## AACE/ACE Algorithm for the Medical Care of Patients with Obesity

### Patient Presentation
- Screen positive for overweight or obesity
  - BMI $\geq 25 \text{ kg/m}^2$ (≥23 kg/m$^2$ in some ethnicities)
- Presence of weight-related disease or complication that could be improved by weight-loss therapy

### Evaluation

#### Antropometric Diagnosis
- Confirm that elevated BMI represents excess adiposity
- Measure waist circumference to evaluate cardiometabolic disease risk

#### Clinical Diagnosis

<table>
<thead>
<tr>
<th>Diagnostic Categories</th>
<th>Staging</th>
<th>Risk Stratification</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORMAL WEIGHT (no obesity)</td>
<td>STAGE 0</td>
<td>No complications</td>
</tr>
<tr>
<td>OVERWEIGHT 25–29.9</td>
<td>STAGE 1</td>
<td>One or more mild-to-moderate complications or may be treated effectively with moderate weight loss</td>
</tr>
<tr>
<td>OBESITY ≥30</td>
<td>STAGE 2</td>
<td>At least one severe complication or requires significant weight loss for effective treatment</td>
</tr>
</tbody>
</table>

### Phases of Chronic Disease Prevention and Treatment Goals

- PRIMARY
  - Prevent overweight/obesity
- SECONDARY
  - Prevent progressive weight gain or achieve weight loss to prevent complications
- TERTIARY
  - Achieve weight loss sufficient to ameliorate the complications and prevent further deterioration

### Treatment Based on Clinical Judgment

- PRIMARY
  - Healthy meal plan
  - Physical activity
  - Health education
  - Built environment
- SECONDARY
  - Lifestyle/behavioral therapy
  - Consider pharmacotherapy if lifestyle alone not effective
- TERTIARY
  - Lifestyle/behavioral therapy
  - Add pharmacotherapy (BMI ≥27)
  - Consider bariatric surgery (BMI ≥35)

### Follow-Up
- Once the plateau for weight loss has been achieved, re-evaluate the weight-related complications. If the complications have not been ameliorated, weight-loss therapy should be intensified or complication-specific interventions need to be employed.
- Obesity is a chronic disease and the diagnostic categories for obesity may not be static. Therefore, patients require ongoing follow-up, re-evaluation and long-term treatment.

### Abbreviation
- BMI = body mass index
ANTHROPOMETRIC COMPONENT OF THE MEDICAL DIAGNOSIS OF OBESITY

Evidence-based screening and diagnosis for excess adiposity in clinical settings

1. Clinical interpretation of BMI: Ensure elevated BMI is indicative of excess adiposity by assessing: age, gender, musculature, hydration status, edema, third space fluid collection, large tumors, sarcopenia
2. Waist circumference if BMI <35: Adds information pertaining to cardiometabolic disease risk; use gender- and ethnicity-specific cut-off values
3. Can consider body composition technologies: e.g., bioelectrical impedance, air/water displacement plethysmography, or dual-energy X-ray absorptiometry scan

Abbreviation: BMI = body mass index.

CLINICAL COMPONENT OF THE MEDICAL DIAGNOSIS OF OBESITY

Evaluation of a checklist of weight-related complications. Candidates for weight-loss therapy can present with either excess adiposity (i.e., the anthropometric component) or weight-related complications (i.e., the clinical component)

Patients Present with Overweight or Obesity (Anthropometric Component)

Patients present with BMI ≥25 kg/m², or ≥23 kg/m² in certain ethnicities, and excess adiposity

Candidates for Weight Loss Therapy

Evaluate for weight-related complications

Evaluate for overweight or obesity

Patients Present with Weight-Related Disease or Complication (Clinical Component)

