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# **Tools for Successful Weight Management in Primary Care**

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This is to acknowledge that Christy Turer has disclosed that she does not have any financial interests or other relationships with commercial concerns related directly or indirectly to this program. Dr. Turer will be discussing off-label uses of medication (for example, metformin, GLP-1-receptor agonists, topiramate, and zonisamide) in her presentation.

## **Biographical Information**

Christy Boling Turer received her medical degree from Johns Hopkins, and completed a combined Internal Medicine/Pediatrics residency, Fellowship in Health Services Research in Primary Care, and Masters in Clinical Research at Duke University. She joined the UTSW faculty in 2010. Her research focuses on primary-care weight management, and currently is supported by a five-year career-development award through the National Heart, Lung, and Blood Institute to examine pediatrician clinical practices and communication strategies associated with weight-status improvement among overweight children. Dr. Turer is the 2013-14 Chair of the Obesity Society's Clinical Management of Obesity Section, and a member (2014-2018) of the Food and Drug Administration's Endocrinologic and Metabolic Drugs Advisory Committee. Her passion for her work comes from a strong family history of obesity/metabolic disease, an amazing husband (Aslan Turer), and parenting two extraordinary children, Sebastian (3 years old—vegetable hater) and Edison (1 year old—gourmand).

## **Purpose and Overview**

The purpose of this presentation is to provide clinicians with the latest information regarding addressing weight management in primary care, including effective communication methods, guideline-based weight-management interventions, safety and efficacy of weight-loss medications and surgery, and reimbursement provisions in the Affordable Care Act (ACA).

## **Objectives**

Upon completion of this Grand Rounds presentation, participants will be able to:

1. Incorporate effective communication with patients regarding weight and weight loss
2. Select appropriate weight-management therapies based on evidence-based criteria and guidelines
3. Articulate the safety, efficacy, and adverse effects of weight-loss medications and bariatric surgery
4. Describe the ACA's weight-management provisions

## **Introduction**

Overweight, including obesity, is one of the most pervasive and costly public-health problems. Two in three adults are overweight, including one in three who is obese.<sup>1</sup>

Physicians now care for patients with many weight-related problems that could be improved by a modicum of weight loss: a 5-10% weight reduction can improve quality of life, reduce pain, and improve cardiovascular disease risk factors such as blood pressure, cholesterol, and blood sugar.<sup>2</sup> Dietary changes, even without weight loss, can prevent progression from prediabetes to diabetes<sup>2</sup>; and normalizing glucose regulation reduces cardiovascular risk.<sup>3</sup> A less-known complication that improves with weight loss is kidney disease. Being overweight or obese at the age of 17 is associated with an eight-fold increased risk of developing end-stage renal disease (ESRD) in a time span of only 20-30 years.<sup>4</sup> The risk is independent of diabetes and hypertension. Causes include focal segmental glomerulosclerosis and obesity-related glomerulopathy, both of which improve with weight loss. Thus, the benefits of weight loss underscore the critical importance of addressing weight management.

For effective primary-care weight management, physicians need helpful tools and adequate reimbursement. Evidence-based weight-management tools, published by the Obesity Society (TOS), American Academy of Clinical Endocrinologists (AACE), and American Heart Association (AHA) include communication, behavioral modification, weight-loss medications, and surgery.<sup>5-8</sup>

Reimbursement for weight management is a provision of the ACA.<sup>9</sup> Thus, primary care visits can be used to convey important information regarding risks of weight gain, benefits of weight loss, weight-management options, plus, need for frequent, long-term follow-up.

## Effective Ways to Communicate with Patients about Weight

*“People will forget what you said, people will forget what you did, but people will never forget how you made them feel.” –Maya Angelou*

To support weight management long-term, physicians may be maximally effective if they can activate patients’ own intrinsic motivations, such as for health and personal growth, and share decision-making regarding utility of available weight-management options.<sup>10</sup> Advice regarding lifestyle behaviors may not be effective unless patients choose the behaviors, goals, and treatments that they consider important. Supporting patient autonomy and activating patients’ intrinsic motivations has been shown to promote adherence, and could stimulate self-sustained successful weight management.<sup>10-11</sup>

It is important to use patient-centered terms to describe excess weight so that patients do not feel judged.<sup>12</sup> For example, instead of using the terms “fat,” “heavy,” or “obese,” one could say: “I noted that your weight has been going up, and I’m concerned about the impact of this on your health.” Frame conversations about weight around health, not size.

Beyond terminology, supporting patients in choosing and sustaining lifestyle changes is made easier by communication methods that facilitate conversations about change, including patient-centered communication. Fundamental to patient-centered communication is spending time relationship-building (for example, using 20% of an office visit to “catch up”), and there is evidence for its efficacy in weight management.<sup>10</sup> Implicit in catching up is not offering advice and resisting the tendency to identify “the problem” and solve it for the patient. In this style of communication, physicians elicit patients’ health needs, beliefs, and expectations, and engage patients in making decisions about their care.<sup>10</sup> Differences between patient-centered and doctor-centered communication include:

### Patient-Centered Communication

Physician:

- Elicits patient’s questions and answers them: *“What questions do you have before we begin?”*
- Asks open-ended questions: *“How do you feel about your weight?”*
- Asks patient’s opinion: *“We’ve discussed some options to manage your weight, what seems doable to you?”*
- Checks patient’s understanding: *“What do you feel are the most important things we’ve talked about today?”*
- Gives statements of empathy and legitimization: *“You struggle to lose weight, but you keep trying because it’s important for you to stay healthy.”*
- Gives patient time to respond

### Doctor-Centered Communication

Physician:

- Asks medical questions before eliciting patient’s questions
- Asks yes/no (closed) questions
- Gives unsolicited biomedical and behavioral advice
- Assumes head nodding indicates understanding
- Gives directive statements (you should...)
- Gives instruction with immediacy, not patience

Motivational interviewing (MI) is one type of patient-centered communication that is used to address behavior change with an ambivalent patient.<sup>10</sup> In this consultation method, one uses a style that guides patients, more than directs or passively listens, to evoke how behavioral changes might be compatible with their goals. Patients are guided to identify a solution, rather than physicians providing one.

