CLINICAL MEDICAL POLICY and PRIOR-AUTHORIZATION POLICY	
Policy Name:	Bariatric
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Approved By:	Medical Management
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Page Number(s):	1 of 15

Disclaimer

Gateway Health℠ (Gateway) medical payment and prior-authorization policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrants individual consideration, based upon review of applicable medical records. Bariatric surgery in children and adolescents may be covered under the Pennsylvania Medicaid fee schedule, if medically necessary. Requests are considered on a case by case basis.

Gateway Health Plan® provides coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary bariatric surgical procedures for members who are 18 years of age or older and diagnosed with persistent morbid obesity for at least two years (24 months).

Routine cholecystectomy performed in conjunction with bariatric surgery is considered medically necessary. A liver biopsy, upper gastrointestinal and esophagogastroduodenoscopy (EGD) are considered an integral component of all bariatric procedures and are not eligible for separate payment when reported on the same day as the bariatric surgical procedure.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Commonwealth of Pennsylvania (PA) Department of Human Services (DHS) and all applicable state and federal regulations.

(Current applicable PA HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS

Prior Authorization Review Panel (PARP) — A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

PROCEDURES

1. The following medical necessity criteria, A-F, must be met:
   a. The patient must have morbid obesity as defined below:
      i. A BMI* greater than or equal to 40; OR
      ii. A BMI* between 35 and 40, in conjunction with one or more comorbidities related to obesity such as:
         - Medically refractory hypertension (i.e., blood pressure greater than 140 mmHg systolic and/or 90 mmHg diastolic despite concurrent use of three anti-hypertensive agents); OR
         - Coronary artery disease with objective documentation (i.e., exercise stress test, radionuclide stress test, angiograph, stress echocardiography); OR
         - Type 2 diabetes mellitus: OR
         - Clinically significant obstructive sleep apnea (OSA) (i.e., patient meets criteria for treatment of OSA); OR
         - Pseudotumor cerebri; OR
         - Severe nonalcoholic steatohepatitis (NASH)
   b. The obesity interferes with daily function to the extent that performance is severely curtailed
   c. Documented history of failure of medical weight loss documented as either participation in a physician supervised nutrition and exercise program OR multi-disciplinary surgical preparatory regiment for at least six consecutive months duration
   d. Is not currently pregnant and/or breast feeding and has agreed to avoid pregnancy for at least one year post-surgical intervention
   e. The individual has participated in preoperative surgical care, directed and provided by the member's physician or through a multidisciplinary surgical preparatory regimen**, including **all** of the following components:
      i. A thorough medical history and physical examination
      ii. Consultation and instruction by a professional provider on low-calorie diets and an exercise program based on the individual's capability
      iii. An assessment by a psychologist or psychiatrist stating that there are no behavioral health contraindications to the bariatric surgery, postoperative follow-up care and nutrition guidelines. The presence of depression due to obesity is not normally considered a contraindication for bariatric surgery.
   f. The patient has no specifically correctable cause for the obesity (i.e., endocrine disorder such as a normal TSH level)
2. Nutrition and Exercise Program
   a. Member participation in a physician-supervised nutrition and exercise program must be documented in the medical record by an attending physician who supervised the member's participation.
   b. The nutrition and exercise program may be administered as part of the surgical preparative regimen, and participation in the nutrition and exercise program may be supervised by the surgeon who will perform the surgery or by another physician.

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c. A physician's summary letter is not sufficient documentation. Documentation should include medical records of physician's contemporaneous assessment of the patient's progress throughout the course of the nutrition and exercise program.
d. For patients who participate in the physician-administered nutrition and exercise program (e.g., MediFast, OptiFast), program records documenting the member's participation and progress may substitute for the physician medical record.
e. Nutrition and exercise program must be supervised and monitored by a physician working in cooperation with dieticians and/or nutritionists, with a substantial face-to-face component (must not be entirely remote).
f. The nutrition and exercise program must be a cumulative total of six months prior to surgery indicating the patient's commitment to lifestyle changes necessary post-bariatric surgery.