- Prediabetes
- Metabolic Syndrome
- Type 2 Diabetes
- Dyslipidemia
- Hypertension
- Cardiovascular Disease
- Nonalcoholic Fatty Liver Disease
- Polycystic Ovary Syndrome
- Female Infertility
- Male Hypogonadism
- Obstructive Sleep Apnea
- Asthma/Reactive Airway Disease
- Osteoarthritis
- Urinary Stress Incontinence
- Gastroesophageal Reflux Disease
- Depression
<table>
<thead>
<tr>
<th>Weight-Related Complication</th>
<th>Basis for Screening and/or Diagnosis</th>
<th>Suggested Secondary Testing When Needed To Confirm Diagnosis, Stage Severity, or Guide Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prediabetes</td>
<td>Fasting glucose; A1C; 2-hour OGTT glucose</td>
<td>If fasting glucose is 100-125 mg/dL, a repeat elevated fasting glucose completes diagnosis of IFG; however, 2-hour OGTT should also be performed to exclude diabetes and IGT. Fasting and 2-hour OGTT should be performed if initial fasting glucose is normal and A1C is elevated, or in high-risk patients based on family history or metabolic syndrome.</td>
</tr>
<tr>
<td>Metabolic Syndrome</td>
<td>Waist circumference, blood pressure, fasting glucose, triglycerides, HDL-c</td>
<td>Initial evaluation completes diagnosis; use OGTT to test for IGT or diabetes.</td>
</tr>
<tr>
<td>Type 2 Diabetes</td>
<td>Fasting glucose; A1C; 2-hour OGTT glucose; symptoms of hyperglycemia</td>
<td>Overtly elevated (i.e., ≥200 mg/dL) or a repeat fasting glucose ≥126 mg/dL completes diagnosis. If fasting glucose and/or A1C is consistent with prediabetes, 2-hour OGTT should be performed to test for diabetes. A1C should be performed to help guide therapy.</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>Lipid panel (total cholesterol, HDL-c, triglycerides, LDL-c, non-HDL-c)</td>
<td>Lipid panel completes diagnosis; lipoprotein subclasses, apoB100 may further define risk.</td>
</tr>
<tr>
<td>Hypertension</td>
<td>Sitting blood pressure</td>
<td>Repeat elevated blood pressure measurements to complete diagnosis; home blood pressure or ambulatory blood pressure monitoring may help complete testing.</td>
</tr>
<tr>
<td>Cardiovascular Disease</td>
<td>Physical exam; ROS; history and medical records</td>
<td>Additional testing based on findings and risk status (e.g., ankle-brachial index, stress testing, coronary artery calcium score and the MESA risk score calculator, arteriography, carotid ultrasound).</td>
</tr>
<tr>
<td>NASH / NAFLD</td>
<td>Physical exam; LFTs</td>
<td>Imaging (e.g., ultrasound, MRI, elastography) and/or liver biopsy needed to complete diagnosis.</td>
</tr>
<tr>
<td>PCOS and Female Infertility</td>
<td>Physical exam; ROS; menstrual and reproductive history</td>
<td>Hormonal testing (e.g., androgen levels, SHBG, LH/FSH, estradiol), ovulation testing, imaging of ovaries, may be needed to complete diagnosis.</td>
</tr>
<tr>
<td>Male Hypogonadism</td>
<td>Physical exam; ROS</td>
<td>Hormonal testing (total and free testosterone, SHBG, LH/FSH, prolactin) as needed to complete diagnosis.</td>
</tr>
<tr>
<td>Obstructive Sleep Apnea</td>
<td>Physical exam; neck circumference; ROS</td>
<td>Polysomnography needed to complete diagnosis.</td>
</tr>
<tr>
<td>Asthma / Respiratory Disease</td>
<td>Physical exam; ROS</td>
<td>Chest X-ray and spirometry may be needed to complete diagnosis.</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>Physical exam; ROS</td>
<td>Radiographic imaging may be needed to complete diagnosis.</td>
</tr>
<tr>
<td>Urinary Stress Incontinence</td>
<td>Physical exam; ROS</td>
<td>Urine culture, urodynamic testing may be needed to complete diagnosis.</td>
</tr>
<tr>
<td>GERD</td>
<td>Physical exam; ROS</td>
<td>Endoscopy, esophageal motility study may be needed to complete diagnosis.</td>
</tr>
<tr>
<td>Depression, Anxiety, Binge Eating Disorder</td>
<td>History; ROS</td>
<td>Screening/diagnostic evaluation or questionnaires based on criteria in Diagnostic and Statistical Manual of Mental Disorders; referral to clinical psychologist or psychiatrist.</td>
</tr>
<tr>
<td>Stigmatization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td>Physical exam; ROS</td>
<td>Functional testing may be helpful.</td>
</tr>
</tbody>
</table>