*“After all, when you seek advice from someone, it’s certainly not because you want them to give it. You just want them to be there while you talk to yourself.” –Terry Pratchett, Jingo*

For effective use of MI, four skills are needed.<sup>13</sup> The first skill is engaging the patient in non-medical conversation before eliciting their medical questions. The second is focusing the visit on a specific change. For example, after asking about the patient’s particular questions/concerns, reflect back their concerns, and then ask permission to address an additional concern: *“I hear you’re concerned about knee pain, correct? Let’s talk about that; and, would it be okay to discuss your weight too? I noticed it’s been going up. I’d like to hear your thoughts about why that might be.”* The third skill is evoking from the patient their own good reasons to change. The physician listens for “change talk” as evidence of some intent to change, then responds with reflective-listening statements to evoke further change talk. For example, the “change talk” in the patient statement: *“I keep eating after dinner...I know I shouldn’t, but I eat healthy things, so I’m not concerned right now,”* is, *“I know I shouldn’t.”* Because the goal is to elicit more change talk, a provider might respond with, *“Tell me more about why you feel you shouldn’t.”* The fourth skill is planning change. If the patient is not ready to make changes, then the plan is to follow-up at the next visit. If the patient is ready, one might ask, *“If, as part of our plan to help your knee pain, you decide to work on getting to a healthier weight, what might be a first step?”* If a patient replies that they do not know, one might respond, *“May I offer some advice based on my experience? [if ok...] I’ve come across this situation before and there are some choices or options that you have. You could start tracking your diet and activity, or maybe try a weight-loss diet. If you already have tried these, there are weight-loss medicines or surgery. What makes the most sense to you?”* In other words, give information that could be absorbed as advice, and let the patient choose.

Patient-centered communication, including use of MI, may activate patients by helping them identify their weight status, risk/presence of related disease, and treatments that can promote a healthier future.

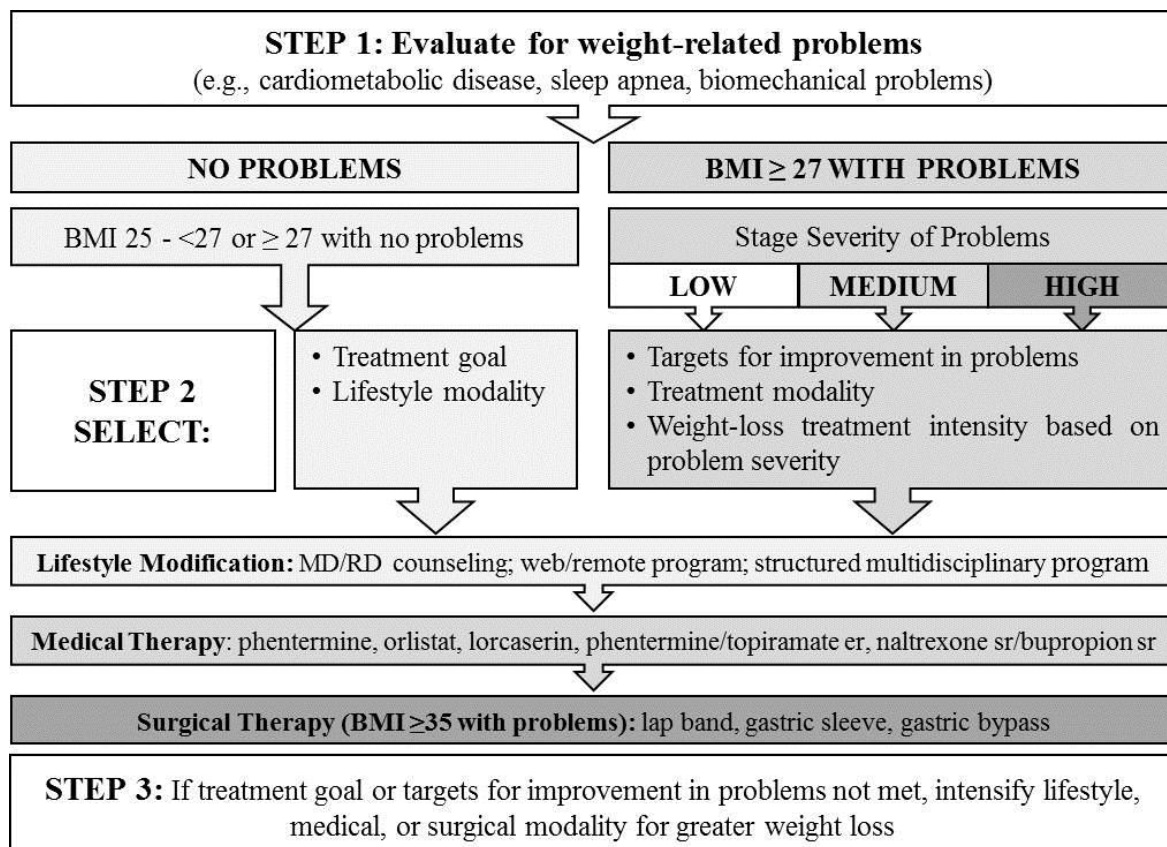
## Selecting Appropriate Weight-Management Plans for Appropriate Patients

A major barrier to weight loss is medications that cause weight gain. To reduce this barrier, consider switching patients to drugs that cause weight loss or are more weight neutral. For example, in patients with diabetes and obesity, instead of insulin, consider a more weight-neutral alternative (See below).

Diabetes Drugs that Cause Weight Gain		More Weight-Neutral Alternatives
<b>Insulin</b>	<ul style="list-style-type: none"> <li>• Insulin (short- more than long-acting)</li> </ul>	<ul style="list-style-type: none"> <li>• Glucophage, Glumetza,...(metformin)</li> <li>• Bydureon, Byetta, Victoza (GLP-1 agonists: exenatide, liraglutide)</li> <li>• Farxiga, Invokana, Jardiance (SGL2 inhibitors cana-, dapa-, and empagliflozin)</li> <li>• Symlin (amylin analogs: pramlintide)</li> <li>• Januvia (DPP4s: sitagliptin)</li> <li>• Glyset, Precose (acarbose, miglitol)</li> </ul>
<b>Meglitinides</b>	<ul style="list-style-type: none"> <li>• Prandin, Starlix (repaglinide, nateglinide)</li> </ul>	
<b>Sulfonylureas</b>	<ul style="list-style-type: none"> <li>• Amaryl, DiaBeta, Glucotrol, Glynase, Micronase (glimepiride, glyburide)</li> </ul>	
<b>Thiazolidinediones</b>	<ul style="list-style-type: none"> <li>• Actos, Avandia (pio- and rosiglitazone)</li> </ul>	

