American Society of Bariatric Physicians ™

Overweight and Obesity Evaluation and Management

Background

The art and science of treating overweight and obesity continues to evolve and improve. Condensing the clinical knowledge and skills of American Society of Bariatric Physicians (ASBP) membership into written guidelines continues to be a work in progress. The introduction of new medications, the continued use of conventional ones, changes to the Physicians Desk Reference (PDR) labeling of some medications, and evolving changes to the treatment of overweight and obesity treatment have generated the need to produce a new set of evaluation and treatment guidelines.

ASBP, organized in 1950, is a national non-profit organization of physicians and interested affiliates who have a special interest in the study and treatment of patients with obesity and associated conditions. The primary goal of the ASBP is to advance and improve the practice and quality of professional service in the field of bariatric medicine. We assert that "*Bariatrics*" is a term that should only apply to the practice of medicine by physicians relating to the areas stated. This would not include a clinic or site that prescribes or dispenses medication without the appropriate examination and continued monitoring and follow-up by a qualified physician. The ASBP does not endorse, support, teach, or promote prescribing controlled substances on the Internet for weight loss.

The ASBP is a member of the Specialty and Service Society of the American Medical Association. The ASBP is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education (CME) for physicians and offers CME at annual and regional meetings of the Society, as well as Internet-based CME.

Membership in the ASBP currently includes approximately 1,100 physicians, both MDs and DOs, from throughout the United States and some foreign countries. ASBP also has approximately 100 NPs and PAs as members. Customary medical specialties represented within the ASBP include family practice, emergency medicine, ob-gyn, internal medicine, surgery, neurology, pathology, pediatrics and psychiatry. Just as members' backgrounds are varied, so are their views on obesity therapy. Agreement should be reached among the membership that long-term lifestyle changes are necessary for long-term success. Just as physicians in other areas of medicine may differ in their choices of therapeutic modalities, ASBP members may utilize similar freedom of choice when treating obesity.

The Obesity Evaluation and Management Committee of the ASBP in drafting these guidelines recommends changing the name of this document from the previous "Anorectic Usage Guidelines" to "Overweight and Obesity: Evaluation and Management." This name change reflects the ASBP's comprehensive approach to

clinical obesity treatment, which includes advice and recommendations for dietary management, behavioral modification, counseling, exercise and appropriate use of medications when indicated, as part of a long-term weight control maintenance program ("weight control" refers to managing excess adipose tissue).

The original Anorectic Usage Guidelines, recent revisions and the new Overweight and Obesity Management Guidelines state that physicians should consider using the Schedule III and IV anorectics as part of a multifaceted obesity treatment program after an appropriate initial patient evaluation and with appropriate ongoing supervision. In addition, for patients who need them, these anti-obesity agents reasonably may be used for maintenance in excess of the manufacturer's labeling of a "few weeks" and, in some cases, in combinations or dosages different from that described on current labeling.

We offer the following recommendations and supporting statements for evaluation and treatment guidelines from peer-reviewed literature and believe these recommendations represent the currently accepted medical practice of bariatric medicine. Any deviation by a practitioner from these guidelines may be appropriate and must be decided by the individual practitioner in caring for the patient. Thus, the bariatrician must not rely on these guidelines or on any other guidelines to provide an infallible blueprint for patient treatment. It is not the intent of these guidelines to limit the bariatrician's judgment in adjusting the therapy based on the patient's condition, medical problems or therapeutic response. These guidelines are not intended to provide specific requirements to be followed by the treating bariatrician.

Another purpose in producing these evaluation and management guidelines is to serve as a recourse based on practical clinical information, current research, and scientific publications from which state medical and pharmacy boards may update any existing obesity management guidelines or requirements and remove antiquated codes or laws that do not represent current evidence-based clinical guidelines. Some state regulatory boards have evaluated physicians' bariatric practices that are based on PDR information that is more than 50 years old. As a result, some boards have taken action against physicians' licenses.