### Additional Evaluation Relevant to the Differential Diagnosis of Obesity

| Interpretation of BMI                      | Physical exam to ensure that BMI value is indicative of excess adiposity | Assess muscularity, edema, volume status, pregnancy, third space fluid accumulation, sarcopenia, large tumors, lipodystrophy, etc. Bioelectric impedance, air/water displacement plethysmography, or dual-energy absorptiometry scan may be considered. |
| Obesity Secondary to Hormonal Disorder     | Physical exam; ROS | TSH for suspected hypothyroidism; salivary/serum/urine cortisol for hypercortisolism if clinical findings or symptoms present. |
| Iatrogenic Obesity (e.g., secondary to medications) | Review current medications and medication history | Withdraw offending medication and/or substitute with weight-neutral alternative. Follow-up assessment may be needed to complete diagnosis. |
| Genetic Syndrome                           | Physical exam; ROS; family history | If clinical findings are suggestive, genetic testing of patient and perhaps family members may be needed to complete diagnosis. |

**Abbreviations:** A1C = glycated hemoglobin; BMI = body mass index; FSH = follicle-stimulating hormone; GERD = gastroesophageal reflux disease; HDL-c = high-density lipoprotein cholesterol; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; LFTs = liver function tests; LDL-c = low-density lipoprotein cholesterol; LH = luteinizing hormone; MRI = magnetic resonance imaging; NAFLD = non-alcoholic fatty liver disease; NASH = non-alcoholic steatohepatitis; OGTT = oral glucose tolerance test; PCOS = polycystic ovarian syndrome; ROS = review of symptoms; SHBG = sex hormone-binding globulin; TSH = thyroid-stimulating hormone.
## LIFESTYLE THERAPY

Evidence-based lifestyle therapy for treatment of obesity should include three components

<table>
<thead>
<tr>
<th>MEAL PLAN</th>
<th>PHYSICAL ACTIVITY</th>
<th>BEHAVIOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reduced-calorie healthy meal plan</td>
<td>• Voluntary aerobic physical activity progressing to &gt;150 minutes/week performed on 3–5 separate days per week</td>
<td>An interventional package that includes any number of the following:</td>
</tr>
<tr>
<td>• ~500–750 kcal daily deficit</td>
<td>• Resistance exercise: single-set repetitions involving major muscle groups, 2–3 times per week</td>
<td>• Self-monitoring (food intake, exercise, weight)</td>
</tr>
<tr>
<td>• Individualize based on personal and cultural preferences</td>
<td>• Reduce sedentary behavior</td>
<td>• Goal setting</td>
</tr>
<tr>
<td>• Meal plans can include: Mediterranean, DASH, low-carb, low-fat, volumetric, high protein, vegetarian</td>
<td>• Individualize program based on preferences and take into account physical limitations</td>
<td>• Education (face-to-face meetings, group sessions, remote technologies)</td>
</tr>
<tr>
<td>• Meal replacements</td>
<td>Team member or expertise: exercise trainer, physical activity coach, physical/occupational therapist</td>
<td>• Problem-solving strategies</td>
</tr>
<tr>
<td>• Very low-calorie diet is an option for selected patients and requires medical supervision</td>
<td></td>
<td>• Stimulus control</td>
</tr>
<tr>
<td>Team member or expertise: dietitian, health educator</td>
<td></td>
<td>• Behavioral contracting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Stress reduction</td>
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<tr>
<td></td>
<td></td>
<td>• Psychologic evaluation, counseling, and treatment when needed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Cognitive restructuring</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Motivational interviewing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Mobilization of social support structures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Team member or expertise: health educator, behaviorist, clinical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>psychologist, psychiatrist</td>
</tr>
</tbody>
</table>

## WHEN TO INITIATE WEIGHT-LOSS MEDICATIONS IN PATIENTS WITH OVERWEIGHT/OBESITY

### INITIATE LIFESTYLE THERAPY

<table>
<thead>
<tr>
<th>No Complications.</th>
<th>Mild to Moderate Complications.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with overweight or obesity who have no clinically significant weight-related complications (secondary prevention)</td>
<td>Patient with mild to moderate weight-related complications when lifestyle therapy is anticipated to achieve sufficient weight loss to ameliorate the complication (tertiary prevention)</td>
</tr>
<tr>
<td>Note: weight-loss medications may also be indicated based on clinical judgment</td>
<td>Note: weight-loss medications may also be indicated based on clinical judgment</td>
</tr>
</tbody>
</table>