Drug Classes and Drugs that Cause Weight Gain		More Weight-Neutral Alternatives
<b>Anti-depressants</b> <b>Tri-cyclics</b> —expect weight gain of ~4 kg/mo.	<ul style="list-style-type: none"> <li>• Elavil, Endep, Vanatrip (amitriptyline)</li> <li>• Tofranil/Tofranil PM (imipramine)</li> <li>• Adapin, Dilenor, Sinequan (doxepin)</li> <li>• Aventyl, Pamelor (nortriptyline)</li> </ul>	<ul style="list-style-type: none"> <li>• Vivactil (protriptyline)</li> <li>• Wellbutrin/sr/xl, Zyban (bupropion)</li> </ul>
<b>SSRIs</b> —expect loss followed by gain within 6 mo.	<ul style="list-style-type: none"> <li>• Paxil/Paxil CR (paroxetine)</li> <li>• Zoloft (sertraline)</li> <li>• Luvox/Luvox CR (fluvoxamine)</li> </ul>	<ul style="list-style-type: none"> <li>• Lexapro (escitalopram)</li> <li>• Effexor (venlafaxine)</li> <li>• Others with norepi/dopa. component</li> </ul>
<b>Other</b>	<ul style="list-style-type: none"> <li>• Remeron (mirtazapine)</li> </ul>	<ul style="list-style-type: none"> <li>• Serzone (nefazadone)</li> </ul>
<b>Antipsychotics</b> <b>Atypical:</b>	<ul style="list-style-type: none"> <li>• Zyprexa (olanzapine)</li> <li>• Risperdal (risperidone)</li> <li>• Seroquel (quetiapine)</li> </ul>	<ul style="list-style-type: none"> <li>• Geodon (ziprasidone)</li> <li>• Abilify (aripiprazole)—more neutral, but expect gain of 0.5 kg/week</li> </ul>
<b>Conventional:</b>	<ul style="list-style-type: none"> <li>• Mellaril (thioridazine)</li> </ul>	<ul style="list-style-type: none"> <li>• Haldol (haloperidol)</li> </ul>
<b>Lithium</b> —gain ~10 kg:	<ul style="list-style-type: none"> <li>• Eskalith/Eskalith CR, Lithobid</li> </ul>	<ul style="list-style-type: none"> <li>• Lamictal (lamotrigine)</li> </ul>
<b>Anticonvulsants</b> —gain 15-20 kg 1 <sup>st</sup> 3 mo.:	<ul style="list-style-type: none"> <li>• Neurontin, Horizant (gabapentin)</li> <li>• Depakote/Depakote ER (valproate)</li> <li>• Tegretol, Carbatrol (carbamazepine)</li> </ul>	<ul style="list-style-type: none"> <li>• Topamax (topiramate)</li> <li>• Lamictal (lamotrigine)</li> <li>• Zonegran (zonisamide)</li> </ul>
<b>Migraine drugs:</b>	<ul style="list-style-type: none"> <li>• Sanomigran (pizotifen)</li> </ul>	<ul style="list-style-type: none"> <li>• Topamax (topiramate)</li> </ul>
<b>Beta Blockers:</b>	<ul style="list-style-type: none"> <li>• Propranolol, metoprolol, atenolol</li> </ul>	<ul style="list-style-type: none"> <li>• ACE, ARB, Calcium channel blocker</li> </ul>

In addition to tailoring medications that impact weight, tools physicians can use to help patients lose weight include: behavioral modification, weight-loss medications, and surgery. A weight-management algorithm, released by AACE, TOS, and AHA, outlines indications for use of each<sup>5</sup>:



The algorithm consists of three steps:

- Step 1—determine the patient's BMI, presence of any cardiometabolic or biomechanical problems, and their severity. For patients who are overweight—including those with a BMI  $<27 \text{ kg/m}^2$  or BMI  $\geq 27 \text{ kg/m}^2$  without weight-related problems, only lifestyle modification is indicated.
- Step 2—treatment goals, modality, and intensity are selected based on BMI and severity of weight-related problems:
  - (i) For all patients, tailor medications that could be contributing to weight gain (See Drugs causing weight gain above), and address lifestyle modification
  - (ii) For patients with a BMI  $\geq 27 \text{ kg/m}^2$  with weight-related problems, in addition to lifestyle changes, FDA-approved weight-loss medications should be considered, as should surgery, for patients who have a BMI  $\geq 35 \text{ kg/m}^2$  with weight-related problems or  $\geq 40 \text{ kg/m}^2$
  - (iii) Select weight-loss treatment intensity based on the severity of weight-related problems; and
- Step 3—reevaluate whether goals for weight-loss and comorbidity improvement have been met, and intensify lifestyle, medication, or surgical weight-loss treatments as needed.

### **Safety, Efficacy, and Adverse Effects of Weight-Loss Medications and Surgery**

Weight-loss drugs that are FDA-approved include phentermine (multiple trade names), orlistat (Xenical, Alli), lorcaserin (Belviq, APD-356), phentermine/topiramate extended release (Qsymia), and naltrexone/bupropion sustained release (Contrave).<sup>7,14</sup> To be eligible for a weight-loss medication, one must have failed to achieve weight-loss goals by lifestyle alone, have a BMI of  $\geq 30 \text{ kg/m}^2$ , or  $\geq 27 \text{ kg/m}^2$  with at least one weight-related complication, and not be pregnant, seeking pregnancy, or nursing.<sup>5</sup> All drugs are approved for adult patients as adjuncts to a reduced-calorie diet and increased physical activity. Measure success by seeing weight loss of one pound per week or more in the first month, loss of  $>5\%$  body weight by 3-6 months, and improvement in baseline risk factors.

**Phentermine** blunts appetite by eliciting noradrenaline release.<sup>7</sup> Benefits include:

- Equivalent efficacy when dosed daily vs. intermittently, for example, 1-3 months on drug followed by 1-3 months off;
- Significant weight loss: placebo-subtracted weight loss of 7-8 kg, or almost 20 lbs. (total weight loss 12-13 kg, or up to 30 lbs.) at 36 weeks; and
- Low-cost—a typical prescription costs only \$10-20 per month; however, patients will have to pay this out-of-pocket because the drug is not covered by insurance.

Adverse effects of phentermine include:

- Sympathetic side effects, such as increased heart rate, blood pressure, insomnia, dry mouth, constipation, and nervousness, which can be mitigated by starting the drug at a low dose, 7.5-15 mg, and increasing to 37.5 mg after 3-7 days on each dosage increase;
- Potential for addiction (Schedule IV drug), and should not be used in patients with a history of drug abuse; and
- Possible worsening of hypertension and hypoglycemia in patients with insulin-requiring diabetes.

Phentermine is contraindicated in patients with renal insufficiency, valvular heart disease, coronary artery disease, hyperthyroidism, or taking MAOIs or stimulants.

