Health Monitor®

Clinician Update

Weight Management

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Content reviewed by:

AACE®

AACE CONSENSUS STATEMENT:

Addressing weight stigma

Expert advice on how to recognize internalized weight bias in patients with obesity, which is often a barrier to effective treatment.

The American Psychological Association defines weight stigma as a "bias against an individual's body size," which leaves many people with obesity feeling ashamed and marginalized.1 Whether this bias is real or imagined, patients with obesity often process their shame into internalized weight bias (IWB), which poses another challenging complication of obesity that needs to be factored into treatment.[2] In addition to the physical health risks of obesity, many are burdened with potentially harmful emotional baggage, with at least 40% feeling stigmatized by perceived bias from others or their self-perceived body image.[3]

"The vast majority of our patients confront some degree of stigma, and nearly all show signs of IWB or describe it," says Karl Nadolsky, DO, chief of the Department of Endocrinology, Obesity and Metabolic Health at Holland Hospital (Holland, MI) and assistant clinical professor of medicine at the Michigan State University College of Human Medicine.

Given how society views people with obesity, and how they view themselves, it's no wonder Dr. Nadolsky calls it "the most stigmatized chronic disease."

The American Association of Clinical Endocrinology (AACE) recognizes IWB as a complication of obesity and as a risk factor that can tack on other obesity-related complications.[2]

This position follows the AACE's landmark 2012 recognition of obesity as a chronic disease characterized by "abnormalities in the mass, distribution and function of adipose tissue." It's also in line with AACE's recommendation to focus on obesity therapy when treating and preventing the complications of obesity that can cause morbidity and mortality, and to intensify therapy based on existence of complications.[2]

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Illustration by Jim Frazier

Illustration by Jing Jing Tsong

A long-standing societal stigma

Weight stigma has persisted for centuries, thanks in part to a pervasive societal image of a normal-weight and well-sculpted "perfect body." (Think Michelangelo's "David.") Obesity also has long been seen as the result of laziness and a poor lifestyle, rather than the chronic and complex metabolic disease it is. Consequently, people with obesity have been viewed as gluttonous, weak-willed outcasts and numerous studies suggest they've been discriminated against in all corners of society.[2,4] Frequent portrayals of people with obesity in the media as clownish misfits have fueled these negative attitudes, both among and toward those who have obesity.[4]

As society embraced diversity and social justice, the tide of "fat shaming" slowly began to turn. Social media movements such as "#bodypositivity" are encouraging people online to reject perfect body myths and accept people regardless of their body size.[5] Also, plus-size models are increasingly seen side-by-side with slimmer models in advertisements.[6]

While Dr. Nadolsky acknowledges that there has been some improvement in the public's perception of individuals with obesity, he says, "I'm not sure it has been enough to move the needle in society yet. There has been a reduced prevalence of stigma, but our polarized social environment has also exposed more extreme negative bias."

In fact, robust data point to the negative psychological effects of obesity stigma and IWB. People with obesity stigma face a 32% higher risk of depression compared with those at normal weight.[7] A 2020 meta-analysis also revealed a link between obesity stigma and mental illness,[8] with depression, anxiety and disordered eating most common among people with obesity.[2]

A vicious cycle with serious consequences

Unfortunately, the impact of stigma and IWB stretch well beyond the emotional:

> "OBESITY IS THE MOST STIGMATIZED CHRONIC DISEASE."
>
> —Karl Nadolsky, DO

The self-blame, low self-esteem and psychological distress that result from weight stigmatization and IWB discourage many patients from seeking help for their obesity and from learning how to manage it, Dr. Nadolsky says.

Many individuals who are stigmatized by their obesity also avoid exercising in public, don't adhere to their prescribed diet and exercise regimens and lack motivation to engage in the behavioral efforts.[5] The resultant patterns of maladaptive eating, physical inactivity, stress and healthcare attrition among people with IWB lead to poorer health, weight gain, lower engagement with treatment and—even worse—increased risk for other potentially dangerous obesity-related complications.[2,9,10] Even after bariatric surgery, obesity stigma can still cause weight gain and suboptimal outcomes.[11]

"The stigma and resulting IWB leads many patients I've seen to feeling like they have 'failed,' and that they must be at fault for their obesity," Dr. Nadolsky says. "This creates a vicious cycle of poor mental and physical health, and their obesity is exacerbated through adverse effects on lifestyle and behavioral efforts."

The consequences of this vicious cycle can be deadly. A meta-analysis of nearly 19,000 patients from 2 national surveys identified a 60% higher risk of mortality among patients who were discriminated against because of their weight, compared with those who were not.[12] Economic losses, reduced quality of healthcare, social isolation and sedentary lifestyle were common among those who grappled with weight stigma, although a specific correlation between stigma and mortality was not defined.[12]

Addressing weight bias

Primary care providers and endocrinologists need to detect and identify IWB in their patients with obesity and to intensify treatment if it's discovered, Dr. Nadolsky advises. He says this could involve stepping up a medication regimen for weight loss or medical complications, or recommending bariatric surgery if that modality is being considered. These strategies can help identify and address IWB in patients with obesity:

AACE GUIDELINE: Screening for internalized weight bias (IWB)[4]

The AACE recommends screening all patients with obesity for weight stigma and IWB—specifically, by using the Weight Bias Internalization Scale (WBIS) and Weight Self-Stigma Questionnaire (WSSQ). The WBIS consists of 19 brief questions focused on how a patient's weight is affecting their self-worth (available at *onlinelibrary.wiley.com*). The WSSQ comprises 12 short questions that address patients' attitudes toward becoming overweight and how people of normal weight will perceive them (available at *semanticscholar.org*).

Any score above 0 on either scale indicates IWB and underscores the need to gauge the severity of a patient's obesity, Dr. Nadolsky notes. The AACE suggests determining severity of obesity based on the existence of complications at 1 of 3 stages, with each stage taking into consideration the existence or risk of IWB or weight stigmatization and the risk for future complications. The stages include:

- Stage 1 (no known physical or medical complications)
- Stage 2 (1 or more mild to moderate complications)
- Stage 3 (at least 1 severe complication)

Many questions from either screening tool can easily be incorporated into the patient history, Dr. Nadolsky says: "In some cases, I'll just look for patients' answers as we go through their weight/medical history along with their diet and exercise history. Patients often just leave the answers there for the taking—if the clinician listens."

Validate their feelings.

The first step in identifying IWB is to understand that the patient who reports weight bias isn't just railing against being misunderstood. "It's critical for providers to first learn about IWB and to have awareness and mindfulness about the condition," says Dr. Nadolsky, adding that many warning signs can surface during the initial interview. "While there are validated screening questionnaires, just letting patients tell their stories of weight struggles, complications and their social interactions will expose IWB," he adds.

That initial interview can go far toward establishing a strong therapeutic alliance with patients, which Dr. Nadolsky says can help them stay engaged with therapy. "I notice that my patients feel heard and develop hope when I acknowledge that what they describe is IWB and is a complication of the disease due to the pervasive societal stigma," he says.

Use screening tools.

There are AACE-recommended screening tools available for gauging the presence of IWB (see box on p. 5). In addition, because of the association between IWB and depression, anxiety and disordered eating, patients identified as having IWB also should be screened for mental health issues, Dr. Nadolsky advises. Two options:

- The 9-item Patient Health Questionnaire (PHQ-9) takes just minutes to administer and can tease out potential warning signs of depression, such as loss of interest in pleasurable activities; poor appetite, sleep or energy; lack of self-worth; feelings of hopelessness; or thoughts of self-harm.[13] Each item is scored on a scale of 0 (not at all) to 3 (nearly every day), and a total score higher than 4 suggests a possible depressive disorder.[13]
- The 7-item Generalized Anxiety Disorder questionnaire (GAD-7) can quickly tease out extreme feelings of worry, fear and restlessness that could suggest anxiety.[14] The items are scored from 0 (not feeling symptoms at all) to 3 (feeling them nearly every day). A total score of 10 to 14 suggests moderate anxiety, while 15 or higher signals severe anxiety.[13]

Take a multidisciplinary approach.

If an emotional disorder is suspected, endocrinologists and obesity treatment experts should work with patients' primary care providers to ensure they are referred to a behavioral specialist, Dr. Nadolsky urges. Allied health professionals, such as dietitians and behavioral therapists, are also important players on the obesity management team and should be called in as needed.

–by Pete Kelly

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Overcoming medical barriers to weight loss

Certain medical conditions can make it difficult to lose weight even when patients are adhering to their weight-loss plan. Here are common culprits and how to work around them.

When a patient can't lose weight despite making several attempts, it can be frustrating for both you and the patient. One issue could be the patient's own unawareness of certain behaviors, such as miscalculating portion sizes. Yet there's another possible culprit: A comorbid medical condition may be thwarting their efforts. "If you don't address the underlying physiologic issue that is causing obesity, it's unlikely that a weight-loss program will be successful over the long term," says Frank Greenway, MD, Chief Medical Officer at Pennington Biomedical Research Center at Louisiana State University.

What's more, carrying excess weight increases the risk of developing problems such as glucose intolerance, type 2 diabetes, osteoarthritis, nonalcoholic fatty liver disease and depression.[1-6] These conditions can alter metabolism and/or result in symptoms (e.g., pain, fatigue, trouble sleeping) that interfere with the patient's ability to make the necessary lifestyle changes to lose weight. This creates a vicious cycle: Their comorbidity leads to weight gain, which in turn may worsen their comorbidity and hamper their ability to follow a weight-loss plan.