### INITIATE WEIGHT LOSS MEDICATION AS AN ADJUNCT TO LIFESTYLE THERAPY

<table>
<thead>
<tr>
<th>Failure to lose weight.</th>
<th>Weight Regain on Lifestyle Therapy</th>
<th>Presence of Weight-Related Complications.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add medication for patients who have progressive weight gain or who have not achieved clinical improvement in weight-related complications on lifestyle therapy alone.</td>
<td>Add medication for patients with overweight (BMI 25 to 29.9 kg/m²) or obesity who are experiencing weight regain following initial success on lifestyle therapy alone.</td>
<td>Initiate medication concurrent with lifestyle therapy for patients with overweight (BMI to 29.9 kg/m²) or obesity who have weight-related complications, particularly if severe, in order to achieve sufficient weight loss to ameliorate the complication (tertiary prevention).</td>
</tr>
</tbody>
</table>
# TREATMENT GOALS BASED ON DIAGNOSIS IN THE MEDICAL MANAGEMENT OF PATIENTS WITH OBESITY

<table>
<thead>
<tr>
<th>DIAGNOSIS</th>
<th>TREATMENT GOALS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anthropometric Component</strong></td>
<td><strong>Clinical Component</strong></td>
</tr>
<tr>
<td>Primordial Prevention BMI ≤25 (≤23 in certain ethnicities)</td>
<td>Obesogenic environment</td>
</tr>
<tr>
<td>Primary Prevention BMI ≤25 (≤23 in certain ethnicities)</td>
<td>High-risk individuals or subgroups based on individual or cultural behaviors, ethnicity, family history, biomarkers, or genetics</td>
</tr>
<tr>
<td><strong>SECONDARY PREVENTION</strong></td>
<td></td>
</tr>
<tr>
<td>Overweight BMI 25–29.9 (BMI 23–24.9 in certain ethnicities)</td>
<td>No clinically significant or detectable weight-related complications</td>
</tr>
<tr>
<td>Obesity BMI ≥30 (≥25 in certain ethnicities)</td>
<td>No clinically significant or detectable weight-related complications</td>
</tr>
<tr>
<td><strong>TERTIARY PREVENTION</strong></td>
<td></td>
</tr>
<tr>
<td>Overweight or Obesity BMI ≥25 (≥23 in certain ethnicities)</td>
<td>Metabolic syndrome 10%</td>
</tr>
<tr>
<td></td>
<td>Prediabetes 10%</td>
</tr>
<tr>
<td></td>
<td>T2DM 5-15% or more</td>
</tr>
<tr>
<td></td>
<td>Dyslipidemia 5-15% or more</td>
</tr>
<tr>
<td></td>
<td>Hypertension 5-15% or more</td>
</tr>
<tr>
<td></td>
<td>Nonalcoholic fatty liver disease Steatosis 5% or more</td>
</tr>
<tr>
<td></td>
<td>Steatohepatitis 10-40%</td>
</tr>
<tr>
<td></td>
<td>Polycystic ovary syndrome 5-15% or more</td>
</tr>
<tr>
<td></td>
<td>Female infertility 10% or more</td>
</tr>
<tr>
<td></td>
<td>Male hypogonadism 5-10% or more</td>
</tr>
<tr>
<td></td>
<td>Obstructive sleep apnea 7-11% or more</td>
</tr>
<tr>
<td></td>
<td>Asthma/reactive airway disease 7-8% or more</td>
</tr>
<tr>
<td></td>
<td>Osteoarthritis ≥10%</td>
</tr>
<tr>
<td></td>
<td>Urinary stress incontinence 5-10% or more</td>
</tr>
<tr>
<td></td>
<td>Gastroesophageal reflux disease 10% or more</td>
</tr>
<tr>
<td></td>
<td>Depression Uncertain</td>
</tr>
</tbody>
</table>

**Abbreviations:** A1C = hemoglobin A1C; BMI = body mass index; BP = blood pressure; HDL-c = high-density lipoprotein cholesterol; T2DM = type 2 diabetes mellitus.
# Preferred Weight-Loss Medications: Individualization of Therapy

## Key
- **Preferred Drug**
- **Use With Caution**
- **Avoid**

## Clinical Characteristics or Co-Existing Diseases

## Medications for Chronic Weight Management

### Diabetes Prevention (metabolic syndrome, prediabetes)
- **Orlistat**: Insufficient data for T2DM prevention
- **Lorcaserin**: Insufficient data for T2DM prevention

### Type 2 Diabetes Mellitus
- **Phentermine/topiramate ER**: Monitor heart rate, rhythm, BP
- **Naltrexone ER/bupropion ER**: Monitor heart rate, BP
- **Liraglutide 3 mg**: Monitor heart rate

### Hypertension
- **Orlistat**: Monitor heart rate
- **Lorcaserin**: Monitor heart rate
- **Phentermine/topiramate ER**: Monitor heart rate, BP
- **Naltrexone ER/bupropion ER**: Monitor heart rate, BP
- **Liraglutide 3 mg**: Monitor heart rate

### Cardiovascular Disease
- **CAD**: Monitor heart rate
- **Arrhythmia**: Monitor heart rate, BP
- **CHF**: Insufficient data

### Chronic Kidney Disease
- **Mild (50–79 mL/min)**: Do not exceed 7.5 mg/46 mg per day
- **Moderate (30–49 mL/min)**: Do not exceed 8 mg/90 mg bid
- **Severe (<30 mL/min)**: Avoid vomiting and volume depletion

### Nephrolithiasis
- **Calcium oxalate stones**: Calcium phosphate stones

### Hepatic Impairment
- **Mild-Moderate (Child-Pugh 5–9)**: Do not exceed 8 mg/90 mg in AM
- **Severe (Child-Pugh >9)**: Not recommended

### Depression
- **Insufficient safety data**: Avoid maximum dose: 15 mg/92 mg per day

### Anxiety
- **Avoid max dose**: 15 mg/92 mg per day

### Psychoses
- **Insufficient data**: Insufficient data

### Binge Eating Disorder
- **Insufficient data; however, possible benefit based on reduction in food cravings**: Insufficient data, though possible benefit based on studies with bupropion

### Glaucoma
- **Contraindicated, may trigger angle closure**: May trigger angle closure

### Seizure Disorder
- **If discontinuing from max dose, taper slowly**: Bupropion lowers seizure threshold

### Pancreatitis
- **Monitor for symptoms**: Monitor for symptoms

### Opioid Use
- **Will antagonize opioids and opiates**: Avoid if prior or current disease

### Women of Reproductive Potential
- **Pregnancy**: Use contraception and discontinue orlistat should pregnancy occur
- **Breast-feeding**: Not recommended
- **Age ≥65 years**: Limited data available
- **Alcoholism/Addiction**: Might have abuse potential due to euphoria at high doses

### Post-Bariatric Surgery
- **Insufficient data**: Data available at 1.8 – 3.0 mg/day

*Use medications only with clear health-related goals in mind; assess patient for osteoporosis and sarcopenia.*

**Abbreviations:** BP = blood pressure; CAD = coronary artery disease; CHF = congestive heart failure; HTN = hypertension; T2DM = Type 2 Diabetes Mellitus.
## Diagnosis and Medical Management of Obesity

<table>
<thead>
<tr>
<th>Anthropometric Component (BMI kg/m²)</th>
<th>Clinical Component</th>
<th>Disease Stage</th>
<th>Chronic Disease Phase of Prevention</th>
<th>Suggested Therapy (based on clinical judgment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25</td>
<td>Normal weight</td>
<td>Primary</td>
<td>• Healthy lifestyle: healthy meal plan/physical activity</td>
<td></td>
</tr>
<tr>
<td>&lt;23 in certain ethnicities waist circumference below regional/ethnic cutoffs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25–29.9</td>
<td>Overweight stage 0</td>
<td>Secondary</td>
<td>• Lifestyle therapy: Reduced-calorie healthy meal plan/physical activity/behavioral interventions</td>
<td></td>
</tr>
<tr>
<td>23–24.9 in certain ethnicities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥30</td>
<td>Obesity stage 0</td>
<td>Secondary</td>
<td>• Lifestyle therapy: Reduced-calorie healthy meal plan/physical activity/behavioral interventions</td>
<td></td>
</tr>
<tr>
<td>≥25 in certain ethnicities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥25</td>
<td>Obesity stage 1</td>
<td>Tertiary</td>
<td>• Lifestyle therapy: Reduced-calorie healthy meal plan/physical activity/behavioral interventions</td>
<td></td>
</tr>
<tr>
<td>≥23 in certain ethnicities</td>
<td>(1 or more mild to moderate complications)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥25</td>
<td>Obesity stage 2</td>
<td>Tertiary</td>
<td>• Lifestyle therapy: Reduced-calorie healthy meal plan/physical activity/behavioral interventions</td>
<td></td>
</tr>
<tr>
<td>≥23 in certain ethnicities</td>
<td>(at least 1 severe complication)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