**Orlistat** causes fecal-fat excretion and malabsorption of 25-30% of calories from fat by inhibiting lipase.<sup>7</sup> Benefits include:

- FDA-approved as safe for long-term use;
- Placebo-adjusted weight loss of 3% of body weight (7-8% total) after up to four years of use; and
- Risk-factor improvement—up to a 40% reduction in conversion from impaired-glucose tolerance to diabetes, 5-10% reduction in LDL cholesterol, and improvements in blood pressure and hemoglobin A1C.

Despite its efficacy and safety, however, orlistat is not extensively used, possibly because of:

- Gastrointestinal side effects—up to a third of people report borborygmi, cramps, flatus, or anal discharge/incontinence;
- Modest weight loss occurs over an extended period of time—patients want rapid results;
- Malabsorption of some drugs and fat-soluble vitamins—patients taking orlistat should be advised to take a multivitamin, and patients on warfarin need closer INR monitoring; and
- Expense: at \$45-75 per month, the drug is expensive and not covered by most insurers.

Orlistat should not be used in patients with a history of malabsorption, cholecystectomy, or who are taking cyclosporine or amiodarone (due to impaired drug absorption).

**Lorcaserin** increases satiety through selective serotonin 2C-receptor agonism.<sup>15</sup> Benefits include:

- Placebo-adjusted weight loss of 3-4 kg at 1 year, those on drug (vs. placebo) are twice as likely to lose 5-10% of their body weight (25% lose  $\geq 10\%$  and 50% lose  $\geq 5\%$ ); and
- Depression and risk-factor improvement (in blood pressure, heart rate, total and LDL cholesterol, C-reactive protein, fasting blood glucose, and insulin).

Disadvantages of lorcaserin include:

- Side effects, though typically mild, are headache (18% drug vs. 11% placebo) and nausea; and
- Expense—a usual dose, 10 mg twice daily, costs \$200 per month or a \$50-60 co-pay—however, colleagues in Texas have reported that some patients have only a \$10 co-pay.

Contraindications include use of drugs that alter serotonin or dopamine metabolism (SSRIs, bupropion, lithium, antipsychotics, tricyclic antidepressants, MAOIs, tramadol, triptans) or CYP 2D6-substrate drugs, valvular heart disease, and a glomerular filtration rate (GFR)  $<30$ .

**Phentermine/topiramate extended release (ER)**, trade name Qsymia, is a combination of the anorectic agent phentermine and the seizure medication topiramate in an extended-release formulation—separately, neither drug has an extended-release form, and must be taken at a considerably higher dose to be effective for weight loss (typical weight-loss dosing for phentermine is 37.5 mg, and for topiramate, 50-100 mg twice a day).<sup>16</sup> Available dosage combinations of phentermine and topiramate are 7.5/26 mg and 15/92 mg, respectively. Benefits include:

- Placebo-adjusted weight loss of up to 10% of body weight and 8-9 kg or 20 lb. at one year; and
- Risk-factor improvement, including an almost 80% reduction in conversion from impaired glucose tolerance to diabetes, increased HDL, and reductions in hemoglobin A1C, triglycerides, LDL-cholesterol, and blood pressure (however, it can lead to an increase in heart rate of about one beat per minute).

Disadvantages of phentermine/topiramate extended release include:

- Side effects, although less than for either drug alone (because of lower doses and extended-release formulation), include both those related to the sympathomimetic phentermine and topiramate's dose-related impact on cognition (e.g., word-finding problems, mental dulling) and depression; and

- Expense—a prescription costs \$160 per month or \$50-60 co-pay, though some patients may have co-pays as low as \$10, depending on their insurance provider.

Caution is recommended if a patient has insulin-requiring diabetes or hypertension (the phentermine component may worsen hypertension or cause hypoglycemia). Contraindications include pregnancy—**topiramate is teratogenic**—glaucoma, hyperthyroidism, cardiovascular disease, uncontrolled hypertension, and use of MAOIs or stimulants.

**Naltrexone/bupropion sustained release (SR)**, trade name Contrave, is a combination of the opioid antagonist naltrexone and the dopamine-reuptake inhibitor bupropion in a sustained-release 8 mg/90 mg pill.<sup>14</sup> Benefits of a 32 mg/360 mg dose combination include:

- Placebo-adjusted weight loss of up to 6% of body weight and 6 kg or 13 lb. at one year, >60% on drug lose  $\geq 5\%$ , and more than one-third lose  $\geq 10\%$ ; and
- Improved ability to control eating behavior and response to food cravings.

Disadvantages of naltrexone/bupropion SR include:

- Side effects, such as nausea, headache, dizziness, constipation, and dry mouth;
- Possible elevation in blood pressure or heart rate, especially during the first three months of use (patients with hypertension should be monitored closely); and
- Expense—a prescription costs \$160 per month or \$50-60 co-pay.

The drug is not approved for treatment of major depressive or other psychiatric disorders. Caution is recommended if a patient has a history of suicidality, because antidepressants like bupropion increase the risk of suicidal thoughts in children, adolescents, and young adults. Contraindications include uncontrolled hypertension, seizures disorder or history of seizures, use of other bupropion-containing products, bulimia (which may increase seizure risk), long-term opioid or opiate agonists, and use of MAOIs.

Importantly, although approved for long-term use, drug responsiveness needs to be determined for patients prescribed lorcaserin, phentermine/topiramate ER, and naltrexone/bupropion SR<sup>7</sup>:

- For lorcaserin, at 3 months, if weight loss is <5% of initial weight, discontinue the medication
- For phentermine/topiramate ER:
  - (i) At 3 months, if weight loss is <3% of initial weight, either advance to a full dose or discontinue the medication; and
  - (ii) At 6 months, if weight loss is <5% of initial weight, discontinue the medication by tapering the dose to every other day for one week.
- For naltrexone/bupropion SR, at four months, if weight loss is <5% of initial weight, discontinue the medication.

In summary, FDA-approved weight-loss drugs provide clinicians with effective weight-management tools that, for the first time, are recommended as part of a comprehensive primary-care weight-management plan. Drugs should be chosen based on risk and side-effect profiles, and should be adjuncts to, not substitutes for, necessary changes in lifestyle—one can “eat through” the drugs’ effects on appetite and satiety. Also, weight regain is the rule upon drug cessation—thus, if patients meet drug-responsiveness criteria for body-weight loss at 3-6 months, the drugs should be continued.