Common weight-related complications

Dr. Greenway urges healthcare providers to suspect a comorbid illness in any patient with a body mass index (BMI) that indicates overweight (BMI ≥25) or obesity (BMI ≥30), echoing the clinical practice guidelines from the American Association of Clinical Endocrinology (AACE) for treating patients with obesity.[7] The following diseases can be associated with weight gain and/or interfere with weight loss:

- **Prediabetes/type 2 diabetes.** Insulin resistance alters glucose and lipid metabolism and promotes fat cell storage. Also, some classes of antihyperglycemics, such as sulfonylureas, thiazolidinediones and insulin, can cause weight gain.
- **Hypothyroidism.** Low levels of thyroid hormone can slow metabolism.
- **Polycystic ovary syndrome (PCOS).** This condition, marked by elevated androgen levels, irregular periods and/or multiple ovarian cysts, afflicts 1 in 10 women of childbearing age. A common symptom is weight gain that is not caused by excessive eating; others include acne, excessive facial hair, thinning hair and difficulty getting pregnant.
- **Obstructive sleep apnea (OSA) and other sleep issues.** The breathing interruptions typical of OSA can leave patients sleep-deprived, inattentive, less able to manage their behavior and less motivated to exercise or eat properly, Dr. Greenway says. Further, sleep deprivation raises cortisol and decreases leptin, leading to metabolic changes that increase appetite and promote weight gain.
- **Chronic pain** due to arthritis and other conditions makes exercise difficult. "Pain is a strong physiologic deterrent," Dr. Greenway says. "Patients think about the pain and not the reasons for losing weight." Plus, the resulting immobility reduces muscle mass and aerobic fitness, further deterring activity.
- **Cardiovascular and pulmonary diseases.** Patients with asthma, heart failure, chronic obstructive pulmonary disease or angina can become tired or short of breath after a few minutes of activity. Also, exercise can trigger symptoms for patients with certain types of asthma.
- **Irritable bowel syndrome (IBS).** Fear of diarrhea can discourage patients with IBS from enjoying walks or other outdoor exercise, Dr. Greenway notes. In addition, bloating, flatulence and other abdominal symptoms can prompt patients to avoid certain foods, such as high-fiber cereals and beans, making healthy eating more difficult.
- **Depression** is common in patients with overweight and obesity.[1,6] "A person who is feeling depressed will have trouble finding the motivation to do all the hard work involved with losing weight and keeping it off," says Ethan Lazarus, MD, Director, Clinical Nutrition Center, Denver and Past-President of the Obesity Medicine Association. Indeed, symptoms such as fatigue, low energy, poor sleep and overeating often go hand-in-hand with depression.
- **Medication side effects.** Certain anticonvulsants, mood stabilizers, corticosteroids and other types of medication can cause weight gain, either by stimulating appetite, slowing metabolism or changing how the body stores glucose and other nutrients.[8]

Identifying medical issues

Prompt detection of weight-related comorbidities is crucial, both for starting treatment of the illness and getting weight loss back on track. The following can point toward a diagnosis or suggest the need for further testing:

THE WORKUP

All patients with overweight/obesity should have an annual physical exam, says Dr. Lazarus, which is often the first step in

Table 1.

Assessment of weight-related complications*[2]

Complication	Identification based on information available in initial evaluation
Metabolic syndrome	Waist circumference, blood pressure, triglycerides, HDL cholesterol, fasting glucose (presence of 3 or more)
Prediabetes	Fasting glucose
Type 2 diabetes	Fasting glucose
Dyslipidemia	Fasting triglycerides and HDL with lipid panel
Hypertension	Systolic and diastolic sitting blood pressure
Nonalcoholic fatty liver disease	Liver function tests, imaging studies
Polycystic ovary syndrome	Physical exam, review of systems
Obstructive sleep apnea	Physical exam, review of systems
Osteoarthritis	Physical exam, review of systems
Urinary stress incontinence	Physical exam, review of systems
Gastroesophageal reflux disease	Physical exam, review of systems
Disability/immobility	Physical exam, review of systems
Psychological disorder and/or stigmatization	Physical exam, review of systems
Obesity secondary to genetic syndromes, hormonal disease, iatrogenic medications	Physical exam, review of systems, review of medications and supplements, family history

*Initial evaluation in patients with overweight/obesity includes: history, physical examination, review of systems, blood pressure, waist circumference, fasting glucose, fasting lipid panel (total cholesterol, LDL, HDL, triglycerides), creatinine and hepatic transaminases.

Table 2.

Medications associated with weight gain[8]

Antidiabetes agents (sulfonylureas, insulin, TZDs, other insulin secretagogues, e.g., glinides)
Antidepressants (tricyclics, MAOIs, mirtazapine and certain SSRIs, including fluvoxamine, paroxetine, sertraline)
Antihistamines (azelastine, diphenhydramine)
Antipsychotics and phenothiazines (clozapine, fluphenazine, loxapine, olanzapine, quetiapine, risperidone)
Antiepileptic medications (valproic acid, carbamazepine, gabapentin)
Beta-blockers
Corticosteroids
Hormones (certain contraceptives, e.g., progestins)
Mood stabilizers (e.g., lithium)
Opiates
Migraine medications (e.g., valproic acid, propranolol)

diagnosing a comorbidity. This should include basics such as checking vital signs, weight and height; heart, lung and abdominal exam; and a review of systems (see Table 1 on p. 9). Along with calculating BMI, key diagnostics include:

- **Blood tests,** which can reveal problems that are caused or worsened by excess weight, such as diabetes and nonalcoholic fatty liver disease, as well as ones that increase the risk of weight gain, particularly hormonal imbalances such as hypothyroidism. *Note*: Be sure to test thyroid function in men, says Dr. Lazarus. "Many men living with obesity have never been properly screened," he says, since thyroid deficiencies are more common in women.[9]
- **Waist measurement.** Suspect diabetes, prediabetes or insulin resistance if waist circumference is ≥35 inches in women or ≥40 inches in men, says Dr. Lazarus.
- **Weight distribution check.** Abdominal weight gain is a major risk factor for cardiovascular disease, diabetes and metabolic syndrome.[10-12] Whereas abdominal obesity is more prevalent in men, women are more prone to peripheral obesity, which is "less likely to cause metabolic disease than central fat, but it can still cause fatigue, immobility, edema and functional problems," Dr. Lazarus says.
- **Neck circumference.** Dr. Lazarus notes that a neck circumference exceeding 16 inches in women or 17 inches in men may signal obstructive sleep apnea.
- **Medication review.** Check to see if weight gain is a possible side effect of any medication the patient is taking (see Table 2). If possible, consider switching to a weight-neutral agent.

THE PATIENT INTERVIEW

Asking your patients about their overall well-being can also uncover clues to undiagnosed comorbidities, notes Dr. Lazarus. Questions that may be helpful include:

1. How are you feeling?

Ask about energy level and mood, and consider using the Patient Health Questionnaire (PHQ), which can indicate depression. Start with the PHQ-2, suggests Dr. Lazarus, which asks: Over the past two weeks, how often have you been bothered by 1) little interest or pleasure in doing things, and 2) feeling down, depressed or hopeless? If the answers suggest depression, perform the extended PHQ-9 and/or refer to a psychiatrist.

In addition, listen for complaints about bothersome but potentially serious symptoms. For example, morning headaches or a spouse's report of loud snoring could signal OSA.

2. Are you sleeping well?

How many hours does the patient sleep each night? Does sleep get interrupted? Does the patient feel tired during the day or while driving? Depression or OSA could be the cause.

3. Do you smoke or use alcohol?

Because these high-risk behaviors are associated with weight gain, find out if or how often the patient engages in these behaviors, advises Dr. Greenway.

4. Did your parents have health problems?

Many serious diseases such as diabetes are hereditary, notes Dr. Greenway, so family history may predict current or future health problems.

Tailoring the weight-loss regimen

If a comorbid illness is diagnosed in a patient with overweight or obesity, assess the severity of the condition and, if necessary, focus on getting that under control first, advises Dr. Lazarus. In the case of diabetes, medications can be tailored to help with weight loss as well as glucose control (e.g., GLP-1 receptor agonists). Once the patient's condition is stabilized, the following strategies can help them work toward their weight-loss goals:

- **Adjust their diet to support treatment.** For example, a lower-carb diet with four to five smaller daily meals that include at least 2 oz. of protein to promote satiety can work for many patients with insulin resistance, Dr. Lazarus says. In addition, a diet rich in soluble fiber (e.g., oats, psyllium) could be helpful for IBS patients who confront frequent diarrhea, adds Dr. Greenway; also consider referring to a dietitian, as some foods can trigger IBS symptoms.
- **Make physical activity easier.** To circumvent limitations imposed by arthritis or chronic pain, Dr. Greenway suggests having patients start by walking 10 minutes a day and then increasing time and intensity as tolerated. For patients who have trouble walking, suggest swimming or water exercises. Referral to a physical therapist should also be considered.
- **Start or resume weight-loss medication** in patients who have a BMI ≥30 kg/m² or ≥27 kg/m² plus at least one weight-related complication, Dr. Lazarus says.
- **Evaluate the effects of weight loss on treatment.** Dr. Greenway says that weight loss may necessitate dosage adjustment of medications. For example, hypertension and diabetes usually improve as the patient loses weight, which may require a lowering or stopping of medication to avoid effects such as hypotension and hypoglycemia.
- **Follow-up early and often.** Monitor patients frequently after starting a new weight-loss plan, advises Dr. Greenway. Also, be aware that patients lose water in the early stages of weight loss, so watch closely for decreases in blood pressure, electrolyte deficiency, constipation and other effects of dehydration. If weight loss is progressing and comorbidities are stabilized, Dr. Greenway advises decreasing the frequency of visits (e.g., every three months) once the patient achieves goal weight and moves into the weight maintenance phase.

