



Coming Soon!

- **June, Evaluation and Management of Sleep Apnea**
- **July, Sepsis Prevention Training**
- **August, CAD: Emphasis on Secondary Prevention, Post AMI/PCI**
- **September, Recent New and Trending Drugs in 2019**
- **October, COPD: Recognizing Severity, Current Treatments of Exacerbation and Readmission Avoidance**

Weight Reduction Strategies: When to Use Medical vs Bariatric Treatments

Charles Carlini, MD/JD, FACOG, and
Dianna Candelaria, PharmD, BCACP

Introducing Your Faculty



Charles Carlini, MD/JD, FACOG



Dianna Candelaria, PharmD, BCACP

Presentation Objectives

At the end of this educational activity, participants should be able to:

- State the relationship between obesity and its impact on one's general health.
- Discuss the importance of a multidisciplinary approach when treating obesity.
- Identify optimal clinical management strategies for obesity.

NIH Guidelines for the Approval of Bariatric Surgery

- "BMI between 35 and 40 with comorbidities (1 or more) or a BMI \geq 40
- Age > 17 years (unless bone maturity is demonstrated)
- Participated in a physician-supervised diet (usually 6 months in length)
- Comprehension of the nature and risks of a bariatric procedure including the compliance needed with substantial lifelong dietary restrictions coupled to medical surveillance
- Dietary consultation and recommendations along with psychological counseling which should begin in the pre-operative period*

As with all bariatric procedures, surgery is ill advised for patients who have:

- A poor surgical risk status
- Untreated endocrine disease
- An inflammatory disease of the GI tract
- Dependency on alcohol or drugs
- Severe learning or cognitive disorders, including emotional instability

Check the member's specific benefit plan documents and any federal or state mandates if applicable

NIH: www.nih.nih.gov/files/docs/guidelines/bob_gdms.pdf

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Bariatric Procedures

- Adjustable Gastric Banding (AGB)
- Sleeve Gastrectomy (SG)
- Roux-en-Y Gastric Bypass Procedure (RYGBP)
- Biliopancreatic Diversion with Duodenal Switch (BPD/DS)
- Biliopancreatic Diversion (BPD)*
- Vertical Banded Gastrectomy (VBG)*



*Rarely requested

UpToDate: www.uptodate.com/contents/bariatric-procedures-for-the-management-of-severe-obesity-descriptions?search=Bariatric%20Procedures&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

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Nurse Support Can Improve Health Outcomes

Pre- and post-surgery nurse support is crucial to improving health outcomes and reducing the chances of readmissions and reoperations

Check the member's specific benefit plan documents and any federal or state mandates if applicable

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Nurse Support Pre-Surgery

Notification received from member or physician

- Eligibility and benefits determination
- **COE** education and guidance
- Member education on bariatric surgery procedures
- Member engagement: welcome letter, quick reference guide, bariatric surgery booklet
- Pre-surgery assessments (telephonic), BMI, medication, weight-related health conditions, readiness to change, lifestyle
- Coordination of behavioral health assessments with provider
- Proactive: telephonic support (4 to 6 calls) over 6 months

Check the member's specific benefit plan documents and any federal or state mandates if applicable

JJA: nexus-sp.odtm.com/Atlas/Document.html?JA9996707

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Nurse Support Post-surgery

Outbound welcome home call within 24 to 48 hours after discharge, within 5 business days of discharge

Initial Post-Surgery call and 30 days

Monitor for signs and symptoms of complications

Advise when to call doctor if appropriate

Review diet, weight, BMI and lifestyle changes

Check the member's specific benefit plan documents and any federal or state mandates if applicable

JJA: nexus-sp.odtm.com/Atlas/Document.html?JA9996707

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Coaching

Areas of interest:

- Permanent lifestyle changes with food intake
- Portion controlling (per meal and number of meals/day)
- Exercising
- Decreasing alcohol consumption
- Creating/joining a support network
- Quitting tobacco and any illicit drugs



NIH: www.nhlbi.nih.gov/files/docs/guidelines/ob_adina.pdf

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Lifestyle Change Prior to Surgery

- Many members who are candidates for bariatric surgery are under the impression that the surgical procedure is the key, and the only key, to weight reduction and maintenance of weight reduction. **This is not the case.**
- Bariatric surgery is only one of the many tools used for weight reduction and may be the most powerful methodology, granted.
- To have successful outcomes in terms of losing weight without regain of weight, behavioral modification is absolutely necessary. The member must engage in activities to prevent weight gain such as maintaining a reasonable diet as specified by her/his surgeon and exercising if possible.
- Candidates for surgery and postoperative members are encouraged to join/form self-help groups to maintain these diet and exercise activities to achieve and maintain weight loss.

NIH: niddk.nih.gov/health-information/weight-management/bariatric-surgery/types

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Weight Loss Prior to Surgery

- **Safety issue** – with weight loss per a regimen imposed upon the member before surgery that usually involves a span of 6 months, the size of the liver will decrease. When this occurs, the visibility of the operative field increases, particularly the area around the stomach (where a good bit of the surgery is performed). This decreases the possibility of complications, particularly internal bleeding and anastomotic leaking after the procedure is completed, and the member is in the recovery room or has been discharged to home.

It should be made quite clear to the surgical candidate prior to surgery that weight loss from an adhered-to-diet will not disqualify the member from the scheduled bariatric surgery.

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Adjustable Gastric Band (AGB)

- AGB: a small gastric pouch above the band provides a continued feeling of *satiety* which limits food intake preventing weight gain. It is the *modus operandi* of this procedure.
- Can sometimes provide significant sustained weight loss with *excess weight loss* reaching 40–60% two years after AGB. It is a purely restrictive procedure with a failure rate higher than any other bariatric procedure as only a modest weight loss is usually achieved compared to other procedures.
- Generally safe, effective and minimally invasive procedure. Most complications can be addressed laparoscopically. It is reversible and adjustable.
- If weight loss after band therapy is unsatisfactory, revision to a gastric bypass procedure or gastric sleeve is acceptable.
- This procedure has been used in the pediatric population.

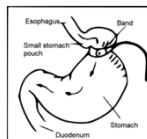


Image Source: Power Point ClipArt

NIH: niddk.nih.gov/health-information/weight-management/bariatric-surgery/types
JA 22210228; pevus-sp.opdam.com/Atlas3Document.html?JA22210228

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Sleeve Gastrectomy (SG)

- Sometimes SG provides significant sustained weight loss over short to intermediate time frames. A purely *restrictive procedure*, it is similar to AGB in weight loss outcome.
- Generally a safe, effective and minimally invasive procedure. An excision of the greater curvature of the stomach (75 – 85%) results in a tubularized structure or gastric reservoir.
- Anatomic change produced provides a continued feeling of *satiety* which limits food intake and prevents weight gain. Additionally, "the portion of the stomach removed may decrease ghrelin release and associated appetite increase.
- If weight loss after SG is unsatisfactory, revision to a gastric bypass procedure is acceptable.

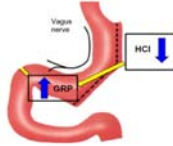


Image Source: Power Point ClipArt

JA 22210624 www.ncbi.nlm.nih.gov/pmc/articles/PMC42210624/

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Roux-en-Y Gastric Bypass (RYGBP)

- A commonly performed malabsorptive bariatric procedure. Reduction in medical comorbidities (Type 2 diabetes (DM), obstructive sleep apnea (OSA), the Pickwickian syndrome (hypercarbia and daytime somnolence), chronic hypertension (CHTN) and gastrointestinal reflux disease (GERD) associated with the *metabolic syndrome*) and improvement in quality of life, have been documented.
- Generally is a safe and effective procedure and involves bypassing a large part of the stomach, the duodenum and a variable length of the proximal jejunum. The anatomic change is accomplished by transecting the proximal jejunum and performing an anastomosis of the distal jejunum with the gastric pouch. The remaining end of the small bowel is anastomosed to the Roux limb and is known as the biliopancreatic limb as it provides the digestive enzymes.



Image Source: Power Point ClipArt

JA 22210625 www.ncbi.nlm.nih.gov/pmc/articles/PMC42210625/

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Metabolic Syndrome

Metabolic Syndrome is a cluster of conditions that occur together

- Abdominal Obesity
- Atherogenic dyslipidemia
- Elevated BP
- Insulin resistance or glucose intolerance
- Proinflammatory state
- Prothrombotic state

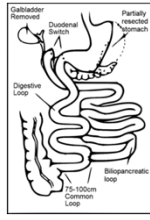
Metabolic Syndrome increases the member's risk of heart disease, stroke and type 2 diabetes

UpToDate: www.uptodate.com/contents/the-metabolic-syndrome-insulin-resistance-syndrome-or-syndrome-x?search=metabolic%20syndrome&source=search_result&selectedTitle=1~150&usage-type=default&display_rank=1

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Biliopancreatic Diversion/Duodenal Switch (BPD/DS)

- Biliopancreatic Diversion/Duodenal Switch (BPD/DS) is an invasive procedure done via laparotomy or laparoscopy.
- Division of the duodenum distal to the pylorus is followed by a pylorus-preserving gastric sleeve.
- Next, a duodenoenterostomy (the alimentary limb) is created and anastomosed to the remaining gastric pouch and is free of biliopancreatic secretions.
- The biliopancreatic limb (carries the digestive enzymes), which bypasses the duodenum, jejunum and proximal ileum, is then anastomosed to the distal ileum creating a common channel that is usually < 100 cm from the ileocecal junction.



JA 22210626: [nexus-isp.optum.com/ASes/Document.html?JA22210626](https://www.nexus-isp.optum.com/ASes/Document.html?JA22210626)

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General Program Guidelines for Coaching

- Pre-surgery:
 - Members must participate **continuously** for a minimum of 6 months (at least one call per month). Any exceptions to this rule is to be determined by the medical director and product manager.
 - Members should be encouraged to complete all 10 calls.
- Post-surgery:
 - Coaching allowed starting **3 months after surgery**.
 - Coaching content post-surgery is limited to supporting the care team's recommendations.
 - Questions should be referred to the BRS nurse and/or the post-surgical care team.
- Recommended Registered Dietitians (RD) coach these members for **one year post-surgery** (remembering that coaching cannot start until 3 months post-discharge).

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Weight-Loss (Obesity) Pharmacotherapy



AHA-ACC-TOS Guidelines: Management Obesity Adults (2013)

- When to add pharmacotherapy
 - BMI ≥ 30 kg/m² or BMI ≥ 27 kg/m² with comorbidity
- When to continue pharmacotherapy
 - 5% loss of initial body weight at 12 weeks on maximum dosage
 - Reassess risk-to-benefit ratio
- Benefit of continued pharmacotherapy
 - Slow weight regain with continued use

AHA/ACC/TOS Prevention Guideline
2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults
 A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society
Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacology Association, American Society for Nutrition, American Society for Parenteral and Enteral Nutrition, American Society for Preventive Cardiology, American Society of Hypertension, Association of Black Cardiologists, National Lipid Association, Preventive Cardiovascular Nurses Association, The Endocrine Society, and WomenHeart: The National Coalition for Women With Heart Disease

AHA/ACC/TOS Guidelines: www.ahajournals.org/doi/pdf/10.1161/01.cir.0000487739.71477.ec
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AAACE / ACE Guidelines: Medical Care of Obesity (2016)

A focus on 2 of the pharmacotherapy questions from the AAACE / ACE Guidelines

- Q7.** "Is pharmacotherapy effective to treat overweight and obesity?"
- Adjunct to lifestyle therapy
 - Greater weight loss and weight-loss maintenance compared to lifestyle therapy
 - Short-term (3 to 6 months) has not produced longer-term health benefits
 - Chronic treatment when potential benefits outweigh risks
 - Combining medications only when sufficient safety and efficacy data
 - Individualized weight-loss pharmacotherapy regimen based on differences in efficacy, side effects, cautions and warnings
- Q8.** "Are there hierarchies of drug preferences in patient with (concurrent) conditions or characteristics?"
- Seventeen (17) conditions/characteristics reviewed within Guideline
 - Individualized based on risks vs. benefits

AAACE/ACE Guidelines: obesity.aace.com/files/obesityguidelines/aace_guidelines_obesity_2016.pdf
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FDA-Approved Medications for Weight Loss

Short-Term (2 to 12 weeks)

Autonomic Sympathomimetic Adrenergic Agonists

- Amphetamine (Evekeo®)
- Benzphetamine (Didrex®)
- Phendimetrazine (Melfiat®)
- Methamphetamine (Desoxyn®)

Psychostimulant Anorectic Agents

- Phentermine (Adipex®, Lomaira®)
- Diethylpropion (Tenuate®)

Long-Term (Potentially Indefinitely)

Gastrointestinal Lipase Inhibitor

- Orlistat (Xenical®, Alli® [OTC])

Psychostimulant Anorectic Agents

- Lorcaserin (Belviq®)
- Bupropion-Naltrexone (Contrave®)
- Phentermine-Topiramate (Qysmia®)
- Liraglutide (Saxenda®)

Clinical Pharmacology: www.clinicalpharmacology.jp.com/default.aspx
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Psychostimulant Anorectic Agents

Lorcaserin (Belviq®)

- Serotonin 2C receptor agonist
- Cardiac valve risk similar to placebo
- Daily to BID dosing (extended-release available)
- Headache, serotonin effects nausea, tremors, anxiety, dizziness, insomnia, dry mouth, suicidal ideation
- Reported weight loss 5.8%

Phentermine-Topiramate (Qsymia®)

- Psychostimulant anorectic + antiepileptic
- Tolerance usually develops to anorectic effects of Phentermine
- Daily dosing QAM; titrated every 14-days to effective (tolerated) dosage (extended-release)
- CNS stimulant and serotonin side effects; mental cognition and teratogenicity risk (Topiramate)
- Reported weight loss 5.1% to 10.9%

Naltrexone-Bupropion (Contrave®)

- Opioid antagonist + antidepressant
- Effects on hypothalamus (appetite regulatory center) and mesolimbic dopamine circuit (reward system)
- Dosage titration over weeks from 1 tab QAM to 2 tabs BID (extended-release)
- Seizure and opioid withdrawal risk
- Headache, N/V, constipation, memory impairment, serotonin effects, suicidal ideation
- Reported weight loss 3.7% to 8.1%

Liraglutide (Saxenda®)

- GLP-1 receptor antagonist
- At least 1 concurrent comorbidity
- Contraindication with thyroid carcinomas
- once-daily SC injection titrated weekly to Effective dosage (3mg/day)
- Diarrhea, N/V, constipation, hypoglycemia, injection site reaction, pancreatitis and cholecystitis risk
- Reported weight loss 4.9% to 7.4%

Clinical Pharmacology: www.clinicalpharmacology.com/default.aspx

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Comparison of Weight-Loss Medications

Total Daily Dosage	Orlistat		Lorcaserin		Phentermine-Topiramate			Naltrexone-Bupropion		Liraglutide	
	360mg	20mg	Drug	Control	7.5-45mg	15-30mg	Drug	Control	1.2-3.6mg	Drug	Control
Baseline (kg)	100.5	101.8	100.3	100.5	102.6	103.0	103.3	99.7	99.5	106.2	106.2
Baseline BMI	36.0	36.1	36.0	35.9	36.2	36.6	36.7	36.1	36.2	38.3	38.3
Weight Loss % Completers	-8.78	-4.26	-7.90	-4.00	-9.60	-12.40	-1.60	-8.10	-1.80	-9.20	-3.50
Weight Loss % Intent-to-Treat	-7.94	-4.14	-5.80	-2.80	-7.80	-9.80	-1.20	-6.10	-1.30	-8.00	-2.60

