedure. Both open and laparoscopic techniques are performed for this procedure.
2. **Biliopancreatic diversion with duodenal switch** combines biliopancreatic/intestinal bypass and stomach size reduction. First, a partial gastrectomy is done, creating a smaller stomach with both the esophageal connection and the pyloris valve remaining in tact. Next, the intestine is resected. A shorter alimentary limb runs from the pyloris to the duodenum and carries food. A longer biliary limb runs from the pancreas and liver and carries bile and pancreatic secretions. The biliary limb is then connected to the alimentary limb, creating a short common channel where limited fat absorption can occur prior to content entry into the colon. This procedure is primarily malabsorptive, with less restriction than that in the Roux-en-Y gastric bypass. Both open and two-stage laparoscopic techniques are performed for this procedure.

MEDICAL NECESSITY CRITERIA

I. Indications for initial procedure
   A. Medica considers the procedure being requested not-investigative. These procedures include:
      1. Open and laparoscopic Roux-en-Y gastric bypass
      2. Open vertical banded gastroplasty
      3. Open biliopancreatic diversion with duodenal switch (BPD/DS)
         a. Approval of an open BPD/DS requires documentation of a body mass index (BMI) equal to or greater than 55 at least one-month preceding surgery.
      4. Laparoscopic adjustable silicone gastric banding
   B. Member is at least 18 years of age
   C. Psychiatric/psychological evaluation conducted within the past 12 months by a *licensed* psychologist or psychiatrist, or other *licensed* mental health professional who has an appropriate working knowledge of the psychosocial issues involved in obesity and bariatric surgery that includes:
      1. Confirmation of cognitive capability of understanding the risks and goals of the surgical procedure
      2. Documented absence of unmanageable acute psychiatric illness and/or psychological distress
      3. Documented understanding of need to comply with long-term aftercare and with the behavioral changes expected after surgery
   D. At least one month span between date of surgery and the initial consultation with the bariatric surgical preparatory team.

<AND>

   E. A BMI ***equal to or greater than 40*** documented at least one-month preceding surgery ***and*** at least one of the following comorbidities documented in the medical record:
      1. Diabetes mellitus requiring medication (insulin or oral hypoglycemic) or a documented glycosylated hemoglobin (HgbA1c) level at or above 7 documented within the 12 months prior to surgical intervention
      2. Clinically significant hyperlipidemia requiring medical management or a documented LDL level greater than 130 milligrams per deciliter.
      3. Hypertension requiring medical management or blood pressure equal to or greater than 140 mmHg systolic and/or 90 mmHg diastolic documented on more than one occasion
      4. Obstructive sleep apnea requiring CPAP or other related sleep apnea treatment

      <OR>

   F. A BMI ***equal to or greater than 40*** documented at least one-month preceding surgery with ***no*** documented comorbidities, ***and*** participation in a diet, nutrition, and exercise counseling regimen for a *consecutive* total of at least ***three*** months and occurring within ***one year*** prior to surgery. Documentation of counseling participation is submitted by the bariatric surgical preparatory team.

      <OR>

   G. A BMI ***between 35 and 39.9*** documented at least one-month preceding surgery, and ***all of the following*** are met:

      1. ***At least two*** of the following comorbidities documented in the medical record:
         a. Diabetes mellitus requiring medication (insulin or oral hypoglycemic) or a documented glycosylated hemoglobin (HgbA1c) level at or above 7 documented within the 12 months prior to surgical intervention
         b. Clinically significant hyperlipidemia requiring medical management or a documented LDL level greater than 130 milligrams per deciliter.
         c. Hypertension requiring medical management or blood pressure equal to or greater than 140 mmHg systolic and/or 90 mmHg diastolic documented on more than one occasion
         d. Obstructive sleep apnea requiring CPAP or other related sleep apnea treatment
      2. Participation in diet, nutrition, and exercise counseling for a *consecutive* total of at least ***three*** months and occurring within ***one year*** prior to surgery. Documentation of counseling participation is submitted by the bariatric surgical preparatory team.

II. Indications for surgical revisions
   A. Documentation in the medical record that the BMI prior to the initial procedure was equal to or greater than 35, ***and***

B. Documentation in medical record of a surgical complication following the primary procedure and any related medical treatment (e.g., imaging results, endoscopic reports), as applicable. Examples of complications include, but are not limited to:
   1. Pouch dilation
   2. Stoma dilation or stenosis
   3. Staple line breakdown
   4. Stoma ulcer
   5. Mechanical obstruction
   6. Malnutrition

III. Contraindications
   A. Member is less than 18 years of age
   B. Documentation in medical record of a history of noncompliance
   C. Documentation in medical record of a psychiatric illness or psychological condition that would make compliance with a disciplined medical regimen highly improbable or impossible
   D. Present alcohol or substance abuse or dependency, or history of alcohol or substance abuse within the past six months.
   E. Pregnancy and/or lactation
   F. Evidence of ongoing growth (e.g., epiphyseal plate non-closure)

IV. Written documentation from the medical record specifying signs, symptoms, and clinical indications verifying medical necessity, according to the criteria above, *may be* required for initial surgery or surgical revision. Documentation should include name of specific weight loss surgical procedure to be performed.

V. Documentation by the physician, surgeon, or other health care professionals of diet, nutrition, exercise, and weight loss program participation *is not* required preceding the initial procedure for patients with a BMI greater or equal to 40 within the last year when documentation of comorbidity is submitted.