–by Pete Kelly

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Wegovy® (semaglutide) injection 2.4 mg is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in:

- adults with an initial body mass index (BMI) of ≥30 kg/m² (obesity) or ≥27 kg/m² (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)
- pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity)

Limitations of Use

- Wegovy® contains semaglutide and should not be coadministered with other semaglutide-containing products or with any GLP-1 receptor agonist
- The safety and effectiveness of Wegovy® in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established
- Wegovy® has not been studied in patients with a history of pancreatitis

Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

- **In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Wegovy® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined**
- **Wegovy® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Wegovy® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Wegovy®**

Contraindications

- Wegovy® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with a prior serious hypersensitivity reaction to semaglutide or to any of the excipients in Wegovy®. Serious hypersensitivity reactions, including anaphylaxis and angioedema have been reported with Wegovy®

Warnings and Precautions

- **Risk of Thyroid C-Cell Tumors:** Patients should be further evaluated if serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging
- **Acute Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including semaglutide. Acute pancreatitis was observed in patients treated with Wegovy® in clinical trials. Observe patients carefully for signs and symptoms of acute pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back, and which may or may not be accompanied by vomiting). If acute pancreatitis is suspected, discontinue Wegovy® promptly, and if acute pancreatitis is confirmed, do not restart
- **Acute Gallbladder Disease:** Treatment with Wegovy® was associated with an increased occurrence of cholelithiasis and cholecystitis. The incidence of cholelithiasis and cholecystitis was higher in Wegovy® pediatric patients aged 12 years and older than in Wegovy® adults. In clinical trials in adult patients, cholelithiasis was reported by 1.6% of Wegovy® patients and 0.7% of placebo patients. Cholecystitis was reported by 0.6% of Wegovy® patients and 0.2% of placebo patients. In a clinical trial in pediatric patients aged 12 years and older, cholelithiasis was reported by 3.8% of Wegovy® patients and 0% placebo patients. Cholecystitis was reported by 0.8% of Wegovy® pediatric patients and 0% placebo patients. Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in Wegovy® patients than in placebo patients, even after accounting for the degree of weight loss. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated
- **Hypoglycemia:** Wegovy® lowers blood glucose and can cause hypoglycemia. In a trial of adult patients with type 2 diabetes, hypoglycemia was reported in 6.2% of Wegovy® patients versus 2.5% of placebo patients. Patients with type 2 diabetes taking Wegovy® with an insulin secretagogue (e.g. sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms. Monitor blood glucose in patients with type 2 diabetes
- **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which in some cases required hemodialysis, in patients treated with semaglutide. Patients with renal impairment may be at a greater risk of acute kidney injury, but some events have been reported in patients without known underlying renal disease. A majority of the events occurred in patients who experienced nausea, vomiting, or diarrhea, leading to volume depletion. Monitor renal function when initiating or escalating doses of Wegovy® in patients reporting severe adverse gastrointestinal reactions and in patients with renal impairment reporting any adverse reactions that could lead to volume depletion
- **Hypersensitivity Reactions:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with Wegovy®. If hypersensitivity reactions occur, discontinue use of Wegovy®, treat promptly per standard of care, and monitor until signs and symptoms resolve. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP-1 receptor agonist
- **Diabetic Retinopathy Complications in Patients with Type 2 Diabetes:** In a trial of adult patients with type 2 diabetes, diabetic retinopathy was reported by 4.0% of Wegovy® patients and 2.7% of placebo patients. Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy
- **Heart Rate Increase:** Mean increases in resting heart rate of 1 to 4 beats per minute (bpm) were observed in Wegovy® adult patients compared to placebo in clinical trials. More Wegovy® adult patients compared with placebo had maximum changes from baseline of 10 to 19 bpm (41% versus 34%) and 20 bpm or more (26% versus 16%). In a clinical trial in pediatric patients aged 12 years and older with normal baseline heart rate, more patients treated with Wegovy® compared to placebo had maximum changes in heart rate of 20 bpm or more (54% versus 39%). Monitor heart rate at regular intervals and instruct patients to report palpitations or feelings of a racing heartbeat while at rest. If patients experience a sustained increase in resting heart rate, discontinue Wegovy®
- **Suicidal Behavior and Ideation:** Suicidal behavior and ideation have been reported in clinical trials with other weight management products. Monitor patients for depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue Wegovy® in patients who experience suicidal thoughts or behaviors and avoid in patients with a history of suicidal attempts or active suicidal ideation

Adverse Reactions

- Most common adverse reactions (incidence ≥5%) are: nausea, diarrhea, vomiting, constipation, abdominal pain, headache, fatigue, dyspepsia, dizziness, abdominal distention, eructation, hypoglycemia in patients with type 2 diabetes, flatulence, gastroenteritis, gastroesophageal reflux disease, and nasopharyngitis

Drug Interactions

- The addition of Wegovy® in patients treated with insulin has not been evaluated. When initiating Wegovy®, consider reducing the dose of concomitantly administered insulin secretagogues (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia
- Wegovy® causes a delay of gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications. Monitor the effects of oral medications concomitantly administered with Wegovy®

Use in Specific Populations

- **Pregnancy:** May cause fetal harm. When pregnancy is recognized, discontinue Wegovy®. Discontinue Wegovy® in patients at least 2 months before a planned pregnancy
- **Pediatric:** Adverse reactions with Wegovy® in pediatric patients aged 12 years and older were similar to those reported in adults. Pediatric patients ≥12 years of age treated with Wegovy® had greater incidences of cholelithiasis, cholecystitis, hypotension, rash, and urticaria compared to adults treated with Wegovy®

Please see the Brief Summary of Prescribing Information about Wegovy® on the following pages.

US24SEMO00358 February 2024

novo nordisk®

WEGOVY® (semaglutide) injection

Rx Only

BRIEF SUMMARY: Please consult package insert for full prescribing information.

WARNING: RISK OF THYROID C-CELL TUMORS: In rodents, semaglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether WEGOVY® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined *[see Warnings and Precautions]*. WEGOVY® is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2) *[see Contraindications]*. Counsel patients regarding the potential risk for MTC with the use of WEGOVY® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with WEGOVY® *[see Contraindications and Warnings and Precautions]*.

INDICATIONS AND USAGE: WEGOVY® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in: adults with an initial body mass index (BMI) of 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia); pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater standardized for age and sex (obesity) Limitation of Use: WEGOVY® contains semaglutide and should not be coadministered with other semaglutide-containing products or with any other GLP-1 receptor agonist. The safety and effectiveness of WEGOVY® in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established. WEGOVY® has not been studied in patients with a history of pancreatitis *[see Warnings and Precautions]*.