Age Range: 41.8 to 53.0 years; 70-85% female; Minimum 2-year duration
 Key Clinical Trials, Baseline Characteristics, and Weight-Loss Efficacy
 Adapted from Tesse 20 Page 26, AACE/ACE Obesity Care Manual April 2018, 225 (upper 8)

- Weight Loss Medication Challenges**
- Not covered by most health plans including government plans
 - Usually high (out of pocket / cash) cost
 - Willingness for medical providers to prescribe
 - Intensity of management; concurrent with lifestyle modifications

AACE/ACE Guidelines: obesity.aace.com/files/obesity/guidelines/aace_guidelines_obesity_2016.pdf, Table 10

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Case Study

Member had lap band placed in 2009 and is currently experiencing constant vomiting & dysphagia due to a slipped band. Provider is requesting a removal of the lap band under CPT Code #43774 and revision to a Gastric Sleeve per CPT Code #43775.

Brief Relevant Member History

- **Name:** Mrs. Jones
- **Age/Gender:** 49 year old female
- **BMI:** Height 68 inches, weight 317 pounds, BMI 47.9
- **Comorbidities:** Hyperlipidemia & Sleep Apnea
- **Policy #:** XXXXXXX
- **Was the member under this employer/insurance for prior procedure?** No - different employer/different plan

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Case Study

Specific Plan Document for Bariatric Surgery Eligibility

- **Network status:** Both surgeon & facility must be a COE
- **Age:** 21 or older
- **BMI:** 35-39.9 with > 2 co-morbidities or BMI > 40
- **Diet:** Physician supervised diet for 6 months must be completed
- **Behavioral health:** Psychological and psychiatric evaluation must be done
- **Second procedure coverage availability:** Yes, if criteria are met or in the event of complications
- **Lap band covered:** Yes
- **Travel and lodging non-standard:** (up to \$50/\$100 per diem; up to \$10,000 lifetime maximum) *applies to member only*
- **Enrollment:** BRS Enrollment is mandatory

Polling Questions #1 and #2 and #3

Case Study

For Referrals: RN Questions/Requests for Medical Director

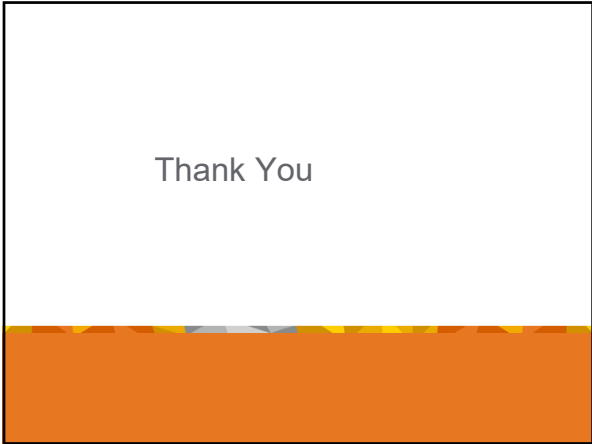
- 1) Is the member eligible for this conversion without completing the criteria?
- 2) What CPT code can they use for this conversion? The provider is proposing removal of lap band 43774 and conversion to a gastric sleeve 43775.

Polling Questions #1 and #2 and #3

Case Study

Medical Director BRS/UM Case Review Note

- **Medical Director Name/Title:** Charles J. Carlini, MD/JD, Optum BRS National Medical Director, Bariatrics
- **Request Reason:** member wishes to address complications of previous bariatric surgery with conversional surgery
- **History:** member is a 49 year old female who is s/p LAGB x 10 years
- **Diagnosis:** morbid obesity, hyperlipidemia, OSA, band slippage, emesis & dysphagia
- **Pertinent findings:** BMI = 47.9 (5'8", 317 pounds)
- **Consults supporting coverage determination:** bariatric surgeon
- **Benefit language from coverage document:** repair of complications of previous bariatric surgery, including the use of conversional surgery, is a covered benefit.
- **Determination:** approve performance of band removal per CPT Code #43774 and LSG per CPT Code #43775
- **Rationale for determination:** Benefit language



Thank You



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