Overweight or obesity and associated metabolic conditions should be viewed on a chronic disease spectrum that produces life-threatening complications. In light of the current obesity epidemic, we believe it is not in the best interest of obese patients to place restrictions on the scientifically valid use of pharmacotherapy in the treatment of obesity.

Pharmacologic Therapy in Overweight and Obesity

Obesity management should be treated similarly to Attention Deficit Disorder (ADD) in which schedule II controlled substances are frequently prescribed yet no special or detailed rules exist. Similarly, we believe that no specific rules are necessary for treatment of overweight or obesity with the much safer schedule III or IV anorectic medications. Years of experience and additional research have shown these medications

to be both effective and considerably safer than was recognized when the scheduling of anorectic medications was initially instituted.

The strict recommendations seen in the past regarding the use of anorectic medication are perhaps a result of the National Institute of Health's (NIH) review of 769 articles,[1] dates of which ranged from the 1980s to the early 1990s, at the height of phentermine/fenfluramine (phen/fen) prescribing. In a later report, [2] the NIH acknowledged that:

> "Pharmacotherapy, which has generally been studied along with lifestyle modification including diet and physical activity, using dexfenfluramine, sibutramine, Orlistat, or phen/fen, results in weight loss in obese adults **when used for 6 months to 1 year**." (p. 53) (emphasis added)
>
> "Since obesity is a chronic disorder, the short-term use of drugs is not helpful. The health professional should include drugs only in the context of a long-term treatment strategy." (p.86)

Although fenfluramine and dexfenfluramine were removed from the market, the other drugs cited were found to be useful in weight loss if used over a longer period of time. The NIH recommendations published more than ten years ago are outdated and do not reflect current medical knowledge. Sixty thousand (60,000) research studies on obesity have been published since the formulation of the NIH guidelines. A substantial and growing body of evidence suggests that treatment based solely on Body Mass Index (BMI) thresholds is inappropriate and that early, more aggressive treatment is warranted.[3] Other methods of measuring obesity-associated risk and excess adiposity are now available. Physicians should be allowed to treat patients with chronic illnesses based on the most recent evidence and modern thinking, whether it is in the treatment of hypertension, depression, glaucoma, or obesity.

Some examples of more modern thinking can be read in an excellent series of articles written by Dr. Bays in 2006. Dr. Bays discusses a pathological accumulation of fat in susceptible patients that he terms "dysfunctional fat" or "adiposopathy".[4-6] According to Dr. Bays "pathological abnormalities in fat function are more directly related to the onset of excessive fat related metabolic diseases (EFRMD)". Furthermore Dr. Bays explains that "in some cases, weight loss therapeutic agents may even affect metabolic parameters and adipocyte function independently of weight loss alone, suggesting that the benefit of these agents in improving EFRMD may go beyond their efficacy in weight reduction." (Reference: *Expert Rev. Cardiovasc. Ther.* 4(6), 871–895 (2006).

As research accumulates on more accurate descriptions of the etiologies and pathophysiology of obesity, more obesity interventions will be developed. This modern approach to the treatment of obesity incorporates medical intervention, dietary, behavioral, and pharmacologic (when indicated) treatments at an earlier stage of the disease and continues therapy for a longer duration of time. Also, aggressive surgical interventions are becoming more common and more appropriate in severe cases.

Overweight, overfat, and obesity are variations of a recurrent life-long disease that carries a high risk of diabetes, prediabetes, metabolic syndrome, cardiovascular disease and ultimately a risk of premature death and debility if left untreated.[7] Overweight and obesity in the U.S. have increased by more than 75 percent in the past three decades.[8] Patients seeking advice from bariatric physicians are typically told that they should expect a weight reduction of approximately 10 percent of their body weight over a six-month period. This can be accomplished by behavioral counseling, diet modification, exercise programs and medication. Weight loss leads to improvement of sleep apnea, diabetes, arthritis pain, improvement of lipids, reduced cardiovascular risk and an increased life expectancy. Also, it may be reasonable to continue some medication for a longer time in selected patients to assure maintenance of weight loss.