CONTRAINDICATIONS: WEGOVY® is contraindicated in the following conditions: A personal or family history of MTC or in patients with MEN 2 *[see Warnings and Precautions]*. A prior serious hypersensitivity reaction to semaglutide or to any of the excipients in WEGOVY®. Serious hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with WEGOVY® *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS: Risk of Thyroid C-Cell Tumors: In mice and rats, semaglutide caused a dose-dependent and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors (adenomas and carcinomas) after lifetime exposure at clinically relevant plasma exposures. It is unknown whether WEGOVY® causes thyroid C-cell tumors, including MTC, in humans, as human relevance of semaglutide-induced rodent thyroid C-cell tumors has not been determined. Cases of MTC in patients treated with liraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans. WEGOVY® is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of WEGOVY® and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with WEGOVY®. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin value may indicate MTC and patients with MTC usually have calcitonin values greater than 50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated. **Acute pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including semaglutide. Acute pancreatitis was observed in patients treated with WEGOVY® in clinical trials *[see Adverse Reactions]*. After initiation of WEGOVY®, observe patients carefully for signs and symptoms of acute pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back, and which may or may not be accompanied by vomiting). If acute pancreatitis is suspected, WEGOVY® should promptly be discontinued and appropriate management should be initiated. If acute pancreatitis is confirmed, WEGOVY® should not be restarted. WEGOVY® has not been studied in patients with a history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on WEGOVY®. **Acute Gallbladder Disease:** Treatment with WEGOVY® was associated with an increased occurrence of cholelithiasis and cholecystitis. The incidence of cholelithiasis and cholecystitis was higher in WEGOVY®-treated pediatric patients aged 12 years and older than in WEGOVY®-treated adults. In randomized clinical trials in adult patients, cholelithiasis was reported by 1.6% of WEGOVY®-treated patients and 0.7% of placebo-treated patients. Cholecystitis was reported by 0.6% of WEGOVY®-treated adult patients and 0.2% of placebo-treated patients. In a clinical trial in pediatric patients aged 12 years and older, cholelithiasis was reported by 3.8% of WEGOVY®-treated patients and 0% placebo-treated patients. Cholecystitis was reported by 0.8% of WEGOVY®-treated pediatric patients and 0% placebo-treated patients *[see Adverse Reactions]*. Substantial or rapid weight loss can increase the risk of cholelithiasis; however, the incidence of acute gallbladder disease was greater in WEGOVY®-treated patients than in placebo-treated patients, even after accounting for the degree of weight loss. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated. **Hypoglycemia:** WEGOVY® lowers blood glucose and can cause hypoglycemia. In a trial of adult patients with type 2 diabetes and BMI greater than or equal to 27 kg/m^2, hypoglycemia (defined as a plasma glucose less than 54 mg/dL) was reported in 6.2% of WEGOVY®-treated patients versus 2.5% of placebo-treated patients. One episode of severe hypoglycemia (requiring the assistance of another person) was reported in one WEGOVY®-treated patient versus no placebo-treated patients. Patients with type 2 diabetes mellitus taking WEGOVY® in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia *[see Adverse Reactions]*. Hypoglycemia has been observed in patients treated with semaglutide at doses of 0.5 and 1 mg in combination with insulin. The addition of WEGOVY® in patients treated with insulin has not been evaluated. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with type 2 diabetes, monitor blood glucose prior to starting WEGOVY® and during WEGOVY® treatment. When initiating WEGOVY®, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia *[see Drug Interactions]*. **Acute Kidney Injury:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which have in some cases required hemodialysis, in patients treated with semaglutide. Patients with renal impairment may be at greater risk of acute kidney injury, but some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, or diarrhea, leading to volume depletion *[see Adverse Reactions]*. Monitor renal function when initiating or escalating doses of WEGOVY® in patients reporting severe adverse gastrointestinal reactions. Monitor renal function in patients with renal impairment reporting any adverse reactions that could lead to volume depletion. **Hypersensitivity Reactions:** Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with WEGOVY®. If hypersensitivity reactions occur, discontinue use of WEGOVY®, treat promptly per standard of care, and monitor until signs and symptoms resolve. WEGOVY® is contraindicated in patients with a prior serious hypersensitivity reaction to semaglutide or to any of the excipients in WEGOVY® *[see Adverse Reactions]*. Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP-1 receptor agonist because it is unknown whether such patients will be predisposed to these reactions with WEGOVY®. **Diabetic Retinopathy Complications in Patients with Type 2 Diabetes:** In a trial of adult patients with type 2 diabetes and BMI greater than or equal to 27 kg/m^2, diabetic retinopathy was reported by 4.0% of WEGOVY®-treated patients and 2.7% placebo-treated patients. In a 2-year trial with semaglutide 0.5 mg and 1 mg once-weekly injection in adult patients with type 2 diabetes and high cardiovascular risk, diabetic retinopathy complications (which was a 4-component adjudicated endpoint) occurred in patients treated with semaglutide injection (3.0%) compared to placebo (1.8%). The absolute risk increase for diabetic retinopathy complications was larger among patients with a history of diabetic retinopathy at baseline (semaglutide injection 8.2%, placebo 5.2%) than among patients without a known history of diabetic retinopathy (semaglutide injection 0.7%, placebo 0.4%). Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. The effect of long-term glycemic control with semaglutide on diabetic retinopathy complications has not been studied. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy. **Heart Rate Increase:** Treatment with WEGOVY® was associated with increases in resting heart rate. Mean increases in resting heart rate of 1 to 4 beats per minute (bpm) were observed in WEGOVY®-treated adult patients compared to placebo in clinical trials. More adult patients treated with WEGOVY® compared with placebo had maximum changes from baseline at any visit of 10 to 19 bpm (41% versus 34%, respectively) and 20 bpm or more (26% versus 16%, respectively). In a clinical trial in pediatric patients aged 12 years and older with normal baseline heart rate, more patients treated with WEGOVY® compared to placebo had maximum changes in heart rate of 20 bpm or more (54% versus 39%) *[see Adverse Reactions]*. Monitor heart rate at regular intervals consistent with usual clinical practice. Instruct patients to inform their healthcare providers of palpitations or feelings of a racing heartbeat while at rest during WEGOVY® treatment. If patients experience a sustained increase in resting heart rate, discontinue WEGOVY®. **Suicidal Behavior and Ideation:** Suicidal behavior and ideation have been reported in clinical trials with other weight management products. Monitor patients treated with WEGOVY® for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue WEGOVY® in patients who experience suicidal thoughts or behaviors. Avoid WEGOVY® in patients with a history of suicidal attempts or active suicidal ideation.

ADVERSE REACTIONS: The following serious adverse reactions are described below or elsewhere in the prescribing information: Risk of Thyroid C-Cell Tumors *[see Warnings and Precautions]*; Acute Pancreatitis *[see Warnings and Precautions]*; Acute Gallbladder Disease *[see Warnings and Precautions]*; Hypoglycemia *[see Warnings and Precautions]*; Acute Kidney Injury *[see Warnings and Precautions]*; Hypersensitivity Reactions *[see Warnings and Precautions];* Diabetic Retinopathy Complications in Patients with Type 2 Diabetes *[see Warnings and Precautions];* Heart Rate Increase *[see Warnings and Precautions];* Suicidal Behavior and Ideation *[see Warnings and Precautions]*. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. **Adverse Reactions in Clinical Trials in Adults with Obesity or Overweight:** *WEGOVY® 2.4 mg Subcutaneous Weekly Dosage:* WEGOVY® was evaluated for safety in 3 randomized, double-blind, placebo-controlled trials that included 2,116 adult patients with overweight or obesity treated with 2.4 mg WEGOVY® for up to 68 weeks and a 7 week off drug follow-up period *[see Clinical Studies (14.1)]*. Baseline characteristics included a mean age of 48 years, 71% women, 72% White, 14% Asian, 9% Black or African American, and 5% reported as other or unknown; and 85% were not Hispanic or Latino ethnicity, 13% were Hispanic or Latino ethnicity and 2% reported as unknown. The baseline characteristics were 42% with hypertension, 19% with type 2 diabetes, 43% with dyslipidemia, 28% with a BMI greater than 40 kg/m^2, and 4% with cardiovascular disease. In clinical trials, 6.8% of patients treated with 2.4 mg WEGOVY® and 3.2% of patients treated with placebo permanently discontinued treatment as a result of adverse reactions. The most common adverse reactions leading to discontinuation were nausea (1.8% versus 0.2%), vomiting (1.2% versus 0%), and diarrhea (0.7% versus 0.1%) for WEGOVY® and placebo, respectively. Adverse reactions reported in clinical trials in adults and greater than or equal to 2% of WEGOVY®-treated patients and more frequently than in placebo-treated patients are shown in Table 5.

Table 5. Adverse Reactions (≥ 2% and Greater Than Placebo) in WEGOVY®-treated Adult with Obesity or Overweight for Chronic Weight Management

	Placebo N = 1,261 %	WEGOVY® 2.4 mg N = 2,116 %
Nausea	16	44
Diarrhea	16	30
Vomiting	6	24
Constipation	11	24
Abdominal Pain[a]	10	20
Headache	10	14
Fatigue[b]	5	11
Dyspepsia	3	9
Dizziness	4	8
Abdominal Distension	5	7
Eructation	<1	7
Hypoglycemia in T2DM[c]	2	6
Flatulence	4	6
Gastroenteritis	4	6
Gastroesophageal Reflux Disease	3	5
Gastritis[d]	1	4
Gastroenteritis Viral	3	4
Hair Loss	1	3

[a]Includes abdominal pain, abdominal pain upper, abdominal pain lower, gastrointestinal pain, abdominal tenderness, abdominal discomfort and epigastric discomfort

[b]Includes fatigue and asthenia

[c]Defined as blood glucose <54 mg/dL with or without symptoms of hypoglycemia or severe hypoglycemia (requiring the assistance of another person) in patients with type 2 diabetes not on concomitant insulin (Study 2, WEGOVY® N=403, Placebo N=402). See text below for further information regarding hypoglycemia in patients with and without type 2 diabetes. T2DM = type 2 diabetes mellitus

[d]Includes chronic gastritis, gastritis, gastritis erosive, and reflux gastritis

WEGOVY® 1.7 mg Subcutaneous Weekly Dosage: WEGOVY® 1.7 mg subcutaneous weekly was evaluated for safety in a 68-week, randomized, double-blind, parallel-group, placebo-controlled trial in 401 patients with overweight or obesity. Adverse reactions observed with WEGOVY® 1.7 mg were similar to those reported with WEGOVY® 2.4 mg.

Adverse Reactions in a Clinical Trial of Pediatric Patients Aged 12 Years and Older with Obesity: WEGOVY® was evaluated in a 68-week, double-blind, randomized, parallel group, placebo-controlled, multicenter trial in 201 pediatric patients aged 12 years and older with obesity. Baseline characteristics included a mean age of 15.4 years; 38% of patients were male; 79% were White, 8% were Black or African American, 2% were Asian, and 11% were of other or unknown race; and 11% were of Hispanic or Latino ethnicity. The mean baseline body weight was 107.5 kg, and mean BMI was 37 kg/m^2. Table 6 shows adverse reactions reported in greater than or equal to 3% of WEGOVY®-treated pediatric patients and more frequently than in the placebo group from a study in pediatric patients aged 12 years and older.