## Choosing Weight-Loss Surgery Wisely

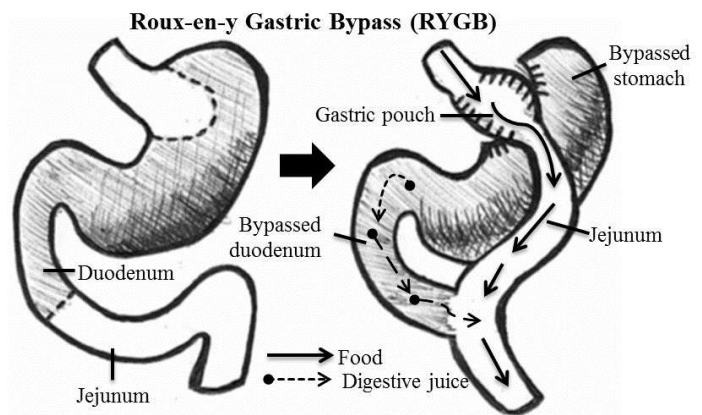
What primary-care providers need to know about bariatric surgery includes indications for and available weight-loss surgeries, relative risks and benefits of each procedure, and how to manage patients in the post-operative period and long-term.

Eligibility criteria for bariatric surgery include:

- BMI  $\geq 40$  kg/m<sup>2</sup> or  $\geq 35$  kg/m<sup>2</sup> with at least one weight-related health condition and failure at non-surgical weight loss attempts;
- No active drug or alcohol abuse or uncontrolled psychiatric illness;
- Comprehension of the risks, benefits, anticipated outcomes, and lifestyle changes required after surgery; and
- Patient commitment, which can be assessed by the patient's ability to track food and activity (using a log or mobile application), and reviewing whether they keep their appointments and adhere to medications and treatment plans.<sup>8</sup>

Available weight-loss procedures include roux-en-y gastric bypass (RYGB), both open and laparoscopic, laparoscopic gastric sleeve (LGS), and laparoscopic adjustable gastric band (LAGB, also called "lap-band," although this also is a trade name for a specific band).

In the RYGB procedure, a surgeon uses a surgical stapler to cut a small pouch, the size of a thumb, at the top of the stomach, then two feet from the stomach, the small bowel is divided, and one end is attached to the new stomach pouch. The other end, which remains connected to the bypassed stomach, is reconnected to the intestinal tract. Food bypasses most of the stomach and the first part of the small intestine. The procedure is both restrictive, because of the small stomach pouch, and malabsorptive, because it bypasses part of the small intestine causing a reduction in nutrient absorption.<sup>8</sup>



Advantages of the RYGB include:

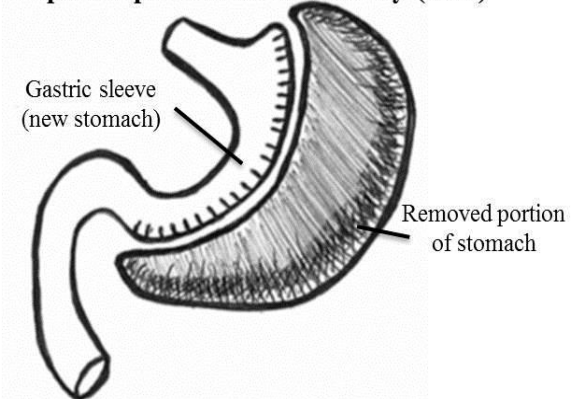
- Increased weight loss due to gastric restriction plus malabsorption; and
- Improvements in weight-related conditions, particularly diabetes.<sup>8</sup>

Disadvantages include:

- Greater risks than other procedures for bleeding, dumping syndrome, vitamin deficiencies, and death; and
- The post-procedure diet is very restrictive.

Gastric sleeve surgery, also called "sleeve gastrectomy," is a restrictive weight-loss procedure that reduces the size of the stomach up to 85%, by surgical removal of a large portion of the greater curvature of the stomach—this results in a sleeve or tube-like structure.<sup>8</sup>

### Laparoscopic Sleeve Gastrectomy (LGS)



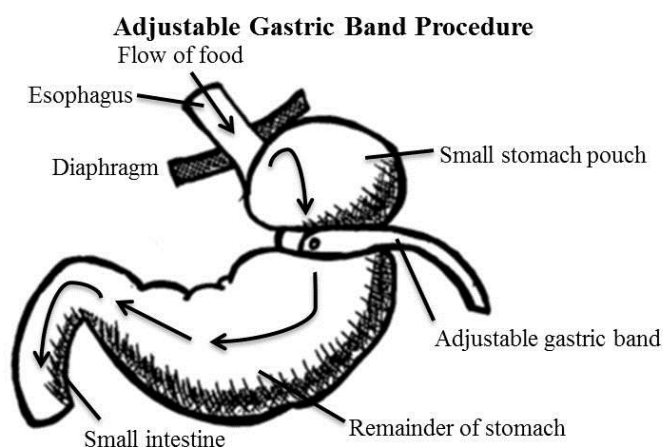
Advantages of LGS are: a less-restrictive post-surgical diet compared to post-RYGB; and for patients in whom a RYGB would be too risky, the procedure may precede RYGB, which can be performed after improvement in weight and comorbidities. Disadvantages of LGS include stretching of the gastric pouch with time, possible leakage at the staple site, and weight loss historically has been believed to be less than following RYGB.

In the adjustable gastric-band procedure, an adjustable belt is placed around the upper portion of the stomach to restrict the amount of food that can be held in the stomach. It also slows the rate of passage of food into the intestines.<sup>8</sup> Advantages include:

- Operation, hospitalization, and recovery times are much shorter than other procedures;
- It is considered reversible (although not inconsequential, because it requires surgery); and
- Less risk of dumping syndrome or vitamin deficiencies, compared to other procedures.

Disadvantages include:

- Once placed, the band is not tightened for up to six weeks leading to a delay in weight loss;
- Follow-up procedures are needed to reposition, replace, or remove the band;
- The band may slip, leak saline, erode into the stomach, and cause infection or rejections; and
- Weight loss is slower and of lower magnitude compared to other procedures.



In a meta-analysis of surgery-related weight and comorbidity improvement, those undergoing RYGB had a net (after subtracting the effect of active lifestyle control) one-year loss of 22% body weight (%BW).<sup>8</sup> LGS led to a net one-year weight loss of 15%. Data for %BW after five years are shown only for RYGB and LGS, but are similar to the one-year results. In terms of comorbidity improvement, diabetes improved the greatest after RYGB (any improvement—not complete resolution), hypertension improved the most following RYGB and LAGB (though not LGS, the reason for which is unclear and inconsistent with other studies<sup>17</sup>), and dyslipidemia improved in all procedures.