Phentermine has proven to be a safe, cost effective and highly successful medication in the treatment of overweight and obese patients.[9] Unfortunately, many of the current guidelines for prescribing it reflect recommendations that are more than 50 years old rather than current evidence of efficacy and safety. There has been an unrealistic and unjustified fear that phentermine is a highly addictive medication.

The Drug Abuse Warning Report of 2006 (DAWN) illustrates that anorectic medications have one of the lowest drug misuse/abuse rates per 100,000 emergency room visits -- even lower than Ibuprofen.[10] See reference below:

DAWN REPORT 2006

Drug	**# of visits**	**Rate/100,000**
Antidepressants	98,789	32.7
Opiates/opioids specified	279,510	92.5
Opiates/opioids, unspecified	55,674	18.4
Amphetamine-Dextroamphetamine	5,608	1.9
Ibuprofen	25,774	8.5
Naproxen/combinations	8,080	2.7
Acetaminophen/combinations	53,835	17.8
Anticonvulsants	36,467	12.1
Antimigraine agents	1,391	0.5
Anorexiants	**1,327**	0.4
Total ED visits	1,742,887	
Total Drug Reports	3,086,984	

Duration of Pharmacologic Therapy

For the majority of the drugs included in the PDR, no duration of treatment is suggested. The duration of use of a medication in any patient is a matter of clinical judgment in each individual case. It is self-evident that putting time limits on use of medications used in treating a chronic illness is inappropriate when the risk of taking the medication is less than the risk of leaving the illness untreated. In the case of chronic diseases, the FDA does not dictate how long a physician can use insulin in a diabetic, an antihistamine in a patient with allergies, an anti-hypertensive in a patient with hypertension, or a benzodiazepine in a patient with anxiety, etc.

Even more pertinent are the statements regarding long-term use of drugs used in treating ADD in children. The PDR usage statements for these category II drugs do not limit the length of usage. The 2003 PDR entry for Ritalin states "patients requiring long-term therapy should be carefully monitored." This statement has been modified in the 2006 PDR, but there is still no injunction to halt therapy after a few weeks. The entry (2003 edition) for Concerta, a newer preparation of methylphenidate, states "the effectiveness of Concerta for long term use, i.e., for more than four weeks, has not been systematically evaluated in controlled trials. Therefore the physician who elects to use Concerta for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient." This too has been changed in the 2006 PDR, but the duration of therapy is left to the physician's discretion. The PDR entry (2006 edition) for Dexedrine (Glaxo Smith Kline's dexamphetamine), does not discuss duration of therapy except to state "when possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy." The 2006 PDR entry for Adderall, another dextroamphetamine, has similar language. These are category II drugs. In fact, the PDR does not address limiting duration of medication usage for any chronic illnesses except for obesity.

Regarding the treatment of obesity, the ASBP believes that a restriction of medication for 12 weeks to treat this life-long chronic disease is unreasonable, just as a restriction that requires physicians to treat diabetes or hypertension for only 12 weeks is unreasonable. No such regulations exist that restrict ADD pharmacotherapy be limited to 12 weeks. Based on a national survey of ASBP membership, physicians report that anorectic medications are one of the more effective tools available to the clinician.[11] In another recently published study these medications were noted to be safe and effective over the long term.[12]

Weight loss is life saving for many patients, as evidenced by a Journal of the American Medical Association (JAMA) article in 2003.[13] According to this study a black male age 20 with a BMI of 45 will have a life expectancy of only 60 years. This patient would obviously benefit from aggressive treatment that would include diet, behavior modification, medication or even surgical intervention. Limiting treatment to 12 weeks would be detrimental to long-term survival and normal life expectancy.

Studies exist in the medical literature that support longer-term use of phentermine than the treatment recommended in the PDR. One such study suggests "Long-term pharmacotherapy when combined with appropriate behavioral approaches to improve diet

and increase physical activity, helps some obese patients lose weight and maintain weight loss for **at least a year**.[14] (emphasis added) The major promise of pharmacotherapy lies not in its ability to improve the amount of weight loss, but in its potential to enhance longer-term maintenance of weight loss with conventional therapies."[5] One continuing major barrier in the use of medication to treat obesity is "licensing boards that persecute physicians for alleged misuse of appetite suppressing drugs."[15]

In another study[12] patients were treated safely for more than 10 years of continuous use with phentermine. There was no abuse noted. Even the NIH states that as long as medicine is working, there is no time line on how long one should prescribe it.[16] As far as the perceived potential addictive properties of phentermine, in 49 years of world-wide use, there has never been a case of addiction reported in the peer-reviewed medical literature. (PubMed search 6/17/2008)

When phentermine was approved by the FDA in 1959, it was classified as a Category IV drug with potential for addiction because of the close similarity in molecular structure to amphetamine. Phentermine, in practice, has proven to have little or no potential for addiction. While addiction specialists have described well-defined addiction or abuse syndromes and withdrawal syndromes for cocaine, amphetamine and other stimulant substances, neither an addiction nor a withdrawal syndrome has ever been described for the category III or IV weight management drugs. (Diagnostic and Statistical Manual of Mental Disorders, DSM-IV). Phentermine does not create cravings for illicit drugs or alcohol in patients with a history of substance abuse. In fact, recent studies suggest that phentermine actually is beneficial in reducing cravings for alcohol and is promising as an adjunct to decrease cravings in patients recovering from cocaine addiction.[12]

Dr. Xavier Pi-Sunyer, one of America's pre-eminent obesity authorities, has stated "the image of drug therapy for obesity has been blemished by the past use of 'diet drugs' such as amphetamine, with harmful or addictive potential. Because amphetamine is addictive, it was presumed that the entire class of B-phenylethlamine compounds shared this trait. **However, other drugs in this class, namely phentermine and sibutramine have no abuse potential.**" (Emphasis added) Furthermore, he states that "obesity is a chronic relapsing disease for which there is no foolproof cure. Therefore pharmacological therapy should be viewed as a useful adjunct to lifestyle modification."[17, 18]

Off-Label Use

Physicians commonly prescribe a wide variety of drugs off-label; one recent estimate was that 21 percent of all prescriptions were for off-schedule use**.**[19] The same study found that 46 percent of cardiac drugs were prescribed off-label. In regard to off-label usage, the following is quoted from the forward of the 2008 edition of the Physicians' Desk Reference:

> "The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may choose to prescribe it for uses or in

treatment regimens or patient populations that are not included in approved labeling. The FDA also observes that accepted medical practice includes drug use that is not included in approved labeling."

Concerns that weight management medications are being prescribed off-label are out of place in view of the fact that the health risks of obesity are so serious. These drugs are now known to be safe and efficacious, particularly in the hands of well-trained practitioners. In a time when public support of patient-centered medicine is growing, it is inappropriate for public officials to place restrictions on the right of physicians and their patients to make informed choices in managing their health risks.

Use in Maintenance

Utilization of anorectic agents for long term as part of a lifelong maintenance program, should be conditional on achieving a clinical response, which may be defined as: (1) loss of weight (fat mass) (an average of at least 1.4 kg per month of therapy has been suggested), (2) loss of 10 percent of maximum (non-pregnant) weight in a healthy patient qualifying for initiation criteria, or (3) loss of 5 percent of maximum (non-pregnant) weight in patients who are at increased risk because of associated co-morbidities. Several researchers, citing a number of articles, [19, 20] conclude that a 5-10 percent decrease in body weight can be clinically significant.

Williamson[21] has noted the tendency for obese patients to gain 0.5 – 1 kg of additional weight per year. Practicing bariatricians treating obese patients have noted the same weight gain tendency with age. Thus, for some patients stopping or at least slowing age-related weight gain may in and of itself constitute a clinical response. Paramount in the treatment with anorectic agents is the physician's responsibility for tailoring the therapy to the individual patient and appropriately documenting therapy and achievements in weight (fat mass) loss and patient health.

Barriers to Appropriate Use

Currently, there are certain barriers to the appropriate use of anorectic medications. These include the following:

- **The perception by the public and some medical professionals that obesity is caused by lack of willpower.**
- **Anorectic medications are held to a higher standard in defining desired outcomes than are other medicines.**
- **The Schedule III and IV anorectics have a tarnished reputation because of their structural relationship to amphetamines and because of inappropriate prescribing by ill-trained or inexperienced physicians using the medications without a comprehensive program.**
- **There is an inappropriate fear of the "dangers" of anorectics and their potential for abuse by patients.**

- **Outdated information and rigid adherence to PDR labeling prevent appropriate "off-label" use of anorectics.**
- **Many physicians, because of a lack of treatment guidelines and the existence of outdated and/or antiquated federal and or state laws, fear regulatory retaliation if they prescribe anorectic medications.**
- **There has been a failure to recognize that adverse metabolic conditions may develop with even small amounts of fat gain or abnormalities in fat cell function.**
- **The positive psychological effect of weight loss and maintenance as an additional benefit of anorectic usage is often overlooked or ignored.**

These barriers will now be addressed individually:

- **Barrier: The perception by the public and some medical professionals that obesity is caused by lack of willpower.**

Comment: As noted by Weintraub and Bray,[22] "obesity is stigmatized and the obese are perceived as lazy, lacking willpower, and being less motivated than others. In a survey on societal views of obesity, students at Michigan State University indicated that they would prefer marrying a cocaine user, a shoplifter, or a Communist over marrying an obese person. The non-obese majority, having no difficulty controlling their weight, finds evidence for the character weakness of the obese in everyday life."

Accusations of gluttony have not been substantiated in a number of studies. In particular, the *Human and Nutritional Evaluation Survey I* (HANES I)[23] which surveyed, among other things, the eating habits of 20,749 individuals across the U.S., found that the obese actually ate *less* than their normal-weight counterparts. To lose weight and to maintain a reduced weight by means of caloric restriction, these individuals must reduce their food intake even further in relation to energy expenditure. To reach and maintain a normal weight, many obese people are forced to live with chronic hunger. Enduring this level of discomfort on a long-term basis is often more than the patient can bear and the weight is regained.

The regaining of lost weight tends to occur not only after the stopping of the anorectic agents but following the cessation of any weight control intervention, whether that involves diet alone, protein-supplemented fasts, exercise, jaw wiring, surgery or other means. Thus, a return back toward baseline weight is a normal response of the body and not related just to medication.

Not only is the treatment of obesity often unsuccessful from the patient's standpoint, but also is frequently demoralizing from the treating physician's standpoint. Someone has said that the physician usually buries his failures, but here is a living failure that keeps returning. For ego protection, the physician is prone to pass out a diet sheet with the admonition to push away from the table. When the patient is unsuccessful, the physician feels relieved of responsibility since the patient only needed to follow instructions, which the patient did not do. For many patients, the physician's advice

that eating less will cure obesity is about as helpful as telling hypertensive patients that relaxing will take care of their problem. Without additional help, change usually does not happen.

- **Barrier: Anorectic medications are held to a higher standard in defining desired outcome than are other medications.**

Comment: Weintraub and Bray [22] note, "the view that obese people need 'only to close their mouths' has caused us to demand a higher standard for medication use in treating obesity than we do for treatments of any other chronic condition. We accept the fact that serum cholesterol values will rise following cessation of therapy. We accept that ulcers will often recur following cessation of H2-blocking medications. We understand that rising intraocular pressure when pilocarpine treatment is stopped means that glaucoma has been controlled but not cured. Even in the absence of cure, patients and physicians still view ocular medication, anti-hypertensive agents, cholesterol-lowering medication, and H2-blockers as valuable. All of these failures to *cure* a problem of mal-regulation in human organisms are acceptable."