3. Eligible surgeries:
   a. Vertical-banded gastroplasty, laparoscopic
   b. Adjustable gastric banding, laparoscopic
   c. Sleeve gastrectomy, laparoscopic
   d. Roux-en-Y gastric bypass with long limb (distal) (greater than 150 cm)
   e. Roux-en-Y gastric bypass with short limb (proximal) (150 cm or less)
   f. Biliopancreatic diversion, laparoscopic
   g. Biliopancreatic bypass with duodenal switch
   h. Coverage for a sleeve gastrectomy performed as part of a two-staged procedure is an eligible procedure for individuals who are 18 years of age or older that meet the following medical necessity criteria:
      i. The sleeve gastrectomy is part of a risk reduction strategy as part of the two-stage procedure
      ii. BMI greater than or equal to 50
      iii. The planned second-stage bariatric surgery procedure is to occur within 24 months following the first-stage sleeve gastrectomy procedure
      iv. Documented history of failure of medical weight loss documented as either participation in a physician supervised nutrition and exercise program OR multi-disciplinary surgical preparatory regiment ** for at least six consecutive months duration
      v. The patient is not currently pregnant and/or breast feeding and has agreed to avoid pregnancy for at least one year postoperatively
      vi. An evaluation by a licensed mental health professional provider that specifically evaluates all of the following: any mental health or substance abuse conditions; the emotional readiness and ability of the individual to make and sustain lifestyle changes; and the adequacy of the individual's support system.

4. The individual has participated in preoperative surgical care, directed and provided by the member's physician or through a multidisciplinary surgical preparatory regimen, including all of the following components:
   a. A thorough medical history and physical examination
   b. Consultation and instruction by a professional provider on low-calorie diets and an exercise program based on the individual's capability

5. Repeat or Revised Bariatric Surgery
   a. Gateway Health Plan® considers revision of bariatric surgeries medically necessary to correct late complications such as stricture, leaks from or dehiscence of anastomoses or staple lines, separation of stapled/sutured areas, wound separation, obstruction, pouch dilatation, erosion or band slippage when the complication causes pain, inability to eat or drink or causes vomiting of prescribed meals.

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b. Repeat surgical procedures for revision or conversion to another surgical procedure for inadequate weight loss are considered medically necessary when the all the following criteria are met:
    i. The patient continues to meet all the medical necessity criteria for the bariatric surgery, including current preoperative nutritional assessment; and
    ii. There is documentation of compliance with the previously prescribed postoperative dietary and exercise program; and
    iii. Weight loss following the original surgery is less than 50% of the preoperative excess body weight and weight remains at least 30% over the ideal body weight at least two years following the primary bariatric surgery procedure
c. Prior to consideration of a second bariatric procedure, patients who have undergone adjustable gastric banding must demonstrate that appropriate band manipulation/adjustments in conjunction with regular postoperative visits and nutritional compliance has failed to result in adequate weight loss.

6. Contraindications
    a. Prohibitive perioperative risk of cardiac complications due to cardiac ischemia or myocardial dysfunction
    b. Severe chronic obstructive airway disease or respiratory dysfunction
    c. Failure to cease tobacco use for at least six weeks prior to surgery
    d. Psychological/psychiatric condition
        i. Schizophrenia, borderline personality disorder, suicidal ideation, severe or recurrent depression, or bipolar affective disorders with difficult-to-control manifestations (e.g., history of recurrent lapses in control or recurrent failure to comply with management regimen)
        ii. Intellectual disability that prevents personally provided informed consent or the ability to understand and comply with a reasonable pre- and post-operative regimen
        iii. Any other psychological/psychiatric disorder that, in the opinion of a psychologist/psychiatrist, imparts a significant risk of psychological/psychiatric decompensation or interference with long-term postoperative management
    e. History of significant eating disorders, including anorexia nervosa, bulimia, and pica (i.e., ingesting sand, clay, or other abnormal substances)
    f. Hepatic disease with prior documented inflammation, portal hypertension, or ascites (i.e., fluid accumulation in the peritoneal cavity)
    g. Severe hiatal hernia/gastroesophageal reflux (for purely restrictive procedures such as laparoscopic adjustable gastric banding)
    h. Autoimmune and rheumatological disorders (including inflammatory bowel diseases and vasculitides) that will be exacerbated by the presence of intra-abdominal foreign bodies (for the laparoscopic adjustable gastric banding procedure)

7. When services are not covered
    a. For conditions other than those listed above, scientific evidence has not been established.
    b. Per ACOG (2009), bariatric surgery is considered experimental and investigational as a treatment for infertility.
    c. Gastrointestinal liners (EndoBarrier®) have not received FDA approval and therefore remain unproven and not medically necessary for the treatment of obesity.