Table 6. Adverse Reactions (≥ 3% and Greater than Placebo) in WEGOVY®-Treated Pediatric Patients Aged 12 Years and Older with Obesity for Chronic Weight Management

	Placebo N = 67 %	WEGOVY® 2.4 mg N = 133 %
Nausea	18	42
Vomiting	10	36
Diarrhea	19	22
Headache	16	17
Abdominal Pain	6	15
Nasopharyngitis	10	12
Dizziness	3	8
Gastroenteritis	3	7
Constipation	2	6
Gastroesophageal Reflux Disease	2	4
Sinusitis	2	4
Urinary tract infection	2	4
Ligament sprain	2	4
Anxiety	2	4
Hair Loss	0	4
Cholelithiasis	0	4
Eructation	0	4
Influenza	0	3
Rash	0	3
Urticaria	0	3

Other Adverse Reactions in Adults and/or Pediatric Patients: *Acute Pancreatitis:* In WEGOVY® clinical trials in adults, acute pancreatitis was confirmed by adjudication in 4 WEGOVY®-treated patients (0.2 cases per 100 patient years) versus 1 in placebo-treated patients (less than 0.1 cases per 100 patient years). One additional case of acute pancreatitis was confirmed in a patient treated with WEGOVY® in another clinical trial. *Acute Gallbladder Disease:* In WEGOVY® clinical trials in adults, cholelithiasis was reported by 1.6% of WEGOVY®-treated patients and 0.7% of placebo-treated patients. Cholecystitis was reported by 0.6% of WEGOVY®-treated adult patients and 0.2% of placebo-treated patients. In a clinical trial in pediatric patients aged 12 years and older, cholelithiasis was reported by 3.8% of WEGOVY®-treated patients and 0% placebo-treated patients. Cholecystitis was reported by 0.8% of WEGOVY®-treated pediatric patients and 0% placebo-treated patients. *Hypoglycemia: Patients with Type 2 Diabetes:* In a trial of adult patients with type 2 diabetes and BMI greater than or equal to 27 kg/m^2, clinically significant hypoglycemia (defined as a plasma glucose less than 54 mg/dL) was reported in 6.2% of WEGOVY®-treated patients versus 2.5% of placebo-treated patients. A higher rate of clinically significant hypoglycemic episodes was reported with WEGOVY® (semaglutide 2.4 mg) versus semaglutide 1 mg (10.7 vs. 7.2 episodes per 100 patient years of exposure, respectively); the rate in the placebo-treated group was 3.2 episodes per 100 patient years of exposure. In addition, one episode of severe hypoglycemia requiring intravenous glucose was reported in a WEGOVY®-treated patient versus none in placebo-treated patients. The risk of hypoglycemia was increased when WEGOVY® was used with a sulfonylurea. *Patients without Type 2 Diabetes:* Episodes of hypoglycemia have been reported with GLP-1 receptor agonists in adult patients without type 2 diabetes mellitus. In WEGOVY® clinical trials in adult patients without type 2 diabetes mellitus, there was no systematic capturing or reporting of hypoglycemia. *Acute Kidney Injury:* Acute kidney injury occurred in clinical trials in 7 adult patients (0.4 cases per 100 patient years) receiving WEGOVY® versus 4 patients (0.2 cases per 100 patient years of exposure) receiving placebo. Some of these adverse reactions occurred in association with gastrointestinal adverse reactions or dehydration. In addition, 2 patients treated with WEGOVY® had acute kidney injury with dehydration in other clinical trials. The risk of renal adverse reactions with WEGOVY® was increased in adult patients with a history of renal impairment (trials included 65 patients with a history of moderate or severe renal impairment at baseline), and occurred more frequently during dose titration. *Retinal Disorders in Patients with Type 2 Diabetes:* In a trial of adult patients with type 2 diabetes and BMI greater than or equal to 27 kg/m^2, retinal disorders were reported by 6.9% of patients treated with WEGOVY® (semaglutide 2.4 mg), 6.2% of patients treated with semaglutide 1 mg, and 4.2% of patients treated with placebo. The majority of events were reported as diabetic retinopathy (4.0%, 2.7%, and 2.7%, respectively) and non-proliferative retinopathy (0.7%, 0%, and 0%, respectively). *Increase in Heart Rate:* Mean increases in resting heart rate of 1 to 4 beats per minute (bpm) were observed with routine clinical monitoring in WEGOVY®-treated adult patients compared to placebo in clinical trials. In trials in which adult patients were randomized prior to dose-escalation, more patients treated with WEGOVY®, compared with placebo, had maximum changes from baseline at any visit of 10 to 19 bpm (41% versus 34%, respectively) and 20 bpm or more (26% versus 16%, respectively). In a clinical trial in pediatric patients aged 12 years and older with normal baseline heart rate, more patients treated with WEGOVY® compared to placebo had maximum changes in heart rate of 20 bpm or more (54% versus 39%). *Hypotension and Syncope:* Adverse reactions related to hypotension (hypotension, orthostatic hypotension, and decreased blood pressure) were reported in 1.3% of WEGOVY®-treated adult patients versus 0.4% of placebo-treated patients and syncope was reported in 0.8% of WEGOVY®-treated patients versus 0.2% of placebo-treated patients. Some reactions were related to gastrointestinal adverse reactions and volume loss associated with WEGOVY®. Hypotension and orthostatic hypotension were more frequently seen in patients on concomitant antihypertensive therapy. In a clinical trial in pediatric patients aged 12 years and older, hypotension was reported in 2.3% of WEGOVY®-treated patients versus 0% in placebo-treated patients. *Appendicitis:* Appendicitis (including perforated appendicitis) occurred in 10 (0.5%) WEGOVY®-treated adult patients and 2 (0.2%) patients receiving placebo. *Gastrointestinal Adverse Reactions:* In clinical trials in adults, 73% of WEGOVY®-treated patients and 47% of patients receiving placebo reported gastrointestinal disorders. The most frequently reported reactions were nausea (44% vs. 16%), vomiting (25% vs. 6%), and diarrhea (30% vs. 16%). Other common reactions that occurred at a higher incidence among WEGOVY®-treated adult patients included dyspepsia, abdominal pain, abdominal distension, eructation, flatulence, gastroesophageal reflux disease, gastritis, and hemorrhoids. These reactions increased during dose escalation. In a pediatric clinical trial, 62% of WEGOVY®-treated patients and 42% of placebo-treated patients reported gastrointestinal disorders. The most frequently reported reactions were nausea (42% vs. 18%), vomiting (36% vs. 10%), and diarrhea (22% vs. 19%). Other gastrointestinal-related reactions that occurred at a higher incidence than placebo among WEGOVY®-treated pediatric patients included abdominal pain, constipation, eructation, gastroesophageal reflux disease, dyspepsia, and flatulence. Permanent discontinuation of treatment as a result of a gastrointestinal adverse reaction occurred in 4.3% of WEGOVY®-treated adult patients versus 0.7% of placebo-treated patients. In a pediatric clinical trial, 2.3% of patients treated with WEGOVY® versus 1.5% of patients who received placebo discontinued treatment as a result of gastrointestinal adverse reactions. *Injection Site Reactions:* In clinical trials in adults, 1.4% of WEGOVY®-treated patients and 1.0% of patients receiving placebo experienced injection site reactions (including injection site pruritus, erythema, inflammation, induration, and irritation). *Hypersensitivity Reactions:* Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) have been reported with WEGOVY®. In a pediatric clinical trial, rash was reported in 3% of

WEGOVY®-treated patients and 0% of placebo-treated patients, and urticaria was reported in 3% of WEGOVY®-treated patients and 0% of placebo-treated patients. In adult clinical trials, allergic reactions occurred in 8/50 (16%) of WEGOVY®-treated patients with anti-semaglutide antibodies and in 114/1659 (7%) of WEGOVY®-treated patients who did not develop anti-semaglutide antibodies. *Dysgeusia:* In clinical trials in adults, 1.7% of WEGOVY®-treated patients and 0.5% of placebo-treated patients reported dysgeusia. *Laboratory Abnormalities: Amylase and Lipase:* Adult and pediatric patients treated with WEGOVY® had a mean increase from baseline in amylase of 15-16% and lipase of 39%. These changes were not observed in the placebo group. The clinical significance of elevations in lipase or amylase with WEGOVY® is unknown in the absence of other signs and symptoms of pancreatitis. *Liver Enzymes:* In a pediatric clinical trial, increases in alanine aminotransferase (ALT) greater than or equal to 5 times the upper limit of normal were observed in 4 (3%) WEGOVY®-treated patients compared with 0% of placebo-treated patients. In some patients, increases in ALT and AST were associated with other confounding factors (such as gallstones). **Postmarketing Experience:** The following adverse reactions have been reported during post-approval use of semaglutide, the active ingredient of WEGOVY®. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. *Gastrointestinal Disorders:* acute pancreatitis and necrotizing pancreatitis, sometimes resulting in death, ileus; *Hypersensitivity:* anaphylaxis, angioedema, rash, urticaria; *Renal and Urinary Disorders:* acute kidney injury

DRUG INTERACTIONS: Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or Insulin: WEGOVY® lowers blood glucose and can cause hypoglycemia. The risk of hypoglycemia is increased when WEGOVY® is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. The addition of WEGOVY® in patients treated with insulin has not been evaluated. When initiating WEGOVY®, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia *[see Warnings and Precautions and Adverse Reactions]*. **Oral Medications:** WEGOVY® causes a delay of gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. In clinical pharmacology trials with semaglutide 1 mg, semaglutide did not affect the absorption of orally administered medications. Nonetheless, monitor the effects of oral medications concomitantly administered with WEGOVY®.