#### Benefits of Surgery: Meta-Analysis of Post-Surgical Weight/Comorbidity Improvement<sup>8</sup>

Characteristic	Control	RYGB	LGS	LAGB
%body-weight lost (%BW) year 1 <sup>a</sup>	10%	32%	25%	17%
%BW at year 5 <sup>a</sup>	—	32%	28%	—
Diabetes improvement, <sup>b</sup> %	18%	95%	—	74%
Hypertension improvement, <sup>b</sup> %	49%	81%	54% <sup>c</sup>	80%
Dyslipidemia improvement, <sup>b</sup> %	5%	63%	83%	61%

<sup>a</sup>Observational study data; <sup>b</sup>RCT, active lifestyle control; <sup>c</sup>Fewer trials of LGS compared to LAGB were included, and other sources report greater improvement in hypertension following LGS compared to LAGB.<sup>17</sup>

Risks of bariatric surgery include a small risk of mortality and complications, both immediately post-operation and months to years later.<sup>8</sup> The proportion of patients who die within 30 days of a procedure is 0% for LAGB, 0.2% for laparoscopic RYGB, and 2% for open RYGB (patients who undergo open RYGB tend to have higher BMIs and surgical risk).<sup>18</sup> The majority of post-operative deaths are due to pulmonary embolism, myocardial infection, congestive heart failure, or respiratory failure.

Other early complications, shown below, include bleeding at anastomoses or staple sites, infections, abscesses, post-operative pneumonia, leaks—which are fairly common after revision surgeries and are associated with a 15% mortality risk—thromboses, and respiratory failure.<sup>8,18-19</sup> An overview of the presentation, evaluation, and treatment of each is provided.

### **Risks of Surgery: Early Post-Operative Complications, Evaluation, and Management<sup>19</sup>**

<b>Complication</b>	<b>Presentation</b>	<b>Evaluation/Treatment</b>
<b>Bleeding</b> at anastomoses or staple sites	<ul style="list-style-type: none"> <li>• Tachycardia</li> <li>• Drop in hematocrit</li> <li>• Melena</li> </ul>	<ul style="list-style-type: none"> <li>• Slow bleed—reverse anticoagulants</li> <li>• Moderate—transfuse, order endoscopy</li> <li>• Rapid/unstable—emergent surgery</li> </ul>
<b>Infection</b> at wound site, abscess, pneumonia,...	<ul style="list-style-type: none"> <li>• Fever, leukocytosis</li> <li>• Erythema, fluctuance</li> </ul>	<ul style="list-style-type: none"> <li>• Antibiotics</li> <li>• Open/drain fluid collections</li> </ul>
<b>Leaks:</b> 2-6% initial RYGB, 35% revisions, 15% mortality	<ul style="list-style-type: none"> <li>• Low-grade fever</li> <li>• Unexplained tachycardia</li> </ul>	<ul style="list-style-type: none"> <li>• Upper GI, barium swallow or CT</li> <li>• Emergent exploratory surgery, drain fluid, broad-spectrum antibiotics</li> </ul>
<b>Thromboses:</b> PE/VTE/MI	<ul style="list-style-type: none"> <li>• Tachycardia</li> <li>• Shortness of breath</li> <li>• Chest pain</li> <li>• Hypoxia</li> </ul>	<ul style="list-style-type: none"> <li>• If suspected, anticoagulate before imaging (many imaging modalities not feasible)</li> <li>• Post-operatively, high-risk patients need 48-72 hr telemetry, EKG, echo (if suspect CHF)</li> </ul>
<b>Respiratory</b> compromise or failure	<ul style="list-style-type: none"> <li>• Shortness of breath</li> <li>• Tachypnea and hypoxia</li> </ul>	<ul style="list-style-type: none"> <li>• Identify/treat OSA pre-operatively</li> <li>• If atelectasis, ambulate, incentive spirometry</li> <li>• Utilize x-rays, labs as needed to evaluate etiology and determine treatment</li> </ul>

Abbreviations: RYGB=roux-en-Y gastric bypass, PE=pulmonary embolism, VTE=venous thromboembolism, MI=myocardial infarction, CHF=congestive heart failure, OSA=obstructive sleep apnea

Late complications of RYGB are shown in the next two tables. Common complications include dumping syndrome, which presents months or years after surgery. When it occurs early, symptoms are usually caused by eating simple carbohydrates (for example, rice, bread, or candy), are rapid in onset—within 15 min. of eating. The food's hyperosmolality causes rapid fluid shifts, resulting in hypotension and a sympathetic-nervous-system response. Late dumping results from the rapid rise in glucose, from food dumping into the small bowel, causing a robust insulin response followed by relative hypoglycemia. Other late complications, not listed, include iron deficiency, metabolic bone disease, gastrointestinal problems, kidney problems, short-bowel syndrome, and elevated risk of suicide.<sup>8,18-19</sup>

For gastric banding, early complications that are unique to LAGB include acute stomal obstruction, band infection, gastric perforation, and delayed gastric emptying. Late complications that are unique to gastric banding include band erosion (>1 year post-band, <10% prevalence), slippage (2-14% prevalence), or prolapse, port malfunction, esophagitis, esophageal dilation (pseudoachalasia), and hiatal-hernia formation.<sup>8,21</sup> Most complications can be identified by upper GI series. Treatment may

include band deflation and dietary modification, band repositioning, or band removal, with or without conversion to another procedure, such as RYGB.

For sleeve gastrectomy, the most common early complication is bleeding; sub-acute to late complications include narrowing or stenosis of the stoma, and leaks.<sup>8,20</sup> Whereas stomal stenosis can be treated by endoscopic dilation, leaks are some of the most serious complications, and early diagnosis, drainage, and gastric decompression are crucial.<sup>20</sup>