COVERAGE ISSUES

1. Prior authorization is required for gastrointestinal surgery for morbid obesity for the initial surgical procedure, for a surgical revision, and for a second procedure.
2. Coverage may vary according to the terms of the member's coverage document.
3. For Medicare members, refer to the following, as applicable:
   - Centers for Medicare and Medicaid Services (CMS). National Coverage Determination for *Bariatric Surgery for Morbid Obesity* (100.1). Available at: http://www.cms.hhs.gov/pf/printpage.asp?ref=http://www.cms.hhs.gov/mcd/viewncd.asp?ncd%5Fid=100%2E1&basket=ncd%3A100%2E1%3A2%3ABariatric+Surgery+for+Treatment+of+Morbid+Obesity&ncd%5Fversion=2. October 5, 2009.
4. Effective with July 1, 2006 enrollments, Medica will begin instituting its Centers of Excellence program for bariatric care. After July 1, 2006, benefits for Medica members will vary depending on their coverage document and should be verified prior to receiving services.
5. Medica network providers who are designated by the Surgical Review Corporation (SRC)/American Society for Metabolic and Bariatric Surgery (ASMBS), the American College of Surgeons (ACS), or Medica as a bariatric surgeon of excellence will be eligible for reimbursement for bariatric surgical procedures or revisions considered not investigative by Medica's Medical Technology Assessment Committee when performed at a facility designated as an *inpatient* bariatric center of excellence (COE) by SRC/ASMBS, ACS , or Medica.Coverage may vary according to the terms of the member's coverage document.
6. Medica network providers who are *not* designated by the SRC/ASMBS, ACS, or Medica as a bariatric surgeon of excellence will be subject to partial or full reimbursement restriction when performing gastrointestinal surgery for morbid obesity. Coverage may vary according to the terms of the member's coverage document.
7. Medica network providers who are designated by the SRC/ASMBS, ACS, or Medica as a bariatric surgeon of excellence, but are performing gastrointestinal surgery for morbid obesity at a facility *not* designated an inpatient bariatric COE , will be subject to partial or full reimbursement restriction when performing gastrointestinal surgery for morbid obesity. Coverage may vary according to the terms of the member's coverage document.
8. A list of approved surgeons and hospitals in the Medica service area is available online at www.medica.com in the Providers" section under "Clinical & Quality Resources," then "Clinical & Quality Programs." This list is

subject to change based on the ongoing approval process for the program. This listing is also available by calling Medica's Provider Literature Request Line at 952-992-2355 or toll-free at 1-800-458-5512, option 1, then option 5, ext. 2-2355.

9. Additional information regarding surgeons or centers of excellence for bariatric care outside the Medica service area can be found on the SRC Web site at www.surgicalreview.org or the ACS Web site at www.facs.org.
10. Gastrointestinal surgical procedures for morbid obesity or surgery for weight loss not specifically mentioned in the Medical Necessity Criteria section are **investigative and therefore not covered**. These include, but are not limited to:
    a. ***Laparoscopic*** vertical banded gastroplasty
    b. ***Laparoscopic*** biliopancreatic diversion with duodenal switch
    c. Gastroplasty (gastric stapling without banding)
    d. Open loop gastric bypass ("mini" gastric bypass)
    e. Unmodified biliopancreatic diversion
    f. Combined vertical banded gastroplasty-gastric bypass
    g. Magenstrasse and Mill Procedure (i.e., sleeve gastrectomy)
    h. Transected silastic ring vertical gastric bypass (Fobi pouch)
    i. Jejuno-ileal bypass
    j. Endoscopic procedures for morbid obesity including, but not limited to, natural orifice transluminal endoscopic surgery and endoscopic revision following bariatric surgery (all methods including, but not limited to, endoluminal suturing and/or stapling, prosthetic insertion, or endoscopic sclerosant injection).
11. ***Open*** vertical banded gastroplasty requires medical director review.
12. A second procedure for gastrointestinal surgery for morbid obesity in the absence of complications is not covered.
13. A reversal (takedown) of gastrointestinal surgery for morbid obesity in the absence of complications is not covered.
14. The following services are NOT covered:
    a. Education classes
    b. Liquid protein diet replacements/supplements
    c. Appetite suppressants
    d. Over-the-counter vitamin and/or mineral supplements
    e. Weight loss program fees
15. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member's coverage document.
16. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica administrative handbook.

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13. Hayes, Inc. *Hayes Directory: Open Malabsorptive Bariatric Surgery: Roux-en-Y Gastric Bypass*. June 2007. Search last updated June 2008. Lansdale PA.
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17. National Institutes of Health; National Heart, Lung, and Blood Institute (NHLBI). *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults.* June 1998. Bethesda MD. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/index.htm. Accessed November 11, 2009.
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APPENDIX 1 – Body Mass Index (BMI) Conversion Table

Body Mass Index Table

	Normal						Overweight					Obese										Extreme Obesity															
BMI	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**	**49**	**50**	**51**	**52**	**53**	**54**
Height (inches)																		**Body Weight (pounds)**																			
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

The BMI describes relative weight for height. It is calculated as weight (in kilograms) / height (in meters) squared. The National Heart, Lung, and Blood Institute (NHLBI) guidelines classify overweight as a BMI of 25 through 29.9 kg/meter squared, obesity as a BMI equal to or greater than 30 kg/meter squared, and extreme obesity as a BMI equal to or greater than 40 kg/meter squared.

Adapted from: National Heart Lung and Blood Institute. Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm.