



Roadmaps for Clinical Practice

Case Studies in Disease Prevention and Health Promotion

Assessment and Management of Adult Obesity:

A Primer for Physicians

Pharmacological
Management

6

Pharmacological Management

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Medical care is determined on the basis of all the facts and circumstances involved in an individual case and is subject to change as scientific knowledge and technology advance and patterns of practice evolve. This publication reflects the view of the experts and reports in the scientific literature as of 2003.

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Preface

In the United States, increasing trends in morbidity and mortality related to chronic diseases and injuries have led the American Medical Association (AMA) and others to address strategies for promoting health and preventing disease and disability. Over the past decade, the AMA has launched national campaigns against violence, alcohol abuse, and tobacco use. Recently, the AMA launched national programs to address low health literacy, patient safety, and disparities in health services and outcomes.

To further address the health challenges facing our nation, the AMA is developing a series of case-based publications for physicians as part of a new program titled *Roadmaps for Clinical Practice: Case Studies in Disease Prevention and Health Promotion*. The Roadmaps project fulfills an AMA and US Department of Health and Human Services (DHHS) partnership established through a Memorandum of Understanding (MOU) signed by both organizations in the year 2000. The series concentrates on the *Healthy People 2010* objectives, which were developed by the US Public Health Service to help professionals address the leading causes of morbidity and mortality in this country. The series also supports the goals of the DHHS *HealthierUS* initiative which was established in 2003 to help Americans lead longer, better, and healthier lives. This primer, produced with support from The Robert Wood Johnson Foundation, is part of the Roadmaps series.

The Roadmaps series aims to help physicians prevent or reduce injury and chronic disease through early detection and disease management in addition to promoting healthier lifestyles through their medical practices and communities. Emphasis is directed at promoting personal behaviors that have both immediate and long-term health benefits and at modifying behaviors that cause the greatest burden of suffering. According to the US Preventive Services Task Force, counseling patients about personal health practices (smoking, diet, physical activity, drinking, injury prevention, and sexual behavior) remains one of the most underused but important parts of the health visit.

This primer focuses on the rising prevalence of a serious, chronic health condition—obesity. Two weight-linked behaviors—physical inactivity and unhealthy eating—are given important consideration. It is estimated that 300,000 preventable deaths occur each year in the United States due to diet and physical inactivity, both of which contribute to obesity—only tobacco use causes more preventable deaths in this country. Growing scientific consensus on the health risks of physical inactivity and improper diet mandates that physicians become informed and prepared to assist patients in leading more active and healthy lives. Physicians have an important opportunity to encourage improvements in health behaviors and outcomes, including influencing motivation and success with weight loss treatment. **It is never too late to start and have a favorable impact on health. Patients of all ages can and will benefit.**

We encourage you to review this primer and to participate in the accompanying continuing medical education (CME) program. Please also take some time to complete and return the evaluation form that accompanies this primer. Your feedback is valuable for updating this publication and for planning future physician education programs. We invite you to use these resources and take action—in your practice and community—to promote healthier lifestyles among your patients, colleagues, and neighbors.

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Objectives

This primer is designed to educate primary care physicians about providing medical care to overweight and obese adults. It is presented in a modular format to facilitate its use as an educational and teaching tool. Patient scenarios are included for self-evaluation and to reinforce information presented. A continuing medical education (CME) component worth 4.5 credit hours is also offered. After completing this program, physician participants should be able to:

- identify overweight and obesity in their patients
- describe the medical and public health implications of adult overweight and obesity and identify opportunities for patient, family, and community intervention
- incorporate assessment and management of adult overweight and obesity into their clinical practices
- identify specific patient comorbidities and health risks that are caused and/or exacerbated by overweight and obesity that may interfere or even contraindicate treatment
- understand the appropriate application of diet, physical activity, behavior changes, pharmacotherapy, and surgery in obesity treatment
- locate information about culturally and linguistically appropriate strategies and resources to prevent and treat adult overweight and obesity
- enhance personal and office practices to optimize sensitivity to the needs and concerns of overweight and obese patients

This primer is not intended to function as a clinical guideline, standard of care, or definitive resource for the assessment and management of obesity. However, more detailed information is available in the references and resources listed in each booklet of this primer.

Case presentation

Julia, a 38-year-old Native American woman, has progressively gained 38 pounds since graduating from college. When she initially visited your practice, she weighed 204 pounds and was 65 inches in height, corresponding to a body mass index (BMI) of 34, or Class I (mild) obesity. She developed hypertension 3 years ago, and it has been well controlled with a diuretic agent and angiotensin converting enzyme (ACE) inhibitor.

Six months ago, Julia expressed an interest in losing weight to improve her body image and health. She began working with you and your staff to control portion sizes, choose lower calorie foods, develop a more structured eating pattern, and begin a daily walking program. She has successfully lost 12 pounds over 5 months, representing 6% of her initial body weight, and was able to discontinue the ACE inhibitor medication with good blood pressure control.

In the past month, however, Julia has not lost any more weight, and she states that she is “struggling” to control portion sizes. She recalls gaining weight after previous diets and doubts whether she can maintain the effort required for further weight loss and maintenance. Julia asks if there are additional treatment options that can help her improve her chances of losing another 10 pounds and discontinuing the diuretic antihypertensive medication.

T

he cornerstone of obesity treatment is lifestyle management that incorporates three essential components: dietary therapy, physical activity, and behavior therapy. Research indicates that the combination of these modalities results in an average of 8% weight loss after 6 months of treatment.¹ However, many patients have difficulty adopting and maintaining new lifestyle patterns. This eventually thwarts their weight loss efforts, resulting in weight regain and feelings of failure. For these patients, the adjunctive use of anti-obesity medications to augment their treatment may be useful.

Prescribing pharmacological treatment for patients assessed at high risk and for whom dietary and physical activity therapy has not been successful is commonly applied to many other chronic disease states treated by the primary care physician, including cholesterol-lowering agents, antihypertensives, and antidiabetic drugs. However, many physicians remain wary of prescribing anti-obesity medications

due to limited experience using these agents, concern over lack of safety data regarding long-term therapy, a general lack of knowledge about obesity in general, and concern about weight regain once the medications are discontinued. Despite this uncertainty, anti-obesity medications are more widely used today than in the early 1990s² and more agents are likely to become available in the coming decade.

This booklet addresses these concerns and reviews the appropriate use of pharmacological agents for the treatment of obesity.

Who should be considered for medication therapy?

According to the National Heart, Lung, and Blood Institute (NHLBI) *Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*¹ and the US Food and Drug Administration (FDA), pharmacotherapy is indicated for:

- obese patients with a BMI ≥ 30 or
- overweight patients with a BMI of ≥ 27 and concomitant obesity-related risk factors or diseases, such as hypertension, diabetes, or dyslipidemia.

However, the BMI threshold is only one part of the criteria for medication treatment. For patients who meet BMI criteria, pharmacotherapy should be considered only if they:

- will be taking the medication in conjunction with an overall weight management program, including a reduced-calorie diet and increased physical activity
- have realistic expectations of medication therapy
- do not have other medical conditions or take other medications that are a contraindication for obesity drugs

Successful use of anti-obesity medications requires that patients deliberately and consciously alter their behavior for weight loss to occur. In other words, the pharmacological action of anti-obesity medications must be *translated* into behavior change. For example, patients taking anorexiant must translate a reduced sense of hunger/increased satiety into eating smaller meals, reducing snacking,

and choosing the right foods. Failure to do so will result in modest or no weight loss. Similarly, if patients do not limit consumption of dietary fat when taking an intestinal fat-blocking agent, they will discontinue the medication because of intolerable side effects.

In this way, there is a bi-directional, mutually beneficial relationship between anti-obesity medications and lifestyle management, each therapy enhancing the efficacy of the other. The importance of adding lifestyle modification therapy and a portion-controlled diet to pharmacological treatment has been demonstrated in a prospective 1-year randomized study.³ After 12 months of treatment, subjects in the medication-alone group lost only 4.1% of initial body weight compared to 16.5% weight loss in the group that received medication in addition to behavior modification therapy and a 1000-kcal/d portion-controlled diet for the first 4 months.³

When should I consider medication therapy?

The criteria listed above are used to determine whether patients are eligible for medication therapy. However, other factors should be considered for deciding when in the course of treatment pharmacotherapy may be implemented. These include:

- When patients are unable to achieve weight loss despite their best use of lifestyle approaches to diet, physical activity, and behavioral changes.

The National Heart, Lung, and Blood Institute *Guidelines* state that medication may be considered if patients have not lost 1 lb/week after at least 6 months of lifestyle modification. However, in practice, the actual timing of medication use can be individualized based on clinical judgment. At the same time, it is important to carefully re-evaluate patients for causes of minimal or no weight loss, including use of weight-gaining medications, certain medical conditions, impeding psychosocial factors (see Booklet 2: *Evaluating Your Patients for Overweight or Obesity*), or low readiness and motivation (see Booklet 3: *Assessing Readiness and Making Treatment Decisions*).

- When patient weight plateaus before goal weight is attained. In this case, medication may potentiate weight loss by augmenting satiety/reducing hunger signals or reducing fat absorption.

Julia's BMI after her initial weight loss is 32, which makes her eligible for pharmacotherapy according to NHLBI Guidelines. The two of you discuss pharmacotherapy as a treatment option, and she expresses the hope that it will help her sustain motivation and enable continued weight loss. Julia understands that she will need to continue lifestyle modifications during the course of this medication therapy.

What medications are available for use?

Three general classes of medications are currently approved by the FDA for treating obesity (see Figure 6.1):

1. sympathomimetic medications approved for long-term use
2. gastrointestinal (GI) lipase inhibitors
3. sympathomimetic medications approved for short-term use

The first two classes, represented by sibutramine and orlistat, respectively, have both undergone long-term (at least 2 years) study and are approved by the FDA for the management of obesity, including weight loss and maintenance of weight loss.

Sibutramine (marketed as Meridia®) acts as an appetite suppressant. It is a Schedule IV anorexiant medication that is not pharmacologically related to amphetamine and does not have any addictive effects. As a serotonin norepinephrine reuptake inhibitor (SNRI), it suppresses appetite primarily by increasing satiation (ie, feeling of fullness). Its ability to increase thermogenesis (increased energy expenditure) as an additional weight loss effect is less clear. Sibutramine was approved by the FDA in 1997.

Orlistat (marketed as Xenical®) blocks the digestion and absorption of about one-third of dietary fat ingested. It is a potent, slowly reversible inhibitor of pancreatic, gastric, and carboxylester lipases and phospholipase A₂, which are required for the hydrolysis of dietary fat in the GI tract. Medication activity occurs in the lumen of the stomach and small intestine, with less than 1% of the drug being absorbed into the body. Taken at a therapeutic dose of 120 mg three times per day at time of meals, orlistat blocks the digestion and absorption of about 30% of dietary fat consumed at the time of drug administration. Orlistat was approved by the FDA in 1999.

Figure 6.1 Guide to Weight Loss Medications

Drug group	Approved treatment duration	DEA schedule	Trade names	Dosage form	Administration	Cost
Sympathomimetic drug approved for long-term use (serotonin-norepinephrine reuptake inhibitor)						
Sibutramine	Long-term	IV	Meridia®	5,10,15 mg	Initial dose: 10 mg/d Maximum dose: 15 mg/d	Approximately \$90-\$110 for 30-day supply
Pancreatic lipase inhibitor						
Orlistat	Long-term	V	Xenical®	120 mg 3 times daily	Maximum dose: 120 mg 3 times daily	Approximately \$120-\$130 for 30-day supply
Sympathomimetic drugs approved for short-term use (norepinephrine reuptake inhibitors)						
Phentermine	Few weeks	IV	<i>Standard release:</i>			Approximately \$35-\$85 for 30-day supply
			Generic available		30 mg/d 2 hours after breakfast	
			Adipex-P®	37.5 mg	37.5 mg in morning	
			Fastin®	30 mg	30 mg/d 2 hours after breakfast	
			Obenix®	37.5 mg	37.5 mg/d 9 am	
			Oby-Cap®	30 mg	30 mg/d 2 hours after breakfast	
			Oby-Trim	30 mg	30 mg/d 2 hours after breakfast	
Zantryl®	30 mg	30 mg/d 2 hours after breakfast				
<i>Slow release:</i>						
			Ionamin®	15,30 mg	15 mg/d before breakfast (30 mg for less responsive patients)	

Adapted with permission from Bray G. Contemporary Diagnosis and Management of Obesity. Handbooks in Health Care Co., Newton, Pa;1998.

Phentermine, a centrally acting anorectic drug, is an amphetamine derivative.* Phentermine increases the amount of norepinephrine (NE) in the neuronal cleft, resulting in appetite suppression (anorexia) and decreased food intake. However, unlike amphetamine, it has little or no effect on dopaminergic neurotransmission, thus minimizing the risk of euphoria.⁴ The development of drug tolerance, a characteristic feature of amphetamine and other drugs in this class, is commonly reported by patients after a few weeks or months. In contrast to benzphetamine and phendimetrazine, which are classified by the Drug Enforcement Agency (DEA) as Schedule III drugs (some potential for abuse), diethylpropion and phentermine are DEA Schedule IV drugs (low potential for abuse) and are marketed under several trade names. Phentermine, originally approved by the FDA in 1959, is currently the most commonly prescribed anti-obesity drug.²

Sibutramine

What are the benefits and risks of therapy with sibutramine?

Sibutramine has been studied in multiple double-blind, placebo-controlled obesity trials with study durations of 12 to 52 weeks and in one 2-year study.^{5,6} In these trials, subjects randomized to sibutramine:

- lost more weight on medication compared to placebo — weight loss at 6 to 12 months was approximately 6% to 8% on medication, compared to 1% to 2% for placebo;
- typically achieved maximal weight loss by 6 months; and
- maintained weight loss or slowed weight regain as long as they continued medication therapy.

These trials also indicated that an early response to medication is predictive of longer term effect. Among patients who lost at least 4 pounds in the first 4 weeks of therapy, approximately 60% had a

* Amphetamine-derived medications (including benzphetamine, phendimetrazine, diethylpropion, and phentermine) have been available for decades but are FDA approved only for short-term use. Between 1994 and 1997, phentermine was commonly prescribed along with fenfluramine—a combination dubbed “phen-fen” by the general public. In 1997, fenfluramine, along with dexfenfluramine (Redux®), were withdrawn from the market due to the reported occurrence of serious regurgitant cardiac valvular disease and pulmonary hypertension.

beneficial effect at 6 months. This is in contrast to those patients who did not lose at least 4 pounds within the first month; approximately 80% did not achieve benefit (benefit is defined as a placebo-subtracted weight loss of >5%).⁵

Two-year data on sibutramine use are available from the Sibutramine Trial of Obesity Reduction and Maintenance (STORM) Study Group.⁷ In this trial, all patients were prescribed sibutramine 10 mg/day (open label), along with a calorie-controlled diet and physical activity for the first 6 months. Patients achieving >5% weight loss were then randomized to continue sibutramine or switched to a placebo (double-blind) for 18 additional months. At 24 months, mean weight loss was 22.5 pounds for the sibutramine group compared to 10.3 pounds for the placebo group, corresponding to 10% and 4.6% weight loss, respectively. Of the subjects who completed the study, 43% of sibutramine-treated and 16% of placebo-treated subjects maintained 80% or more of their original 6-month weight loss while still taking the medication.

Sibutramine has several commonly reported side effects, which are generally mild and well tolerated. These include:

- headache 30.3%
- dry mouth 17.2%
- insomnia 10.7%
- constipation 11.5%

The principal concern with sibutramine is a dose-related increase in blood pressure and heart rate that must be monitored closely and may require discontinuation of the medication. On average, a dose of 10–15 mg/day causes an:

- increase in systolic and diastolic blood pressure of 2 to 4 mmHg and
- increase in heart rate of 4 to 6 beats/min.

However, no cases of regurgitant cardiac valvular disease or primary pulmonary hypertension have been reported with this medication. (See Figure 6.2 for side effects and contraindications of sibutramine.)

Figure 6.2 Current FDA-approved Long-term Medications for Obesity

	Sibutramine (Meridia®)	Orlistat (Xenical®)	Phentermine (several names)
Mechanism of action	<ul style="list-style-type: none"> • Inhibits reuptake of serotonin and norepinephrine (SNRI) • Increases satiety (sense of fullness) 	<ul style="list-style-type: none"> • Gastrointestinal lipase inhibitor • Blocks absorption of one third of dietary fat 	<ul style="list-style-type: none"> • Stimulates release of norepinephrine • Decreases hunger
Dosing	<ul style="list-style-type: none"> • 5–15 mg once daily 	<ul style="list-style-type: none"> • 120 mg with each meal 	<ul style="list-style-type: none"> • 15, 30, or 37.5 mg once daily
Side effects	<ul style="list-style-type: none"> • Mean heart rate increase of 3–6 beats/min • Mean blood pressure increase of 1–3 mmHg • Headache • Dry mouth • Insomnia • Constipation 	<ul style="list-style-type: none"> • Oily stools • Increased defecation • Fecal urgency or incontinence • Flatus with discharge 	<ul style="list-style-type: none"> • Increased heart rate and blood pressure • Headache • Dry mouth • Insomnia • Constipation • Restlessness
Contraindications and safety concerns	<ul style="list-style-type: none"> • Monoamine oxidase inhibitors (MAOIs) • Other centrally active appetite suppressants and selective serotonin reuptake inhibitors (SSRIs) • Uncontrolled hypertension • Seizures • Coronary artery disease • Congestive heart failure • Arrhythmias • Stroke • Severe renal impairment or hepatic dysfunction 	<ul style="list-style-type: none"> • Chronic malabsorption syndrome • Other fat-soluble medications 	<ul style="list-style-type: none"> • Monoamine oxidase inhibitors (MAOIs) • Other centrally active appetite suppressants • Uncontrolled hypertension • Seizures • Coronary artery disease • Congestive heart failure • Arrhythmias • Stroke • Agitated states

How do I decide whether sibutramine is a good choice for my patients?

Positive factors

- patients have difficulty controlling portion sizes due to hunger or not feeling full; think often about food
- previous beneficial response to an anorexiatic agent
- gastrointestinal conditions such as irritable bowel syndrome that would make it difficult to take orlistat
- once-a-day dosing

Negative factors

- Medical contraindication. Patients with uncontrolled hypertension, coronary artery disease or angina, arrhythmias, congestive heart failure, stroke or transient ischemic attacks, seizure disorder, or severe kidney or liver disease should not take sibutramine.
- Drug interactions. Patients taking monoamine oxidase inhibitors (MAOIs) are an absolute contraindication. Caution should be used for patients on selective serotonin reuptake inhibitor antidepressants.

See Figures 6.2 and 6.3 for additional information on prescribing sibutramine.

Figure 6.3

American Medical Association
Physicians Individual in the Health of America

Form 613
Patient's Guide to Sibutramine

Patient name _____ Date _____

Your dose is _____ mg
Take _____(s) _____(s)

Do not change your dose.
Do not take any other medication(s), including over-the-counter or herbal medications, without consulting your physician.

Side effects	Week	Date	Systolic BP	Diastolic BP	Heart Rate
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
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Figure 6.3 and other reduced size figures are shown at full size beginning on page 24.

How do I initiate treatment with sibutramine?

The recommended starting dose of sibutramine is 10 mg once daily, with or without food. The dose should be taken in the morning to avoid any sleep disturbance.

Initiation of treatment includes telling patients how the medication works, what side effects they may experience, and what weight loss benefits to expect. The following sample script highlights the importance of dietary behavior in achieving success.

Following is a sample script for doctors to present to patients.

“Sibutramine (Meridia®) is absorbed into the body and travels to the appetite center in the brain. It works by helping you feel full. So if you respond, you’ll feel full sooner while eating your meal than you did before taking sibutramine. You’ll need to slow down your eating and pay attention to this feeling of fullness. Sibutramine helps you lose weight **only** if you stop eating when you feel full. Side effects may include headache, dry mouth, insomnia, and constipation.”

In reviewing the side effects, you may find it helpful to share the Patient’s Guide to Sibutramine with your patients (see Figure 6.3).

What needs to be monitored during sibutramine use?

Patients should return for a follow-up visit approximately 1 month after initiation of treatment. During this visit, measure body weight and vital signs and review side effects and intended effects. It is important to ask patients about their feelings of hunger and fullness on the medication.

Give careful notice to blood pressure and heart rate, because a significant increase in either may warrant lowering the dose or discontinuing the medication entirely.

At this time, the dosage of sibutramine may be maintained or increased as follows:

- If patients have a good response to medication — decreased hunger and/or early satiety, approximately 4 pounds weight loss, and minimal or no side effects — the medication can be continued at the same dose.
- If patients do not perceive a change in appetite and there is inadequate weight loss, the dose can be increased to 15 mg once daily.

Provided patients report minimal or no side effects, it is reasonable to evaluate patients every 1 to 2 months during the first 6 months of treatment. Perform similar assessment and dosage adjustments at each visit until weight stabilizes. One study suggests that intermittent therapy (3 months “on” and 6 weeks “off”) may be as effective as continuous treatment over a 48-week period.⁸ Doses greater than 15 mg are not recommended and are not approved by the FDA.

Orlistat

What are the benefits and risks of therapy with orlistat?

Multiple randomized, double-blind, placebo-controlled, parallel studies assessing the safety and efficacy of orlistat for weight loss and maintenance over 1 or 2 years have been published,⁹ in addition to one 4-year trial. In these trials, subjects randomized to orlistat:

- lost approximately twice as much weight on medication compared to placebo (9% to 10% of initial weight compared with a 4% to 6% weight loss in the placebo-treated groups) and
- typically achieved maximal weight loss by 6 months, with continued effects to the end of the study.

In addition, pooled data show that early weight loss (>3% of initial weight after 3 months) predicted weight loss at 12 months.

Because orlistat is minimally (<1%) absorbed from the gastrointestinal tract, it lacks systemic side effects. The tolerability of the medication is related to the malabsorption of dietary fat and subsequent passage of fat in the feces. Seven symptomatic gastrointestinal tract effects have been reported to occur in orlistat-treated patients:¹⁰

	Year 1	Year 2
• oily spotting	26.6%	4.4%
• flatus with discharge	23.9%	2.1%
• fecal urgency	22.1%	2.8%
• fatty/oily stool	20.0%	5.5%
• oily evacuation	11.9%	2.3%
• increased defecation	10.8%	2.6%
• fecal incontinence	7.7%	1.8%

The events are generally experienced early, diminish over time as patients moderate their dietary fat intake, and infrequently cause patients to withdraw from clinical trials. A recent study shows that psyllium mucilloid helps to control the orlistat-induced GI side effects when taken concomitantly with the medication.¹¹

Serum concentrations of the fat-soluble vitamins D, E, and beta-carotene have been found to be significantly lower in some of the trials, although they generally remain within normal ranges. The manufacturer’s package insert for orlistat recommends that patients take a multivitamin supplement to prevent potential deficiencies. (See Figure 6.2 for side effects and contraindications.)

In addition to weight loss, orlistat also has beneficial effects on serum cholesterol and low density lipoprotein (LDL)-cholesterol concentrations that are independent of weight loss alone. The mechanism is directly related to orlistat’s effect on dietary cholesterol absorption. Additional studies have shown that orlistat prevents the progression to the development of impaired glucose tolerance and Type 2 diabetes.¹²

How do I decide whether orlistat is a good choice for my patients?

Positive factors

- patients want additional motivation to adhere to a fat-modified diet
- elevated LDL-cholesterol
- contraindication to use sibutramine or another anorexiatic medication
- patients prefer not to take an anti-obesity medication that is systemically absorbed

Negative factors

- chronic malabsorption syndrome
- interaction with other lipophilic drugs, particularly with cyclosporine (If patients still choose to take orlistat, cyclosporine should be taken at least 2 hours before and after orlistat)
- dosing three times daily

How do I initiate treatment with orlistat?

The recommended dose of orlistat is one 120-mg capsule with each meal containing fat (during or up to 1 hour after the meal). It is preferable for patients to take the dose at the start of the meal because this “commits” them to eating less fat. The GI effects may occur 24 to 48 hours after administration, depending on intestinal transit time.

Initiation of treatment includes telling patients how the medication works, what side effects they may experience, and what weight loss benefits to expect. The following sample script highlights the importance of dietary behavior in achieving success.

Following is a sample script for doctors to present to patients.

“Orlistat blocks one-third of the fat in your food. So if you eat 30 grams of fat with lunch, orlistat will block 10 grams, and your body will only absorb 20 grams. You may see the blocked fat floating in the toilet bowl when you go to the bathroom. In order to tolerate orlistat, you need to eat less fatty foods, meaning less oils, margarine, butter, dressings, gravy, chips, fries, pizza, and so forth. In general, no more than 30% of the calories in your diet should come from fat. The side effects of the medication are directly related to the amount of fat you consume.”

When taking orlistat, patients should also take a daily multivitamin at least 2 hours before or after the administration of one of the orlistat doses. In prescribing the multivitamin and discussing side effects, you may find it helpful to share the Patient’s Guide to Orlistat with your patients (see Figure 6.4).

Figure 6.4

American Medical Association
Physicians dedicated to the health of America

Page 6.4

Patient's Guide to Orlistat

Patient name _____ Date _____

Your dose is _____ mg
Take _____ capsule(s) _____

Do not change your dose.
Do not take any other medication(s), including over-the-counter or herbal medications, without consulting your physician.

Side effects
You may experience one or more of the following side effects with orlistat. An increase in dietary fat may intensify side effects.

- Oily spotting
- Flatus with discharge
- Fecal urgency
- Fatty/oily stool
- Oily excretions
- Increased defecations
- Fecal incontinence

Vitamins
Take a multivitamin containing fat-soluble vitamins once a day (vitamins A, E, K, D) at least 2 hours before or after orlistat, such as at bedtime.

Adapted with permission from the Centers for Obesity Research and Education (C.O.R.E.)
The program was funded by the National Institutes of Health (NIH) through the National Center for Human Genome Research, November 2003. www.cerh.nih.gov

What needs to be monitored during orlistat use?

Patients should return for a follow-up visit approximately 1 month after initiation of treatment. During the visit, measure body weight and vital signs and review side effects and intended effects.

It is important to ask patients about GI effects and dietary intake of fat. Approximately 10% to 25% of patients experience a GI effect, such as oily spotting, flatus with discharge, fecal urgency, and fatty stool, at least once during the first 3 months of therapy. At this point, patients will verbalize whether this treatment approach is tolerable and desirable. It is important to re-emphasize the importance of following a reduced-calorie and fat-modified diet, taking the medication at meal time, and adding a multivitamin supplement.

If patients have lost less than 4 pounds or have gained weight, it is important to review in greater detail the fundamental aspects of treatment as follows:

Following is a sample script for doctors to present to patients.

“In order to lose weight, you need to reduce the total number of calories in your diet. The four sources of calories include fat, carbohydrates, protein, and alcohol. Orlistat partially blocks the absorption of only one of these sources — fat. As you eat less fat, you have to be careful that you are not eating more carbohydrates and protein or drinking more alcohol. If you do, you might actually take in more calories than before, so you will end up gaining weight. Be sure to pay attention to your entire diet, not just fat, and continue physical activity.”

It is reasonable to follow up with patients every 1 to 2 months over the first 6 months of treatment, quarterly thereafter.

Although sibutramine and orlistat have different mechanisms of action and may hypothetically produce an additive or even synergistic effect, one small pilot study found no additional benefit from combining the medications.¹³

Phentermine

What are the benefits and risks of therapy with phentermine?

Because phentermine was originally approved for short-term use only, there are no published studies of phentermine monotherapy beyond 9 months.¹⁴ Nonetheless, in the trials that have been reported, phentermine appears to be effective during use, causing a reduction in hunger and appetite.¹⁵

The development of drug tolerance, a characteristic feature of amphetamine and other drugs in this class, is commonly reported by patients after a few weeks or months. Side effects include those associated with central nervous system stimulation, ie, elevation of blood pressure, increased heart rate, palpitations, insomnia, and dry mouth. Although phentermine was not voluntarily removed from the market in 1997, it carries a warning in the *2003 Physicians' Desk Reference (PDR)* stating that the possibility of an association between valvular heart disease and primary pulmonary hypertension and the use of phentermine alone cannot be ruled out.

How do I decide whether phentermine is a good choice for my patients?

Positive factors

- patients have difficulty controlling portion sizes due to hunger or not feeling full; thinks often about food
- previous beneficial response to an anorexiatic agent
- gastrointestinal conditions, such as irritable bowel syndrome, that would make it difficult to take orlistat
- once-a-day dosing
- costs less than sibutramine

Negative factors

- Medical contraindication. Patients with uncontrolled hypertension, coronary artery disease or angina, arrhythmias, congestive heart failure, stroke or transient ischemic attacks, seizure disorder, or agitated states should not be prescribed phentermine.

- Past complication (valvular heart disease or primary pulmonary hypertension) from previous exposure to phentermine–fenfluramine or dexfenfluramine.
- Drug interactions. Use of monoamine oxidase inhibitors (MAOIs) are an absolute contraindication.
- Because phentermine was one of the earliest anorectic drugs approved by the FDA, its approved indication has never been updated and remains indicated only as a short-term (a few weeks) adjunct in the management of exogenous obesity.

How do I initiate treatment with phentermine?

The medication is available in a timed-release resin under the brand name Ionamin® (15 or 30 mg) or a more quickly released hydrochloride form (15, 30, or 37.5 mg) under various brands and generic forms. Treatment is usually begun with the lowest dose available and administered in the morning. Late evening administration is typically avoided because of the possibility of insomnia.

Initiation of treatment includes telling patients how the medication works, what side effects they may experience, and what weight loss benefits to expect. The following sample script highlights the importance of dietary modification in achieving success.

Following is a sample script for doctors to present to patients.

“Phentermine is absorbed into the body and travels to the appetite center in the brain. It works by helping you feel less hungry. So if you respond, you’ll feel less hungry during the day and have better control of how much food you choose to eat. You’ll need to slow down your eating and pay attention to how hungry and full you are. Phentermine helps you lose weight **only** if you stop eating when you feel you have had enough food. Side effects of the medication may include dry mouth, headache, insomnia, agitation, and constipation.”

In reviewing the side effects, you may find it helpful to share the Patient’s Guide to Phentermine with your patients (see Figure 6.5).

What needs to be monitored during phentermine use?

Patients should return for a follow-up visit approximately 1 month after initiation of treatment. During this visit, measure body weight and vital signs and review side effects and intended effects. Be certain to ask patients about their feelings of hunger and fullness on the medication.

Give careful notice to blood pressure or heart rate because a significant increase in either may warrant lowering the dose or discontinuing the medication entirely. Also, ask your patients about agitation and irritability.

At this visit, the dosage of phentermine may be maintained or increased as follows:

- If patients have a good response to medication — decreased hunger, approximately 4 pounds weight loss, and minimal or no side effects — the medication can be continued at the same dose.
- If patients do not perceive a change in appetite and experience inadequate weight loss, the dose can be increased if a lower starting dose was initially chosen, eg, increase from 15 mg to 30 mg.

Because Julia’s hypertension is well controlled, prescribing sibutramine or phentermine is not a contraindication. (The effect of sibutramine on blood pressure is no greater in patients with controlled hypertension than in those who do not have hypertension.) For Julia, sibutramine, orlistat, or phentermine can be considered for adjunctive use. You explain the benefits and risks of these medications with her and discuss how each can address the difficulties she is experiencing with the lifestyle change program. With your assistance, Julia chooses a medication based on her personal preferences.

Figure 6.5

American Medical Association
PHENTERMINE (L-AMPHETAMINE) TABLETS

Figure 6.5
Patient's Guide to Phentermine

Patient name _____ Date _____

Your dose is _____ mg
 Take _____ tablet(s) _____

Do not change your dose.
 Do not take any other medication(s), including over-the-counter or herbal medications, without consulting your physician.

Side Effects

You may experience one or more of the following:

- Increased heart rate
- Increased blood pressure
- Restlessness
- Insomnia
- Headache
- Dry mouth

Now, unexplained symptoms that you must report immediately to your physician

- Dizziness (difficulty breathing or absence of breath)
- Angina (chest pain)
- Syncope (fainting)
- Edema of the lower extremities (swelling of legs, ankles, or feet)

Blood Pressure

It is important to monitor your blood pressure and heart rate at least every 4 weeks. If you are monitoring your blood pressure at home, keep a log of your measurements, and bring the results to your follow-up appointments with your physician. Report an increase in your blood pressure to your physician immediately. If you will not be monitoring your blood pressure at home, make arrangements with your physician to have it measured at the office regularly.

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Adapted with permission from the Centers for Obesity Research and Education (CORE).
 This project was funded by the American Medical Association and the Robert Wood Johnson Foundation. • November 2002

How long can my patients continue medication therapy?

Both sibutramine and orlistat are approved by the FDA for weight loss and maintenance of weight loss without an automatic stop date. Orlistat is also approved to reduce the risk for weight gain after prior weight loss. The safety and effectiveness of sibutramine has not been determined beyond 2 years, whereas orlistat has been studied in a trial that lasted 4 years.

In deciding whether to continue or discontinue medication therapy, it is important to remember that obesity is a long-term chronic disease, similar to other conditions commonly treated in the physician’s office. According to the report of the National Task Force on the Prevention and Treatment of Obesity on Long-term Pharmacotherapy in the Management of Obesity, “The major promise of pharmacotherapy lies not in its ability to improve the amount of weight lost during the initial months of treatment, but in its potential to enhance longer-term maintenance of weight lost with conventional therapies.”¹⁶ For many patients, weight maintenance after an initial weight loss may be enough to justify continued medication use. Use the following points as a more specific guide:

- If your patients have not responded to the medication after 3 months of therapy, it should be discontinued.
- If weight is lost within 6 months of therapy and is maintained after the initial weight loss phase, the medication may be continued. It can be continued as long as the patient continues to maintain weight loss and there are no significant adverse effects.
- While patients remain on the medication, it is reasonable to see them for follow-up every 3 months.

Unfortunately, patients are likely to regain lost weight when medication is discontinued. This post-treatment effect is similar to other medications used for chronic diseases, eg, discontinuation of an antihypertensive drug is likely to be followed by an elevation in blood pressure. Patients who have previously taken sibutramine may report feeling less content with the same amount of food and eating larger portions or snacking more often, and patients who have previously taken orlistat may resume consuming fattier foods.

These post-therapy dietary and behavioral changes can lead to weight regain unless patients understand the importance of long-term lifestyle modification. Physicians must continually encourage their patients to maintain these lifestyle changes.

There are no published prospective studies evaluating whether failure or success with one medication predicts failure or success with another. However, it may be reasonable to provide a trial of another medication if patients are interested and the goals are clearly established.

Is there a role for dietary supplements in weight loss?

Multiple dietary supplements are available that may or may not be effective in promoting weight loss. In contrast to medications, dietary supplements and herbal products are officially classified as foods and therefore do not undergo the same rigorous approval process by the FDA that medications do. In accordance with the Dietary Supplement Health and Education Act (DSHEA) of 1994, they neither require premarket approval of safety or demonstration of efficacy nor are there generally accepted quality standards in the manufacturing of these preparations. Under the DSHEA law, herbal products for weight reduction use a structure-function claim for “achieving and maintaining a healthy body weight” to be considered botanical dietary supplements that are approved for sale to the general public.¹⁷

Although some products may be found to be useful in the future, herbal medications are not currently recommended as part of a weight loss program, according to National Heart, Lung, and Blood Institute *Guidelines*.¹ For physicians, the primary concern is safety of the product that their patients wish to take. According to a critical review of alternative treatments for weight loss,¹⁸ ephedrine-containing products warrant the greatest safety concerns.

Ephedrine alkaloids used in dietary supplements are usually derived from one of several herb species of the genus *Ephedra* (also called ma huang or Chinese ephedra). Ma huang, commonly found as the active ingredient in herbal weight loss products, reduces appetite and potentially increases energy expenditure through sympathomimetic

mechanisms. Ma huang is often combined with other herbal ingredients, such as St. John’s wort, guarana (caffeine), garcinia cambogia (hydroxytric acid), and chromium picolinate.¹⁹

An analysis of the scientific literature indicates that the short-term use of ephedrine- and ephedra-containing dietary supplements has modest short-term benefits with respect to weight loss.²⁰ However, there is also evidence that these supplements are associated with two to three times the risk of psychiatric symptoms (eg, agitation, anxiety), autonomic symptoms (eg, insomnia, tremor), upper gastrointestinal symptoms (eg, nausea, vomiting, gastroesophageal reflux), and heart palpitations. Furthermore, case reports raise the possibility that the supplements may cause more serious adverse effects, including hypertension, myocardial infarction, seizure, and stroke.²⁰ The FDA is currently reviewing proposals for mandatory warning labels and dosing recommendations on all ephedra products. In all cases, patients who choose to take these supplements should be informed of potential risks and be monitored closely.

Physicians should be aware of over-the-counter (OTC) products for weight loss in order to provide appropriate counseling. Several Internet resources are available (see Suggested additional reading on page 23). All patients seeking weight loss should be queried about the use of OTC products so that safety and efficacy issues can be addressed.

References

- National Heart, Lung, and Blood Institute (NHLBI) and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: evidence report. *Obes Res.* 1998;6(suppl 2):51S–210S. Available at: www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.htm.
- Stafford RS, Radley DC. National trends in anti-obesity medication use. *Arch Intern Med.* 2003;163:1046–1050.
- Wadden TA, Berkowitz RI, Sarwer DB, Prus-Wisniewski R, Steinberg C. Benefits of lifestyle modification in the pharmacologic treatment of obesity. *Arch Intern Med.* 2001;161:218–227.
- Kordik CP, Reitz AB. Pharmacological treatment of obesity: therapeutic strategies. *J Med Chem.* 1999;42:181–201.
- Meridia® package insert. Revised: July 2001.
- Finer N. Sibutramine: its mode of action and efficacy. *Int J Obes.* 2002;26(suppl 4):S29–S33.
- James WPT, Astrup A, Finer N, Hilsted J, Kopelman P, Rossner S, Saris WHM, Gaal LFV. Effect of sibutramine on weight maintenance after weight loss: a randomized trial. *Lancet.* 2000;356:2119–2125.
- Wirth A, Krause J. Long-term weight loss with sibutramine. A randomized controlled trial. *JAMA.* 2001;286:1331–1339.
- Lucas KH, Kaplan-Machlis B. Orlistat — a novel weight loss therapy. *Ann Pharmacother.* 2001;35:314–328.
- Xenical® package insert. Revised: Sept 2000.
- Cavaliere H, Floriano I, Medeiros-Neto G. Gastrointestinal side effects of orlistat may be prevented by concomitant prescription of natural fibers (psyllium mucilloid). *Int J Obes.* 2001;25:1095–1099.
- Heymsfield SB, Segal KR, Hauptman J, et al. Effects of weight loss with orlistat on glucose tolerance and progression to type 2 diabetes in obese adults. *Arch Intern Med.* 2000;160:1321–1326.
- Wadden T, et al. Effects of sibutramine plus orlistat in obese women following 1 year of treatment by sibutramine alone: a placebo-controlled trial. *Obes Res.* 2000;8:431–437.
- Goldstein DJ, Potvin JH. Long-term weight loss: the effect of pharmacologic agents. *Am J Clin Nutr.* 1994;60:647–657.
- Glazer G. Long-term pharmacotherapy of obesity 2000. A review of efficacy and safety. *Arch Intern Med.* 2001;161:1814–1824.
- National Task Force on the Prevention and Treatment of Obesity. Long-term Pharmacotherapy in the Management of Obesity. *JAMA.* 1996;276:1907–1915.
- Heber D. Herbal preparations for obesity: are they useful? *Prim Care Clin Office Pract.* 2003;30:441–463.
- Allison DB, Fontaine KR, Heshka S, Mentore JL, Heymsfield SB. Alternative treatments for weight loss: a critical review. *Critical Reviews in Food Science and Nutrition.* 2001;41:1–28.
- Bent S, Tiedt TN, Odden MC, et al. The relative safety of ephedra compared with other herbal products. *Ann Intern Med.* 2003;138:468–471.
- Shekelle PG, Hardy ML, Morton SC, Maglione M, Mojica WA, Suttorp MJ, et al. Efficacy and safety of ephedra and ephedrine for weight loss and athletic performance: a meta-analysis. *JAMA.* 2003;289:1537–1545.

Suggested additional reading

Agency for Healthcare Research and Quality. Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects. Summary, Evidence Report/Technology Assessment: Number 76. AHRQ Publication Number 03-E021, March 2003. Rockville, Md. Available at: www.ahrq.gov/clinic/epcsums/ephedsum.htm.

Bray GA, Tartaglia LA. Medicinal strategies in the treatment of obesity. *Nature.* 2000;404:672–677.

Hensrud DD. Pharmacotherapy for obesity. *Med Clin North Am.* 2000;84:463–476.

Kushner RF, Manzano H. Obesity pharmacology: past, present, and future. *Curr Opin Gastroenterol.* 2002;18:213–220.

Phelan S, Wadden TA. Combining behavioral and pharmacological treatments for obesity. *Obes Res.* 2002;10:560–574.

Yanovski SZ, Yanovski JA. Obesity. *N Engl J Med.* 2002;346:591–602.

Internet resources

National Center for Complementary and Alternative Medicine:
www.nccam.nih.gov

Office of Dietary Supplements:
www.ods.od.nih.gov

US Food and Drug Administration Center for Food Safety and Applied Nutrition:
www.vm.cfsan.fda.gov



Figure 6.3

Patient's Guide to Sibutramine

Patient name _____ Date _____

Your dose is _____ mg.

Take _____ capsule(s) _____

Do not change your dose.

Do not take any other medication(s), including over-the-counter or herbal medications, without consulting your physician.

Side effects

You may experience one or more of the following with sibutramine:

- Headache
- Dry mouth
- Anorexia (ie, loss of appetite)
- Constipation
- Insomnia (inability to sleep)
- Appetite increase
- Dizziness
- Nausea

Blood pressure

It is important to monitor your blood pressure (BP) in the morning and at the same time daily (for consistent results) and heart rate at least every 4 weeks. If you are monitoring your blood pressure at home, keep a log of your measurements, and bring the results to your follow-up appointments with your physician. Report an increase in your blood pressure to your physician immediately. If you do not plan to monitor your blood pressure at home, make arrangements with your physician to have it monitored at the office regularly.

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Figure 6.4

Patient's Guide to Orlistat

Patient name _____ Date _____

Your dose is _____ mg.

Take _____ capsule(s) _____

Do not change your dose.

Do not take any other medication(s), including over-the-counter or herbal medications, without consulting your physician.

Side effects

You may experience one or more of the following side effects with orlistat. An increase in dietary fat may intensify side effects.

- Oily spotting
- Flatus with discharge
- Fecal urgency
- Fatty/oily stool
- Oily evacuation
- Increased defecation
- Fecal incontinence

Vitamins

Take a multivitamin containing fat-soluble vitamins once a day (vitamins D, E, A, K) at least 2 hours before or after orlistat, such as at bedtime.



Figure 6.5

Patient's Guide to Phentermine

Patient name _____ Date _____

Your dose is _____ mg.

Take _____ tablet(s) _____

Do not change your dose.

Do not take any other medication(s), including over-the-counter or herbal medications, without consulting your physician.

Side Effects

You may experience one or more of the following:

- Increased heart rate
- Increased blood pressure
- Restlessness
- Insomnia
- Headache
- Dry mouth

New, unexplained symptoms that you must report immediately to your physician

- Dyspnea (difficulty breathing or shortness of breath)
- Angina (chest pain)
- Syncope (fainting)
- Edema of the lower extremities (swelling of legs, ankles, or feet)

Blood Pressure

It is important to monitor your blood pressure and heart rate at least every 4 weeks. If you are monitoring your blood pressure at home, keep a log of your measurements, and bring the results to your follow-up appointments with your physician. Report an increase in your blood pressure to your physician immediately.

If you will not be monitoring your blood pressure at home, make arrangements with your physician to have it monitored at the office regularly.

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Strategy for treatment of overweight and obesity

Evaluate your patients for current and potential health risks related to weight (Booklet 2)

- Measure body mass index (BMI)
- Measure waist circumference
- Assess for presence/extent of suspected comorbid diseases

Talk to your patients about weight loss (Booklet 3)

- Explain the importance of weight loss
- Assess your patients' readiness to make behavior changes
- Work with your patients to establish realistic treatment goals

Help your patients manage weight through dietary management (Booklet 4)

- Collaborate on strategies for reducing calories and balancing the diet
- Recommend weight loss programs and resources as needed
- Follow up with your patients to monitor progress and provide support

Help your patients manage weight through physical activity (Booklet 5)

- Collaborate on strategies for increasing physical activity in the daily lifestyle
- Recommend physical activity programs and resources as needed
- Follow up with your patients to monitor progress and provide support

If indicated, help your patients manage weight through pharmacotherapy (Booklet 6)

- Determine whether your patients are candidates for pharmacotherapy at this time
- If pharmacotherapy is an option, help your patients make and carry out treatment decisions
- Monitor your patients for weight loss and medication side effects

If indicated, help your patients manage weight through surgery (Booklet 7)

- Determine whether your patients are candidates for bariatric surgery at this time
- If surgery is an option, help your patients and their bariatric team make and carry out treatment decisions
- Manage your patients post-operatively

Optimize your communication and counseling style (Booklet 8)

- Establish an effective patient–physician partnership
- Help your patients obtain skills for self-management
- Be sensitive to anti-fat bias and approach the topic of weight sensitively

Optimize your office environment (Booklet 9)

- Be more sensitive to your patients' needs by adapting office practices and the waiting room configuration
- Set up your office with the equipment needed to assess and manage your patients
- Facilitate patient care through a team approach

Adapted from Serdula MK, Khan LK, Dietz WH. Weight loss counseling revisited. *JAMA*. 289;1747-1750:2003.