### **Late Complications of RYGB Surgery, and Their Evaluation and Management<sup>20</sup>**

<b>Complication</b>	<b>Timing</b>	<b>Risk Factors</b>	<b>Presentation</b>	<b>Evaluation/Treatment</b>
Dumping syndrome: ~50% prevalence	•Weeks, months, or years	•Simple carbs •Robust insulin response to hyperglycemia	•Colic, nausea, diarrhea •Sweating and anxiety •Dizziness and fatigue •Weakness	•Avoid simple carbs and eat small, frequent, protein-rich meals •Separate solid/liquid intake •Resolves within 7-12 weeks
Gallstones: ~40%	•1 <sup>st</sup> six months	•Rapid weight loss	•Biliary colic	•Prevent with bile salts •Diagnose/treat with M/ERCP, cholecystectomy, as needed
Stomal stenosis: 6-20%	•Many weeks	•Lap RYGB	•Nausea/vomiting •Unable to eat/drink	•Upper GI or endoscopy •Endoscopic balloon dilation
Marginal ulcers: 2-16%	•Any	•Excess acid •NSAID use •H.pylori infection •Smoking	•Nausea •Pain •Bleeding/melena •Peritoneal signs	•Upper endoscopy •PPI +/- sucralfate •Stop NSAID use •Smoking cessation
Hernias, ventral or internal: 0-5% lap, up to 25% open	•Any	•High abdominal pressure	•Ventral: bulge, pain, obstructive symptoms •Internal: colic, worse with eating, improves when prone	•Ventral: postpone repair until after significant weight loss •Internal: emergent referral to surgery for evaluation and urgent exploratory surgery
Gastric-remnant distension/rupture	•Any	•Vagal-nerve injury •Ileus	•Hiccups •Belly pain/distension •Peritoneal signs	•KUB—large gastric bubble •Emergent decompression with a G-tube, then surgery
Failure to lose weight and weight regain	•Any	•BMI>50 kg/m <sup>2</sup> •Gastrogastric fistula, gastric-pouch/G-J dilation •Maladaptive eating	•Weight gain •New or recurrent reflux •Ability to eat more per eating session •Binge-eating	•Upper GI series, endoscopy •Referral to surgery to evaluate for endoscopic stenting (for fistulas) or revisional surgery (for dilation)

Abbreviations: carbs=carbohydrates, M/ERCP=magnetic/endoscopic resonance cholangiopancreatography, NSAID=non-steroidal anti-inflammatory drugs, H. pylori=helicobacter pylori, PPI=proton-pump inhibitor, KUB: abdominal x-ray

## Risks of Nutrient Deficiencies following Weight-Loss Surgery<sup>21</sup>

Complication	Timing	Risk Factors	Presentation	Evaluation/Treatment
Thiamine deficiency	• 1 <sup>st</sup> six months	• Poor oral intake • Recurrent vomiting	• Fatigue, insomnia • Paresthesia, weakness • Ataxia and falls	• Blood thiamine, erythrocyte thiamine TKA, urine thiamine • See Ref. #21 for treatment dosing
Folate deficiency	• 4-6 mo.	• Alcohol abuse • Elderly	• Megaloblastic anemia	• CBC/MCV, folate (if <4, check RBC folate), B12, MMA • See Ref. #21 for treatment dosing
B12 deficiency	• ≥1 year	• Pernicious anemia • Prolonged PPI use • Metformin use • Vegetarian diet	• Megaloblastic anemia • Paresthesias, weakness • Impaired memory, ataxia, loss vibration/position sense	• CBC, MCV, serum B12, MMA, homocysteine, folate • See Ref. #21 for treatment dosing
Copper deficiency	• Years	• Iron supplements • Zinc supplements	• Neuro symptoms above • Anemia mimics IDA • Skin depigmentation	• CBC, MCV, serum copper • Treat with 2 mg elemental copper, oral or parentally
Zinc deficiency: 6-40% post-gastrectomy	• Months to years	• Copper supplements	• Hair loss, impotence • Abnormal taste • Immune dysfunction	• CBC, serum zinc • Treat with 100 mg zinc/day

Abbreviations: TKA=transketolase, CBC=complete blood count, MCV=mean corpuscular volume, RBC=red blood cell, MMA= methylmalonic acid, IDA=iron deficiency anemia

## Long-Term Care of Patients Following Bariatric Surgery

In the period immediately following bariatric surgery, providers should be familiar with post-operative dietary advancement and vitamin/mineral-supplementation requirements. Following RYGB/LGS, patients are advanced from clear to full liquids, then soft, moist protein-rich foods (for example, an egg), soft fruits and vegetables, and as more volume is tolerated, solid foods. Patients are counseled to drink fluids to prevent dehydration, 30 minutes apart from consuming solids. Lifelong vitamin/mineral supplements are required, although specific supplements are tailored using regular bloodwork.<sup>21</sup>

### Standard Postoperative Vitamin and Mineral Supplements for RYGB/LSG Patients<sup>21</sup>

Supplement	Dosage <sup>a</sup>
Multivitamin	• 1-2 daily
Calcium <b>citrate</b> (PPI recommended after bariatric surgery) with vitamin D <sup>a</sup>	• Calcium citrate: 1,200-2,000 mg/day • Vitamin D: 3,000 U/day, titrate to 25-OHD >30 ng/mL
Elemental iron (menstruating females only) <sup>a</sup>	• 40-65 mg/day
Vitamin B12 <sup>a</sup>	• >500 µg/day orally, 1,000 µg/month IM, 3,000 µg every six months IM, or 500 µg/week intranasal

<sup>a</sup>Patients with deficiency states need treatment beyond these recommendations.<sup>21</sup>

For LAGB, following band placement, patients resume a normal diet, and the first band tightening occurs 4-6 weeks after placement. Band tightening occurs gradually, at 4-6-week intervals over 1-2 years. As patients begin to feel satiety, they are encouraged to eat smaller meals and chew food more thoroughly.

Long-term, after all surgical weight-loss procedures, lifestyle recommendations mirror those for patients who have not undergone weight-loss surgery, with adjustments for food aversions/intolerances that may develop following RYGB (for example, red meat).<sup>21</sup> Focus shifts to weight-loss maintenance, including regular exercise, sleep, minimal sedentary activity, and promoting optimal mental health, including addressing any issues not addressed or revealed prior to weight-loss surgery.



**Long-term monitoring** of bariatric-surgery patients includes regular follow-up visits and laboratory assessments. During follow-up visits, review patients' diet and lifestyle habits, medications and supplements, and reinforce the importance of medication adherence, daily exercise, smoking cessation, and not taking NSAIDs. Also, conduct a thorough assessment of alcohol intake, sexual activity, and dysfunctional eating, particularly following RYGB: there are increased risks of incident alcoholism (increase of 50% two years post-operatively compared to pre-surgical rates<sup>22</sup>) and eating disorders.<sup>22-23</sup> Women who seek to become pregnant should be advised to delay pregnancy for 12-18 months following surgery (to optimize weight loss and avert adverse effects of surgery-related nutritional deficiencies).<sup>24</sup>

Follow-up visits in the immediate post-operative period are particularly important for patients receiving RYGB and LSG who take medications for diabetes and high blood pressure. In patients with insulin-requiring diabetes, consider checking a c-peptide level to determine how much endogenous insulin the patient makes. Those with undetectable c-peptide levels will most likely require exogenous insulin administration despite weight loss. For patients with hypertension, the first medications to reduce or stop in the setting of weight loss (regardless of whether through diet, medication, or surgery-induced weight loss) are diuretics—as the liver releases glycogen stores, because glycogen is heavily complexed with water, diuresis ensues, which can lead to dehydration in the setting of diuretic use.