8. Post-payment Audit Statement
    a. The medical record should include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health Plan® at any time pursuant to the terms of your provider agreement.

9. Place of Service

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a. Inpatient and/or Outpatient

10. The following procedures are typically considered inpatient procedures:
    a. Biliopancreatic Diversion with Duodenal Switch
    b. Rous-en-Y Gastric Bypass
    c. Sleeve Gastrectomy
    d. Bariatric Revisional Surgery

11. Governing Bodies Approval
    a. In 2001, the U.S. Food and Drug Administration (FDA) premarket approval for the LAP-BAND® System and the REALIZE™ indicates it is for use only in the severely obese adult patients. Devices that are used for laparoscopic adjustable gastric banding do not have FDA approval in the U.S. for individuals younger than age 18 years.
    b. StomaphyX®, and endoscopically guided system is indicated for use in endoluminal transoral tissue approximation, ligation in the GI tract, received FDA approval in 2007.

BODY MASS INDEX (BMI) CHARTS

These tables were adapted from the clinical guidelines for the identification, evaluation, and treatment of overweight and obese adults and were prepared by the National Institutes of Health (NIH), National Heart, Lung, and Blood Institute.

BODY MASS INDEX (BMI) chart for up to 287 pounds

To use this table, find the appropriate height in the left-hand column. Move across the row to a given weight. The number at the top of the column is the BMI for the selected height and weight. Pounds have been rounded off.

BMI

Height (inches)	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272

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75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287
Body Weight (pounds)																	

BODY MASS INDEX chart for up to 443 pounds

To use this table, find the appropriate height in the left-hand column. Move across the row to a given weight. The number at the top of the column is the BMI for the selected height and weight. Pounds have been rounded off.

BMI

Height (inches)	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
58	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443
Body Weight (pounds)																			

Procedure Codes

Code 43843 should not be reported if there is a more specific bariatric surgery code within code range listed below.

43236	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance
43253	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided transmural injection of diagnostic or therapeutic substance(s) (e.g., anesthetic, neurolytic agent) or fiducial marker(s) (includes endoscopic examination of the esophagus, stomach, and either the duodenum or a surgically altered stomach where the jejunum is examined distal to the anastomosis)

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43631	Gastrectomy, partial, distal; with gastroduodenostomy
43632	Gastrectomy, partial, distal; with gastrojejunostomy
43633	Gastrectomy, partial, distal
43634	Gastrectomy, partial, distal; with formation of intestinal pouch
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 restrictive device (gastric band and subcutaneous port components)
43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (e.g., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity
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 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity with short limb (150 cm or less) Rous-en-Y gastroenterostomy
43847	;with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection, without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection, with vagotomy
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
47001	Biopsy of the liver, needle; percutaneous (in the absence of signs or symptoms of liver disease (e.g., elevated liver enzymes, enlarged)
47001	Biopsy of liver, needle; when done for indicated purpose at time of other major procedure (list separately in addition to code for primary procedure) [in the

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	absence of signs or symptoms of liver disease (e.g., elevated liver disease, enlarged liver)]
47100	Biopsy of liver, wedge [in the absence of signs or symptoms of liver disease (e.g., elevated liver disease, enlarged liver)]
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline
S9449	Weight management classes, non-physician provider, per session
S9451	Exercise classes, non-physician, per session
S9452	Nutrition classes, non-physician provider, per session

Diagnosis Codes

ICD-10	Description
E66.0	Obesity
E66.01	Morbid (severe) obesity due to excess calories
E66.09	Obesity, unspecified
E66.3	Overweight
E66.8	Other obesity
K95.01	Infection due to gastric band procedure
K95.09	Other complications of gastric band procedure (dilated gastrojejunal stoma)
K95.81	Infection due to other bariatric procedure
K95.89	Other complications of other bariatric procedure (dilated gastrojejunal stoma)
Z46.51	Encounter for fitting and adjustment of gastric lap band
Z68.35 – Z68.39	Body Mass Index (BMI) 35.0 - .39.9 or greater, adult
Z68.41 – Z68.45	Body Mass Index (BMI) 40 or greater, adult
Z98.84	Bariatric surgery status

REIMBURSEMENT

Participating providers will be reimbursed per their Gateway Health Plan® contract.

SUMMARY OF LITERATURE

The American Society for Metabolic and Bariatric Surgery (ASMBS) Pediatric Committee released best practice guidelines for treatment of obese adolescents in 2012. While the guidelines outlined acceptable criteria, the ASMBS stated that the available evidence based literature was insufficient to identify recommendations for specific bariatric procedures. It was also noted that there is a lack of long-term follow up on the risks of micronutrient and vitamin deficiencies.

In 2011, Keidar et al. performed a review of bariatric surgery in obese adolescents and indicated that evidenced based literature was still lacking. The authors also stated that patient selection criteria, appropriate surgical procedures and the extent of the multidisciplinary preoperative and postoperative care are not defined.
In 2013, Black et al. reported on a systematic review of the current state of peer-reviewed literature on the safety and effectiveness of bariatric surgery in obese adolescents. It was reported that while there were significant decreases in one year follow-up BMI, the risk of complications has not been well defined and that long-term studies are needed to establish the harms and benefits of bariatric surgery in the this patient population.

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Hofman (2013) reported that the evidence for bariatric surgery in children and adolescents is scare and of poor quality. There are moral issues regarding performance of bariatric surgery in young individuals such as: too young to consent, lack of maturity, treatment end-points, hidden interests of patients, parents, professionals, industry and society. More evidence is needed to be able to balance benefits and risks, provide information for a valid consent or assent and to advise minors and parents.

According to Nobili et al. (2015), weight loss surgery should be the last resort in the pediatric population due to lack of consensus on appropriate bariatric surgical intervention selection criteria.

Research to date has not adequately addressed important issues specific for children and adolescents that may receive bariatric surgery. These issue would include the rate of complications, compliance with therapy and the potential limitations in the lifespan of surgical interventions and the associated ling-term metabolic consequences. Additional research is necessary to address these issue as well as subpopulations of adolescents who might particularly benefit from bariatric surgery.

Windover (2013) states that tobacco use persists as the leading cause of preventable death worldwide and is prevalent among bariatric surgical candidates. Based on the author's research, it is recommended that bariatric surgery centers establish a standard protocol that includes assessment of tobacco use and referrals for tobacco use treatment and intervention for individuals identified as at-risk future tobacco use.

Finks et al. (2011) reported that there is an association between tobacco use and respiratory complications following bariatric surgery. Patients who smoked cigarettes within one year of have bariatric surgery were at increased risk for developing pneumonia. There is an increased incidence of developing marginal ulcers (AOR 30.6, 95% CI, 6.4-146, $p<0.001$) and wound dehiscence (OR 20.9, 95% CI, 1.1-411, $p<0.046$) postoperatively (Wilson et al. 2006). The latest evidence-based bariatric surgery guidelines recommend advising tobacco users to quit tobacco at least six weeks prior to bariatric surgery (Blackburn et al. 2009).

In 2013, Mechanick et al. updated the clinical practice guidelines for the perioperative nutritional, metabolic and nonsurgical support of the bariatric surgical patient. Recommendation includes that tobacco use should be avoided at all time by all patients. In particular, patients who smoke cigarettes should stop preferably at least 6 weeks before bariatric surgery (Grade A; BEL 2, upgraded by consensus). In addition, patients should avoid tobacco use after bariatric surgery due to known increased risk of poor wound healing, anastomotic ulcer, and overall impaired health.

AUTHORIZATION

Prior authorization is required for all bariatric surgeries performed as an inpatient and outpatient.

SCIENTIFIC BACKGROUND AND REFERENCE SOURCES

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