They continue, "obesity is the only analogous clinical setting where failure of medications to achieve cure is unacceptable."

- **Barrier: The Schedule III and IV anorectics have a tarnished reputation because of their structural relationship to amphetamines and because of inappropriate prescribing by ill-trained or inexperienced physicians using the medications without a comprehensive program.**

Comment: All anorectics are phenylethylamines. By definition, the Schedule II anorectic drugs are more stimulating and thus have more potential for street abuse. These medications are therefore not recommended for the treatment of overweight and obese patients. The Schedule III and IV anorectics offer acceptable alternatives with very little potential for street abuse.

In some cases, physicians and other practitioners have utilized anorectic medications *as* the treatment for obesity rather than using the anorectic medications *in* the treatment of obesity. The educational efforts of the ASBP through the years, plus the efforts of regulatory agencies, have substantially curtailed this type of activity. Therefore, these guidelines indicate that anorectic medications should only be used *in conjunction with* a program of weight management inclusive of behavior modification, nutritional counseling and appropriate exercise recommendations.

At a minimum treatment should include direct physician contact at the time of initiating therapy and at reasonable intervals thereafter. If local laws allow refills by a physician extender, the physician generally should be available for consultation regarding the patient.

- **Barrier: There is an inappropriate fear of the "dangers" of the anorectics and their potential for abuse by patients.**

Comment: Both short- and long-term studies have not validated these concerns. It is exceedingly rare for a patient receiving anorectics in a reasonably supervised program to demonstrate even psychological dependence. However, some patients may need the anorectic medications on an ongoing basis to help achieve the needed reduction in food intake.

Although the majority of the published anorectic studies have run for no more than 12 weeks, there are a number of studies that have continued treatment for longer periods of time. These studies indicate both the safety and effectiveness of the anorectic medications. Douglas and Munro,[24] and Sullivan and Comai[25] and Goldstein and Potvin[26] in their review articles cite multiple reports of the continuous use of anorectics for 14 to 60 weeks. In addition, these review articles summarize adverse effects of the Schedule III & IV anorectics as adapted from Bray.[27] Side effects occasionally seen with Schedule III and IV anorectics are nervousness, insomnia, headaches, dizziness, nausea and constipation. With appropriate starting doses, attentive monitoring and judicious dosage titration depending upon a patient's clinical response, even these listed side-effects can be avoided in most cases.

In 1992 Michael Weintraub, MD,[28] of the University of Rochester School of Medicine and Dentistry, published a study using anorectic medications for up to three and one-half years in the treatment of obesity. In this study patients utilizing active medication lost more weight than those on placebo. There was no tolerance or drug dependence noted and relatively few side effects.

Richard & Lasagna[29] cite the Griffiths, et. al.,[30] review of the literature on five Schedule III and IV anorectic drugs which concluded that they "were all associated with relatively low or zero anorectic-reinforcement ratios: "Clinically, all of the latter five compounds have anorectic properties...there are, however, relatively few case reports involving abuse of these drugs."

Considering the large amounts of Schedule III and IV anorectics that have been prescribed in the U.S. and abroad, the reported incidents of serious side effects is low indeed, and in some of the case reports, it is impossible to establish for certain that the anorectic medications are primary causes of the reported incidents.

- **Barrier: Outdated information and rigid adherence to PDR labeling prevent appropriate "off-label" use of anorectics.**

Comment: Until 1999 anorectic medication labeling had not changed significantly since 1974. The original labeling with recommendations dating from 1974 was generally based on short-term studies (12 weeks or less) and was the result of negotiations between the drug companies and the FDA. The studies on what this labeling was based included about 200 double blind studies, which were analyzed by

Scoville of the FDA.[31] These indicated weight loss of about one pound per week with the anorectic medications versus 1/2 pound per week with the placebos. Using the anorectics for only a few weeks may indeed make the results trivial.