### Notes:

- **a.** All patients with BMI ≥25 have either overweight or obesity stage 0 or higher, depending on the initial clinical evaluation for presence and severity of complications. These patients should be followed over time and evaluated for changes in both anthropometric and clinical diagnostic components. The diagnoses of overweight/obesity stage 0, obesity stage 1, and obesity stage 2 are not static, and disease progression may warrant more aggressive weight-loss therapy in the future. BMI values ≥25 have been clinically confirmed to represent excess adiposity after evaluation for muscularity, edema, sarcopenia, etc.
- **b.** Stages are determined using criteria specific to each obesity-related complication; stage 0 = no complication; stage 1 = mild to moderate; stage 2 = severe.
- **c.** Treatment plans should be individualized; suggested interventions are appropriate for obtaining the sufficient degree of weight loss generally required to treat the obesity-related complication(s) at the specified stage of severity.
- **d.** BMI ≥27 is consistent with the recommendations established by the US Food and Drug Administration for weight-loss medications.

**Abbreviation:** BMI = body mass index.
AACE OBESITY CARE MODEL

HEALTHY BUILT ENVIRONMENT
- Obesity care legislation
- Public health policy
- Health messaging
- Promotes healthy lifestyle

REFORMED HEALTH CARE SYSTEM
- Payment reform
- Preventive care paradigm
- Optimize drug pipeline
- Education/research
- Patient access to therapy

ACTIVATED PATIENT
- Decision support
- Delivery system design
- Informatics/registries
- Leadership/behaviors
- Continuity of care
- Enhanced access to care
- Coordinated care

PREPARED OBESITY PRACTICE
- Clinical research design
- Relevant metrics
- Improved overall health
- Economic outcomes
- Feedback to revise
- Clinical Care Model