USE IN SPECIFIC POPULATIONS: Pregnancy: Pregnancy Exposure Registry: There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to semaglutide during pregnancy. Pregnant women exposed to WEGOVY® and healthcare providers are encouraged to contact Novo Nordisk at 1-877-390-2760 or www.wegovypregnancyregistry.com. Risk Summary: Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. Additionally, weight loss offers no benefit to a pregnant patient and may cause fetal harm. When a pregnancy is recognized, advise the pregnant patient of the risk to a fetus, and discontinue WEGOVY® *(see Clinical Considerations)*. Available pharmacovigilance data and data from clinical trials with WEGOVY® use in pregnant patients are insufficient to establish a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. In pregnant rats administered semaglutide during organogenesis, embryofetal mortality, structural abnormalities and alterations to growth occurred at maternal exposures below the maximum recommended human dose (MRHD) based on AUC. In rabbits and cynomolgus monkeys administered semaglutide during organogenesis, early pregnancy losses and structural abnormalities were observed at below the MRHD (rabbit) and greater than or equal to 2-fold the MRHD (monkey). These findings coincided with a marked maternal body weight loss in both animal species *(see Data)*. The estimated background risk of major birth defects and miscarriage for the indicated population are unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. Clinical Considerations: *Disease-associated maternal and/or embryo/fetal risk:* Appropriate weight gain based on pre-pregnancy weight is currently recommended for all pregnant patients, including those who already have overweight or obesity, because of the obligatory weight gain that occurs in maternal tissues during pregnancy. Data: *Animal Data:* In a combined fertility and embryofetal development study in rats, subcutaneous doses of 0.01, 0.03 and 0.09 mg/kg/day (0.04-, 0.1-, and 0.4-fold the MRHD) were administered to males for 4 weeks prior to and throughout mating and to females for 2 weeks prior to mating, and throughout organogenesis to Gestation Day 17. In parental animals, pharmacologically mediated reductions in body weight gain and food consumption were observed at all dose levels. In the offspring, reduced growth and fetuses with visceral (heart blood vessels) and skeletal (cranial bones, vertebra, ribs) abnormalities were observed at the human exposure. In an embryofetal development study in pregnant rabbits, subcutaneous doses of 0.0010, 0.0025 or 0.0075 mg/kg/day (0.01-, 0.1-, and 0.9-fold the MRHD) were administered throughout organogenesis from Gestation Day 6 to 19. Pharmacologically mediated reductions in maternal body weight gain and food consumption were observed at all dose levels. Early pregnancy losses and increased incidences of minor visceral (kidney, liver) and skeletal (sternebra) fetal abnormalities were observed at greater than or equal to 0.0025 mg/kg/day, at clinically relevant exposures. In an embryofetal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (0.4-, 2-, and 6-fold the MRHD) were administered throughout organogenesis, from Gestation Day 16 to 50. Pharmacologically mediated, marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with the occurrence of sporadic abnormalities (vertebra, sternebra, ribs) at greater than or equal to 0.075 mg/kg twice weekly (greater than or equal to 2 times human exposure). In a pre- and postnatal development study in pregnant cynomolgus monkeys, subcutaneous doses of 0.015, 0.075, and 0.15 mg/kg twice weekly (0.2-, 1-, and 3-fold the MRHD) were administered from Gestation Day 16 to 140. Pharmacologically mediated marked initial maternal body weight loss and reductions in body weight gain and food consumption coincided with an increase in early pregnancy losses and led to delivery of slightly smaller offspring at greater than or equal to 0.075 mg/kg twice weekly (greater than or equal to 1 time human exposure). **Lactation:** Risk Summary: There are no data on the presence of semaglutide or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Semaglutide was present in the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk *(see Data)*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for WEGOVY® and any potential adverse effects on the breastfed infant from WEGOVY® or from the underlying maternal condition. Data: In lactating rats, semaglutide was detected in milk at levels 3-12 fold lower than in maternal plasma. **Females and Males of Reproductive Potential:** Because of the potential for fetal harm, discontinue WEGOVY® in patients at least 2 months before they plan to become pregnant to account for the long half-life of semaglutide *[see Use in Specific Populations]*. **Pediatric Use:** The safety and effectiveness of WEGOVY® as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management have been established in pediatric patients aged 12 years and older with a BMI corresponding to ≥95th percentile standardized for age and sex. Use of WEGOVY® for this indication is supported by a 68-week, double-blind, placebo-controlled clinical trial in 201 pediatric patients aged 12 years and older with a BMI corresponding to ≥95th percentile for age and sex and from studies in adult patients with obesity. Adverse reactions with WEGOVY® treatment in pediatric patients aged 12 years and older were similar to those reported in adults. Pediatric patients aged 12 years and older treated with WEGOVY® had greater incidences of cholelithiasis, cholecystitis, hypotension, rash, and urticaria compared to adults treated with WEGOVY® *[see Adverse Reactions]*. There are insufficient data in pediatric patients with type 2 diabetes treated with WEGOVY® for obesity to determine if there is an increased risk of hypoglycemia with WEGOVY® treatment similar to that reported in adults. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In pediatric patients aged 12 years and older with type 2 diabetes, monitor blood glucose prior to starting WEGOVY® and during WEGOVY® treatment. When initiating WEGOVY® in pediatric patients aged 12 years and older with type 2 diabetes, consider reducing the dose of concomitantly administered insulin secretagogue (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia *[see Warnings and Precautions]*. The safety and effectiveness of WEGOVY® have not been established in pediatric patients less than 12 years of age. **Geriatric Use:** In the WEGOVY® clinical trials, 233 (9%) WEGOVY®-treated patients were between 65 and 75 years of age and 23 (1%) WEGOVY®-treated patients were 75 years of age and over. No overall differences in safety or effectiveness have been observed between patients 65 years of age and older and younger adult patients. **Renal Impairment:** No dose adjustment of WEGOVY® is recommended for patients with renal impairment. In a study in patients with renal impairment, including end-stage renal disease, no clinically relevant change in semaglutide pharmacokinetics was observed. **Hepatic Impairment:** No dose adjustment of WEGOVY® is recommended for patients with hepatic impairment. In a study in patients with different degrees of hepatic impairment, no clinically relevant change in semaglutide pharmacokinetics was observed.

OVERDOSAGE: Overdoses have been reported with other GLP-1 receptor agonists. Effects have included severe nausea, severe vomiting, and severe hypoglycemia. In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. In the event of an overdose of WEGOVY®, consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdosage management recommendations. A prolonged period of observation and treatment for these symptoms may be necessary, taking into account the long half-life of WEGOVY® of approximately 1 week.

More detailed information is available upon request.

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark

For additional information about WEGOVY® contact: Novo Nordisk Inc., 800 Scudders Mill Road, Plainsboro, NJ 08536, 1-833-934-6891

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PATENT INFORMATION: http://www.novonordisk-us.com/products/product-patents.html

wegovy®
semaglutide injection 2.4 mg

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Illustartion by Chiara Vercesi

PATIENT ENGAGEMENT

Implementing **lifestyle therapy**

Experts in behavioral change discuss how to motivate your patients to adopt—and maintain—better habits, with the goal of improving their health as well as quality of life.

Research suggests that, on average, about 70% of patients are not able to adequately adhere to the lifestyle modifications recommended by their healthcare provider—a higher percentage than even nonadherence to medication, typically estimated at 50%. While motivating patients to adopt, and maintain, healthier habits is no easy task, you are uniquely positioned to empower them to take control of their health. Case in point: A study of patients with hypertension found that trust in their healthcare provider predicted attempts to lose weight and influenced their attempts to reduce salt and increase exercise.[1]

Add to that the knowledge gained from behavioral research, recent insights into patient motivators and access to technology aids, and there are several strategies you can use to inspire change and help facilitate better outcomes. Experts suggest the following:

Continued on next page ►

"WE STRESS THAT MODERATION IS KEY. IT IS DIFFICULT TO STAY ON ANY DIET WITH TIGHT RESTRICTIONS—BUT A HEALTHY EATING PLAN WITH OCCASIONAL TREATS IS MORE SUSTAINABLE LONG-TERM."

—Dorothy M. Davis, MSN, APRN, FNP-C

Share your own struggles

Dorothy M. Davis, MSN, APRN, FNP-C, Senior Clinical Nurse at Johns Hopkins Hospital and an expert in lifestyle modification, knows exactly how hard it can be to adopt better habits: In 2012, she committed to getting healthier and lost 70 lbs. by choosing healthier foods, reducing portion sizes and starting an exercise program. When working with her patients, Davis often shares this information to connect with them. "I use my personal story to help motivate patients, as well as reinforce that they can do this, and say, 'I know it's hard. I've been there. I struggled. I still struggle.'"

While not every healthcare provider has faced the same challenges as their patients, just sharing how you adopted a healthier habit may be a benefit, says Davis. For example, "It's really hard to quit drinking soda. So I tell them my story about how I went from regular to diet soda. And then eventually I dropped the diet soda for sparkling water if I wanted the carbonation." This is a simple yet powerful way to inspire patients, Davis says. "It builds trust, and patients often appreciate that we have that in common, we are human, we are not perfect and we all struggle."

Shift the focus to health

In conversations with patients, put the emphasis on overall wellness, suggests Traci Mann, PhD, a professor of health psychology at the University of Minnesota's Health and Eating Lab. "Healthy behaviors, such as eating fruits and vegetables, moving more, minimizing alcohol and not smoking, will improve everyone's health, no matter what they weigh, even if they don't lose many pounds by doing them," notes Mann. "These habits don't make you healthier just because they make you thin. They work because they promote overall health." Therefore, the better goal is striving for improved markers such as decreased blood pressure, lipids and AlC as well as increased energy and better sleep.