### Monitoring of Patients Following Bariatric Surgery<sup>21</sup>

Clinical Practice	RYGB	LSG	LAGB
Visit interval			
• Immediately post-procedure (first three months)	Monthly	Monthly	Monthly
• During active weight-loss (up to 12-18 months)	3 months	3-6 months	3-6 months
• Once weight stable	6-12 months	12 months	12 months
Consider gout and gallstone prophylaxis	0-12 months	0-6 months	1-6 months
Recommended at 3 months, 6 months, then annually thereafter:			
• Complete blood count	x	x	x
• Electrolytes, AST/ALT, alk phos, bilirubin, and albumin	x	x	x
• Glucose and hemoglobin A1C	x	x	x
• Iron studies, ferritin (in males, check only until stable)	x	x	x
• Vitamin B12, folate, and thiamine	x	x	x
• Lipid profile	x	x	x
• 25-hydroxyvitamin D, parathyroid hormone (intact PTH)	x	x	x
• Zinc, copper	x	x	—
Bone densitometry every 1-2 years	x	x	x

In summary, available weight-management interventions, by intensity, include:

More Intense 		
 More Intense	<u>Behavior Modification</u>	<u>Pharmacotherapy</u>
	<u>Bariatric surgery</u>	
	<ul style="list-style-type: none"> <li>• Weight-loss advice</li> <li>• Self-help: e.g., internet</li> <li>• Dietitian advice</li> <li>• Structured program: e.g., Weight Watchers</li> </ul>	<ul style="list-style-type: none"> <li>• Orlistat</li> <li>• Lorcaserin</li> <li>• Naltrexone/bupropion SR</li> <li>• Phentermine/topiramate ER</li> </ul>
	<ul style="list-style-type: none"> <li>• Gastric banding</li> <li>• Gastric sleeve</li> <li>• Gastric bypass</li> </ul>	

Behavior modification ranges from weight-loss advice to a physician-monitored multidisciplinary program. Now that there is an obesity medicine certification exam, the American Board of Obesity Medicine or ABOM, primary-care providers may consider partnering with these obesity specialists who also are knowledgeable about obesity medications and surgeries. For pharmacotherapy, orlistat, lorcaserin, and naltrexone/bupropion SR are the least effective, providing 3-6% net weight loss at a year and phentermine/topiramate ER is the most effective, providing 8-10% net weight loss at a year. For surgery, gastric banding is the least effective, at 7-10% net weight loss at a year; and gastric bypass is the most effective, providing 20-30% net weight loss.

### **Weight-Management Provisions of the Affordable Care Act (ACA)**

Many physicians cite lack of reimbursement as a key barrier to addressing weight management in primary care.<sup>5</sup> Historically, it was financially more advantageous to address weight-related comorbidities once they had developed, rather than prevent them through early weight management. To address this problem, the ACA includes several provisions to promote preventive care: coinsurance, copayments, and deductibles are waived for Medicare/Medicaid-covered preventive services the United States Preventive Services Task Force (USPSTF) has given a grade A or B recommendation, including obesity screening and counseling.<sup>9</sup> All states must provide body mass index (BMI) screening and intensive behavioral counseling, defined as 12-26 counseling sessions per year. Optional provisions that vary by state include weight-loss medications and bariatric surgery. Medicare covers a maximum of 22 “intensive behavioral therapy” (IBT) sessions/12-month period, including:

- One face-to-face visit every week for the first month;
- One face-to-face visit every other week for months 2-6; and
- One face-to-face visit every month for months 7-12, if the beneficiary meets the 3 kg (6.6 pound) weight-loss requirement during the first six months.

To be eligible for coverage of IBT for obesity ( $\text{BMI} \geq 30 \text{ kg/m}^2$ ), Medicare beneficiaries must receive counseling by a primary-care provider (e.g., a physician or nurse practitioner) in a primary-care setting (e.g., a clinic or outpatient setting).<sup>9</sup>

## Future Directions

In terms of future directions in primary-care weight management, the field is moving toward personalization, early intervention, and expansion of drug options. Factors amenable to treatment tailoring include comorbid illnesses, specific behavioral patterns, and genotypes—for example, treating prediabetes/diabetes with drugs that promote weight loss, targeting problems with hunger and satiety with anorexic agents, treating binge eating with naltrexone/bupropion SR, or treating metabolic syndrome with tailored diets, such as Mediterranean or low-carbohydrate diets. Genotype-by-diet interactions also have been reported.<sup>25</sup> Early intervention is a hot topic, and pediatricians are being urged to identify and treat obesity in children and families earlier, more seriously, and more aggressively. In the future, new therapeutic targets may be identified through high-throughput drug-testing platforms (looking to repurpose drugs in use, and for new experimental targets), and drug engineering, harnessing new knowledge about the neuro-hormonal bases for changes in metabolism and appetite following bariatric surgery, or induced by cold temperatures and high altitude.<sup>26-27</sup>

## Conclusion

Right now, physicians care for overweight patients in their practices, and to maximize the effectiveness of this opportunity to help overweight patients manage their weight, can apply evidence-based clinical practices, including patient-centered communication, partnered decision-making regarding weight-management goals, weight-loss medications, and bariatric surgery. The first maxim we are taught in medicine is, “First do no harm.” We know that obesity causes harm—the outcome is going to be bad unless something is done; therefore, not addressing weight management with overweight and obese patients is causing harm. The health costs of obesity and benefits of weight loss demand action. Although patient progress in weight management can be slow and fraught with setbacks, we must remember the ancient Chinese proverb, “*A journey of a thousand miles begins with a single step.*” Supporting patients in weight management, including activating their intrinsic motivation by providing tools and working towards feasible goals, could stimulate lifelong, self-sustained successful weight management.



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## **Appendix: Resources**

1. Obesity Action Coalition: “Dedicated to improving the lives of individuals affected by the disease of obesity.” For educational resources (in English and Spanish), information regarding obesity treatments, and for patient advocacy and support groups, see: <http://www.obesityaction.org/>.
2. For information regarding bariatric-surgery benefits, including claims-processing instructions, visit: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=57&bc=AgAAgAAAAAAA&ncdver=3>.
3. Texas Obesity and/or Health and Nutrition Programs: Texas Department of State Health Services  
Phone: 512-458-7200, Fax: 512-458-7618, E-mail: [www.dshs.state.tx.us/obesity/](http://www.dshs.state.tx.us/obesity/)