IMPROVED POPULATION-BASED OUTCOMES
- Technology-driven
- Outcome-driven

FUTURE INNOVATIONS
- Self-management
- Empanelment
- Patient-team partner
- Activated community
- Access to information
<table>
<thead>
<tr>
<th>Anti-obesity Medication (Trade Name)</th>
<th>Mechanism of Action, Study Name, Study Duration: % TBWL Greater Than Placebo</th>
<th>Dose</th>
<th>Common Side Effects</th>
<th>Contraindications, Cautions, and Safety Concerns</th>
<th>Monitoring and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orlistat</strong> (Xenical™) (Alli™) - OTC</td>
<td>Lipase inhibitor XENDOS 1 yr: 4.0% 4 yr: 2.6%</td>
<td>120 mg PO TID (before meals) OTC: 60 mg PO TID (before meals)</td>
<td>• Steatorrhea • Fecal urgency • Incontinence • Flatulence • Oily spotting • Frequent bowel movements • Abdominal pain • Headache</td>
<td>✓ Pregnancy and breastfeeding ✓ Chronic malabsorption syndrome ✓ Cholestasis ✓ Oxalate nephrolithiasis ✓ Rare severe liver injury ✓ Cholelithiasis ✓ Malabsorption of fat-soluble vitamins ✓ Effects on other medications: • Warfarin (enhance) • Anti-epileptics (decrease) • Levothyroxine (decrease) • Cyclopenthiazide (decrease)</td>
<td>Monitor for: • Cholelithiasis • Nephrolithiasis - Recommend standard multivitamin (to include vitamins A, D, E, and K) at bedtime or 2 hours after orlistat dose - Eating &gt;30% kcal from fat results in greater GI side effects - FDA-approved for children ≥12 years old - Administer levothyroxine and orlistat 4 hours apart</td>
</tr>
<tr>
<td><strong>Lorcaserin</strong> (Belviq®)</td>
<td>Serotonin (5HT2c) receptor agonist BLOSSOM BLOOM 1 yr: 3.0%-3.6% 2 yr: 3.1%</td>
<td>10 mg PO BID</td>
<td>• Headache • Nausea • Dizziness • Fatigue • Xerostomia • Dry eye • Constipation • Diarrhea • Back pain • Nasopharyngitis • Hyperprolactinemia</td>
<td>✓ Pregnancy and breastfeeding ✓ Serotonin syndrome or neuroleptic malignant syndrome ✓ Safety data lacking in patients who have depression • Concomitant use of SSRI, SNRI, MAOI, bupropion, St. John’s wort as may increase risk of developing serotonin syndrome • Uncontrolled mood disorder • Cognitive impairment • Avoid in patients with severe liver injury or renal insufficiency • Caution for patients with bradycardia, heart block, or heart failure • Unproven concern for potential cardiac valvulopathy • Leukopenia</td>
<td>Monitor for: • Symptoms of cardiac valve disease • Bradycardia • Serotonin syndrome • Neuroleptic malignant syndrome • Depression • Severe mood alteration, euphoria, dissociative state • Confusion/somnolence • Priapism • Leukopenia • Euphoria at high doses could predispose to abuse • Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas</td>
</tr>
<tr>
<td><strong>Phentermine/Topiramate ER</strong> (Qsymia®)</td>
<td>NE-releasing agent (phentermine) GABA receptor modulation (topiramate) EQUIP CONQUER SEQUEL 1 yr: 8.6%-9.3% on high dose; 6.6% on treatment dose 2 yr: 8.7% on high dose; 7.5% on treatment dose</td>
<td>Starting dose: 3.75/23 mg PO QD for 2 weeks Recommended dose: 7.5/46 mg PO QD Escalation dose: 11.25/69 mg PO QD Maximum dose: 15/92 mg PO QD</td>
<td>• Headache • Paresthesia • Insomnia • Decreased bicarbonate • Xerostomia • Constipation • Nasopharyngitis • Anxiety • Depression • Cognitive impairment (concentration and memory) • Dizziness • Nausea • Dysgeusia</td>
<td>✓ Pregnancy and breastfeeding (topiramate teratogenicity) ✓ Hyperthyroidism ✓ Acute angle-closure glaucoma ✓ Concomitant MAOI use (within 14 days) ✓ Bradycardia • Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas • Acute kidney stone formation • Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas • Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas • Acute kidney stone formation • Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas • Acute kidney stone formation • Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas</td>
<td>Monitor for: • Increased heart rate • Depressive symptomatology or worsening depression especially on maximum dose • Hypokalemia (especially with HCTZ or furosemide) • Acute myopia and/or ocular pain • Acute kidney stone formation • Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas • Combined use with alcohol or other substances that may increase heart rate or risk of hypoglycemia • Increased risk of seizure; taper over at least 1 week - Health care professional should check ßHCG before initiating, followed by monthly self-testing at home - Monitor electrolytes and creatinine before and during treatment - Can cause menstrual spotting in women taking birth control pills due to altered metabolism of estrogen and progesterin</td>
</tr>
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### Monitoring and Comments

- **Orlistat**
  - Can cause menstrual spotting in women taking birth control pills due to altered metabolism of estrogen and progesterin.
- **Lorcaserin**
  - Monitor for: Symptoms of cardiac valve disease, Bradycardia, Serotonin syndrome, Neuroleptic malignant syndrome, Depression, Severe mood alteration, euphoria, dissociative state, Confusion/somnolence, Priapism, Leukopenia, Euphoria at high doses could predispose to abuse, Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas.
- **Phentermine/Topiramate ER**
  - Monitor for: Increased heart rate, Depressive symptomatology or worsening depression especially on maximum dose, Hypokalemia (especially with HCTZ or furosemide), Acute myopia and/or ocular pain, Acute kidney stone formation, Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas, Combined use with alcohol or other substances that may increase heart rate or risk of hypoglycemia, Increased risk of seizure; taper over at least 1 week.
  - Health care professional should check ßHCG before initiating, followed by monthly self-testing at home.
  - Monitor electrolytes and creatinine before and during treatment.
  - Can cause menstrual spotting in women taking birth control pills due to altered metabolism of estrogen and progesterin.
<table>
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<th>Anti-obesity Medication (Trade Name)</th>
<th>Year of FDA Approval</th>
<th>Mechanism of Action, Study Name, Study Duration</th>
<th>Dose</th>
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| **Naltrexone ER/Bupropion ER** *(Contrave®)* | 2014 | Opiate antagonist (naltrexone) | *Titrate dose:*  
- Week 1: 1 tab (8/90 mg) PO QAM  
- Week 2: 1 tab (8/90 mg) PO BID  
- Week 3: 2 tabs (total 16/180 mg) PO QAM and 1 tab (8/90 mg) PO QHS  
- Week 4: 2 tabs (total 16/180 mg) PO QHS | • Nausea  
• Headache  
• Insomnia  
• Vomiting  
• Constipation  
• Diarrhea  
• Dizziness  
• Anxiety  
• Xerostomia | ✓ Pregnancy and breastfeeding  
✓ Uncontrolled hypertension  
✓ Seizure disorder  
✓ Anorexia nervosa  
✓ Bulimia nervosa  
✓ Severe depression  
✓ Drug or alcohol withdrawal  
✓ Concomitant MAOI (within 14 days)  
✓ Chronic opioid use  
✓ Cardiac arrhythmia  
✓ Dose adjustment for liver or kidney impairment  
✓ Narrow-angle glaucoma  
✓ Uncontrolled migraine disorder  
✓ Generalized anxiety disorder  
✓ Bipolar disorder  
✓ Safety data lacking in patients who have depression  
✓ Seizures (bupropion lowers seizure threshold) | Monitor for:  
- Increased heart rate and blood pressure  
- Worsening depression or suicidal ideation  
- Worsening of migraines  
- Liver injury (naltrexone)  
- Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas  
- Seizures (bupropion lowers seizure threshold)  
- MAOI (allow ≥14 days between discontinuation)  
- Dose adjustment for patients with renal and hepatic impairment  
- Avoid taking medication with a high-fat meal  
- Can cause false positive urine test for amphetamine  
- Bupropion inhibits CYP2D6 |