Discuss barriers and how to overcome them

Davis advises asking patients about individual barriers, such as cultural or emotional ties to certain foods or lack of access to a gym. "Sometimes, we don't understand that it's not as simple as trying to eat better—maybe they can't afford the healthier options in the grocery store. Trying to understand our patients and meeting them where they are is important, so we can help them find easy things to do," notes Davis. For example, she says that if patients lack access to fresh vegetables or can't afford them, suggest low-sodium canned vegetables at more cost-effective markets such as Aldi or Dollar stores, and remind them to rinse canned vegetables well before use to reduce sodium content. Another option is frozen fruit, which is usually cheaper and lasts longer than fresh fruit.

Reframe the weight-loss conversation

Mann suggests that dieting can actually be an obstacle to long-term weight management, citing a prospective population study that found people who had dieted over 10 years gained more weight than people who had simply eaten regularly.[2] And it's interesting to note that researchers identified one factor that did help curb weight gain: having high life satisfaction. Mann uses this same idea, advising people to aim for "your leanest livable weight—a weight you can maintain while having a normal life. If it's a weight you can't maintain, that is not your leanest livable weight."

Take advantage of technology

Research has shown that mobile-based digital platforms can help reinforce healthy behaviors and impact the efficacy of lifestyle therapy.[3] One tool for patients to consider is a food-tracking app, such as MyFitnessPal and Lose It!, to become more aware of what and how much they're eating.

There are also free fitness apps such as HASFit (Heart and Soul Fitness), which offer home workouts and modified exercises for seniors, and pedometer apps (e.g., Pacer) that can track daily steps to help encourage more movement.

Other great options include apps for stress reduction. While meditation apps may work for certain patients, Mann often recommends breathing apps such as Breathe2Relax. The reason: Meditation can feel intimidating to some people, but the simple act of deep, slow breathing, which can help lower heart rate, blood pressure and cortisol levels, may feel more accessible.

Simplify fitness goals

Most patients understand that exercise is important for managing their weight and related health risks, but incorporating workouts into their daily schedule can be challenging. In such cases, suggest they focus on sitting less throughout the day. Taking frequent breaks for a quick stroll around their workplace is one example. Davis encourages patients to track their steps and aim for 10,000 a day, which equals approximately 5 miles. Breaking up exercise into chunks can also make it easier. If a patient's goal is 30 minutes, she says, "We suggest, 'Maybe you could do 10 minutes in the morning, 10 minutes at lunch and 10 minutes when you get home—then you've done your 30 minutes for the day.'"

Tailor strategies to improve eating habits

Following a specific dietary regimen for losing weight and improving weight-related complications isn't easy for many patients. In such cases, Davis offers these suggestions:

- ***Narrow the scope.*** It's important that patients don't feel overwhelmed, says Davis. "We ask each patient to choose one or two areas of their diet to work on—and we never ask a patient to completely overhaul their eating habits at the initial consultation."
- ***Look at frequency.*** Rather than giving up their favorite foods completely, she suggests guiding patients to reduce the amount and frequency—for example, going from having chips four days a week to three, then two, etc. "I find this to be helpful for patients because they don't feel as though they are giving up what they love completely."
- ***Suggest reaching for water first.*** "Our brain does not differentiate between thirst and hunger; it is the same signal for both," notes Davis. "I ask a patient to drink a glass of water when they feel hungry, wait 20 minutes and then if still hungry have a healthy snack like nuts, fruit, veggies and hummus."
- ***Emphasize that perfection is not the goal.*** "We stress that moderation is key to any sustained healthy lifestyle," Davis says. "Will they never eat pizza or cake again? No, we are humans and it is difficult to stay on any diet with tight restrictions—but a healthy eating plan with occasional treats is more sustainable for us long-term." ●

—by Beth Shapouri

Illustartion by Chiara Vercesi

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PATIENT: SAM, 54, WEIGHED 288 LBS. WITH A BMI OF 40. HE HAD COMPLICATIONS, INCLUDING PREDIABETES AND METABOLIC SYNDROME

"He was at very high risk of progressing to type 2 diabetes"

PHYSICIAN:

Karl Nadolsky DO, FACE

Diplomate, American Board of Obesity Medicine; Assistant Clinical Professor of Medicine, Michigan State University; Chair, AACE Obesity & Nutrition Disease State Network

History:
Sam was referred to me for obesity management after years of dietary and exercise efforts with minimal weight reduction response and continued progression of complications. At his initial exam, his weight was 288 lbs. and his BMI was 40 kg/m2. He had at least a 4-year history of prediabetes (most recent A1C 6.4%, fasting blood glucose 124 mg/dL, 2-hour glucose tolerance test 196 mg/dL, but a fasting BG of 109 mg/dL around age 50). He also had metabolic syndrome and was taking an ARB for hypertension and a statin for dyslipidemia. Sam tried metformin for prediabetes and weight loss but suffered GI effects and had minimal benefit.

Further evaluation showed his AST was 48 and ALT 88 U/L, respectively, along with a platelet count of 210. When considering his high risk of hepatic steatosis, these data allowed us to calculate an FIB-4 of 1.32 points putting him at an intermediate-range risk for advanced fibrosis from MASLD/MASH (previously known as nonalcoholic steatohepatitis or NASH). Sam was overweight as a child, but he improved in adolescence with exercise from sports and dietary efforts. He gained weight in college despite playing sports and continued gaining weight after starting a sedentary office job. He went on a ketogenic diet but could not adhere to the lower- or higher-fat versions. Sam also tried intermittent fasting and time-restricted eating, but his hunger derailed his efforts and led him to binge on snacks.

Initiating treatment:
Sam's prediabetes and metabolic syndrome with likely MAFLD meant he was at very high risk of progressing to type 2 diabetes along with the complications of atherosclerotic cardiovascular risk, cirrhosis and hepatocellular carcinoma. The data for GLP-1 receptor agonists (GLP-1 RAs) confirm these agents are effective for weight loss and help delay or prevent the progression to type 2 diabetes. In addition to the nutrition modifications, we discussed including GLP-1 RAs in his treatment plan. Sam lost 17 lbs. during the 2-month titration phase of the GLP-1 RA. After 3 months, he lost a total of 49 lbs. with improved overall well-being. He also had a good exercise routine. He said he was able to adhere to a dietary plan without significant hunger. He continued to lose weight slowly while also feeling like he was retaining muscle and strength in the gym. After 12 months, Sam's weight was stable at 230 lbs., and his A1C was 5.6%. His blood pressure normalized and he was able to stop his antihypertensive medication. Sam lost >10% of his body weight, and he had a low risk for advanced fibrosis.

Considerations:
Sam's case illustrates that obesity may drive significant cardiometabolic complications that can be dramatically improved with weight reduction, good nutrition, exercise and medication. GLP-1 RAs play an important role for patients who have obesity with a high risk of complication progression. It should be strongly considered in patients with multiple metabolic syndrome components, prediabetes and/or NAFLD, as the clinical benefits of weight reduction and metabolic improvements are so robust.

NEW!
KOL ON DEMAND VIDEO
Scan here for more insight on Sam's case.

PATIENT: TERESA, A 34-YEAR-OLD HISPANIC WOMAN, HAD SEVERAL OBESITY-RELATED CONDITIONS THAT WERE AFFECTING HER ABILITY TO CONCEIVE.

"Teresa was motivated to lose weight because of fertility issues"

History:
When Teresa came to me, she was at her highest weight of 260 lbs., with a BMI of 46.1. Our workup confirmed prediabetes (A1C 6%, fasting plasma glucose 120) and dyslipidemia. She was referred to our clinic by a hospital bariatric surgery program for evaluation and presurgical preparation. She also had a history of obesity-related comorbidities in addition to prediabetes, including PCOS, infertility and depression. Teresa tried many diets in high school and college with modest weight loss followed by regain. She was motivated to overcome obesity because she and her husband were trying to get pregnant, and a fertility specialist told her losing weight would help her to conceive. She also was afraid of developing diabetes because her grandmother died from diabetes complications.

Teresa reported walking at least 30 minutes a day, 5 days a week, and being active at work, where she was an RN at a nursing home. She described her diet of "typical Mexican food," which included tortillas and eggs or a pastry for breakfast with juice. Her lunch and dinners consisted of rice, beans, salsa and animal protein. She also consumed 5 sugar-sweetened beverages daily and ate dessert and snacks after dinner while watching TV. Her Patient Health Questionaire-8 suggested moderate depression, which Teresa attributed to problems getting pregnant and frustration with her weight. She felt degraded by her former PCP who recommended she do "push-aways" and "isometric jaw strengthening," which he laughingly explained meant, "push away from the table and strengthen your jaw so it stays shut."

Initiating treatment:
Teresa and I discussed various interventions to develop a treatment plan using shared decision-making. First, I referred her to a bariatric surgical program for cognitive behavioral therapy to prepare for possible surgery. We also discussed the risks and benefits of medication, and she started an agent but discontinued it due to side effects. Teresa elected to try another medication and increase her physical activity. We created a plan for her emotional eating, which included talking with her husband or friend, taking walks outside and journaling. She also stopped buying comfort foods.