**Liraglutide 3 mg** *(Saxenda®)*  
2014 | GLP-1 analog  
SCALE Obesity & Prediabetes  
1 yr: 5.6% | *Titrate dose weekly by 0.6 mg as tolerated by patient (side effects):*  
- 0.6 mg SC QD  
- 1.2 mg SC QD  
- 1.8 mg SC QD  
- 2.4 mg SC QD  
- 3.0 mg SC QD | • Nausea  
• Vomiting  
• Diarrhea  
• Constipation  
• Headache  
• Dyspepsia  
• Increased heart rate | ✓ Pregnancy and breastfeeding  
✓ Uncontrolled thyroid cancer or MEN2  
✓ Pancreatitis  
✓ Acute gallbladder disease  
✓ Gastroparesis  
✓ Severe renal impairment can result from vomiting and dehydration  
✓ Use caution in patients with history of pancreatitis  
✓ Use caution in patients with cholelithiasis  
✓ Suicidal ideation and behavior  
✓ Injection site reactions | Monitor for:  
- Pancreatitis  
- Cholelithiasis and cholecystitis  
- Hypoglycemia in patients having T2DM treated with insulin and/or sulfonylureas  
- Increased heart rate  
- Dehydration from nausea/vomiting  
- Injection site reactions  
- Titrate dose based on tolerability (nausea and Gl side effects) |

**Abbreviations:** BID = twice daily; CYP2D6 = cytochrome P450 2D6; DA = dopamine; FDA = US Food and Drug Administration; GI = gastrointestinal; GLP-1 = glucagon-like peptide 1; HCTZ = hydrochlorothiazide; MAOI = monoamine oxidase inhibitor; MEN2 = multiple endocrine neoplasia type 2; NE = norepinephrine; OTC = over-the-counter medication; % TBWL = percent total body weight loss from baseline over that observed in the placebo group; PO = oral; QAM = every morning; QD = daily; QHS = every bedtime; SC = subcutaneous; SNRI = serotonin-norepinephrine reuptake inhibitor; SSRI = selective serotonin reuptake inhibitor; TID = 3 times a day; T2DM = type 2 diabetes mellitus.  

**FDA indication for all medications:** BMI ≥30 kg/m² or BMI ≥27 kg/m² with significant comorbidity.  

**After 3 to 4 months of treatment with anti-obesity medication:**  
- For naltrexone ER/bupropion ER and lorcaserin:  
  If the patient has not lost at least 5% of their baseline body weight at 12 weeks on the maintenance dose, the medication should be discontinued.  
- For phentermine/topiramate ER:  
  Continue medication if the patient has lost >5% body weight after 12 weeks on recommended dose (7.5 mg/42 mg); if the patient has not lost at least 3% of body weight after being on the recommended dose for 12 weeks then the medication should be discontinued, or the patient can be transitioned to maximum dose (15 mg/92 mg); if patient has not lost at least 5% after 12 additional weeks on the maximum dose, the medication should be discontinued.  
- For liraglutide 3 mg:  
  If the patient has not lost at least 4% of body weight 16 weeks after initiation, the medication should be discontinued.  

**References:**  