Teresa recognized that her diet was highly processed, so she started meal-prepping with her husband. They made her favorite meals with an 1,800 caloric deficit daily, which incorporated protein, good fats and healthy carbohydrates. She joined a group exercise program and bought a wearable fitness device to track calories and activity. Teresa was highly motivated and engaged with the treatment plan, which led to a 38-lbs. weight loss over 6 months. Her glucose metabolism normalized, lipids improved and depressive symptoms resolved. To achieve further weight loss with the goal of getting pregnant, Teresa then had a sleeve gastrectomy and continued care with the bariatric service. Twenty months post-op (and a nearly 100-lbs. weight loss), Teresa had a healthy baby girl without complications or weight regain.

Considerations:
Teresa's case illustrates the success of a personalized, multifaceted approach to obesity treatment, integrating physical activity, nutrition, behavioral health and pharmacotherapy. It also shows the benefits of bariatric surgery for certain patients. Additionally, there is a cautionary tale here for clinicians to be aware of possible negative biases toward patients who have had a lifelong struggle with overweight or obesity.

CLINICIAN:

Thomas George, Jr., DNP, CRNP, FNP-C

Assistant Professor, Frontier Nursing University; Doctor of Nursing Practice, Wellspring Family Medicine, Oakland, MD

Illustrations by Juhee Kim

Q A

Expert insight on managing overweight/obesity

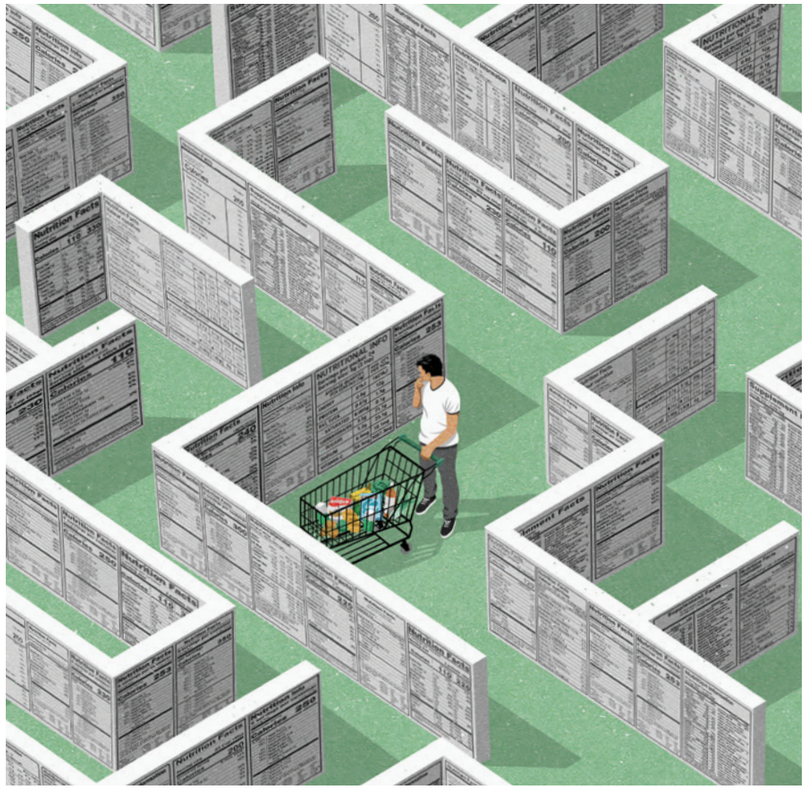

illustration by John Holcroft / Ikon Images

Overcoming food insecurity

Q: How do you help patients who rely on processed and fast food because of cost or lack of access to healthy food?

A: I work primarily in rural, underserved areas where people buy fast, packaged or prepared foods rather than healthier options. Most of our patients are surprised to learn that they can prepare and eat healthier meals while saving money and time. Planning meals for the week is one way to reduce costs. I encourage patients to make a shopping list based on their meal plan and look for deals and coupons for healthy foods. For example, a whole chicken costs less per pound than individual pieces. Buying non-perishable or dried ingredients like rice, legumes and other staples saves money in the long run. Frozen vegetables and fruit are often less expensive than fresh, store easily and have good nutritional value. Store brands are also cheaper than advertised products, and shopping in bulk for low or non-processed foods is equally cost effective.

Healthy meals made in advance save time and money and are a better option than grabbing a burger at the drive-through. Leftovers can also be repurposed. Sunday's roasted chicken, brown rice and vegetables can become Monday's stir fry. A pot of steel-cut oatmeal can be portioned and reheated on busy mornings. Top with Greek yogurt, berries and almonds and you have a nutritionally balanced breakfast that costs less than fast food.

I challenged myself to create delicious and nutritious recipes within a budget using ingredients found at a Dollar store, online and at farmer's markets. (Farmer's markets often sell fresh produce and proteins for less than some retail stores.) Tell your food-insecure patients to buy locally and in season whenever possible. The lunch and dinners we made averaged $3 per person and took less than 30 minutes to prepare. I shared my recipe for a chickpea stew with several patients, who told me it has become a family favorite.

*–**Thomas George, Jr., DNP, CRNP, FNP-C,** Assistant Professor, Frontier Nursing University; Doctor of Nursing Practice, Wellspring Family Medicine, Oakland, MD*

Managing stress

Q: What do you recommend to patients for managing daily stressors that trigger overeating?

A: For most of my patients, stress is rooted in time challenges, financial constraints, work environment or relationship issues. I encourage patients that writing down stressors that may cause them to overeat can be a powerful exercise. Another way to reduce emotional eating is to remove calorically dense snacks from the pantry. Prepare some meals that are less calorically dense and store them in the freezer. This will reduce the temptation to binge on comfort food and make healthier choices instead. Swap food rewards with focused meditation, breathing exercises, yoga or walks in the park.

Also, the brain creates cravings (usually for sugar, fat or both) that blunt the relaxation response and trigger the reward center. To help build stress resilience, lifestyle interventions, such as getting restorative sleep (optimally 7.5 hours), will improve mood and strengthen executive function, all of which helps to overcome emotional eating. The immediate and long-term benefits of regular, moderately intense physical activity have also been proven to reduce stress, build resilience and decrease cortisol levels that can contribute to weight gain.

Finally, I try to encourage my patients who have emotional eating patterns to practice mindful eating and portion control. Mindful eating allows them to recognize their thoughts, emotions and sensations while slowing the rate of food intake, which improves satiety and enhances taste.

*–**Thomas George, Jr., DNP, CRNP, FNP-C***

Counseling on titration

Q: How do you respond when patients don't lose much weight after starting obesity medication?

A: Currently, we are fortunate to have many different obesity medications approved by the FDA that help our patients lose weight, in conjunction with dietary and lifestyle modifications. There is a wide variability in terms of the amount of weight loss that can be seen depending on the class of medication used. When added to lifestyle modifications, weight loss can range anywhere from 5% to as high as 22.5%. I always counsel my patients that most of the medications require titration, and I emphasize the importance of staying in touch with me to let me know if they are tolerating the medication and are ready for an increase in dose. I would recommend that if patients do not lose 4-5% of their body weight after 12 weeks of therapy at the maximum tolerated dose, an alternate medication should be considered. It's extremely important to tailor the choice of obesity medication to the individual patient and to let patients know you are on the journey to a healthier body weight with them.

*–**Rachel Pessah-Pollack, MD, FACE,** Clinical Associate Professor of Endocrinology, Diabetes and Metabolism, NYU Langone Health*

Special thanks to our medical reviewer:
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Health Monitor

Clinician Update

EXAM TOOL

Screening for overweight/obesity

The American Association of Clinical Endocrinology recognizes obesity as a chronic disease and recommends annual screening of BMI and other health parameters. When a patient presents with excess weight, use the checklist below to gauge the need for medical intervention, including lifestyle therapy and, when appropriate, obesity medication or surgery. And keep in mind: The success of treatment should be measured not solely by number of pounds lost but also by improvements in weight-related complications and overall health.

1. **Does the patient have a body mass index (BMI) and weight-related complications that meet indications for prescribing obesity medication?**

- ☐ **BMI ≥30** (obesity) (all BMI cutoffs may be lower in certain ethnicities)
- ☐ **BMI ≥27** (overweight) with at least one weight-related complication, such as:
  - Prediabetes or type 2 diabetes
  - Metabolic syndrome
  - Hypertension
  - Dyslipidemia
  - Cardiovascular disease
  - Nonalcoholic fatty liver disease
  - Obstructive sleep apnea
  - Asthma/reactive airway disease
  - Osteoarthritis
  - Hormonal issues (e.g., polycystic ovarian syndrome)
  - GERD
  - Urinary stress incontinence

2. **If BMI <35, is waist circumference indicative of cardiometabolic disease (use gender- and ethnicity-specific cutoffs)?**

- ☐ **Women: ≥35 inches**
- ☐ **Men: ≥40 inches**

3. **Has the patient attempted lifestyle therapy, including nutritional and behavioral changes and increased physical activity)?**

- ☐ **Yes;** measures tried: _____
- ☐ **No**

4. **Is the patient aware obesity is a chronic disease caused by genetic, metabolic, behavioral and environmental factors?**

- ☐ **Yes**
- ☐ **No**

5. **Is the patient motivated to set weight-loss goals and work with you on a personalized treatment plan?**

- ☐ **Yes**
- ☐ **No**

Note: For detailed recommendations on weight management, see Garvey WT, et al. AACE/ACE Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. *Endocrine Practice.* 2016;22(suppl 3):1-203.