Since that time, a number of long-term studies, as noted previously, have been completed and testify to both the efficacy and safety of the anorectics when used on a long-term basis. More than 50 percent of the members of the ASBP responding to a society survey have had patients on anorectic treatment for time spans measured in multiple years without significant side effects occurring.[11]


2008 ASBP Survey Poster v3 (2).pdf

The North American Association for the Study of Obesity has stated in their *Guidelines for the Approval and Use of Drugs to Treat Obesity:*[32]

> "Tolerance is a misnomer if a medication continues to have a sustained effect in maintaining a lower body weight. As long as a drug helps to maintain a significant clinical response the medicine should be considered efficacious, even if no further additional weight loss occurs. Continuation of the medication and the dosage should depend on maintaining a beneficial balance between the health benefits of the maintenance of weight loss and the side effects of the medicine."

Albert Stunkard,[33] professor of psychiatry at the University of Pennsylvania Medical School, argued as early as 1982 that appetite suppressants act primarily by lowering the body weight set point and only secondarily by suppressing appetite. The evidence, he contends, does not support the development of tolerance to the anorectics. He concludes that regarding appetite suppressant medication, patients should "use it on a chronic basis or not at all." He later stated in the publication *The Salmon Lecture-Some Perspectives on Human Obesity*:[34]

> "For many years it has been established practice to prescribe appetite suppressant medication for only limited periods of time. The evidence for this belief is obscure, and a set point interpretation of tolerance makes clear its limitation. In terms of body weight, tolerance to appetite suppressants does not develop, which means that the old argument against their use (a loss of efficacy) is no longer valid. These agents retain their efficacy. Paradoxically, it is precisely this maintenance of efficacy that argues against their short term use.
>
> "If any benefits of appetite suppressants are lost when the medication is discontinued, then such medication should not be used on a short term basis. Current policy appears to be diametrically opposed to rational use of appetite suppressant medication, and current practice appears wholly unwarranted.

> Furthermore, the myth of tolerance seems to have prevented use of appetite suppressants in precisely those situations in which they are indicated which is over the long term.
>
> "There are strong positive indications for the long term use of appetite suppressants. Many obese hypertensive and diabetic patients can control their conditions by weight loss. Unfortunately, however, many of them cannot lose weight by diet alone. As a result, they are forced to rely on long term use of medication to control their hypertension, diabetes, and other conditions. If these patients must receive long-term medication, they may well be better off on appetite suppressants than on the usual remedies. At the very least, weight loss will control their complications in a more physiologic manner. Over the long term, the risks of treatment with appetite suppressant medication may be less than those of the medications they are now taking. Long term studies of the safety of appetite suppressant medication are needed. If they can be shown to be safe, major changes in the treatment of obesity-related disorders could result."

Douglas and Munro[24] summarize some of the long-term studies with mean durations running from 10-16 months. They write:

> "A number of studies have suggested that diethylpropion, phentermine, fenfluramine and mazindol can be given for periods of up to several years with reasonable safety and without weight regain occurring. As the risk increases with the degree of obesity, long term therapy could be most readily justified in the most overweight."

Even though use of long-term and combination anti-obesity medications does not appear in FDA approved labeling of the drugs involved, it is consistent with the American Medical Association's (AMA) policy of off-label use.[35] It is the consensus of the ASBP that short-term labeling for other anti-obesity pharmacological agents should be updated. However, since there are insufficient monetary incentives for long-term pharmaceutical studies of generic anorectic medications, such studies are unlikely to occur.

Although not described in approved labeling, it may be appropriate to use anti-obesity agents in combination with one another or with other medications (e.g. anti-depressants), which has been described in various articles, books and shared clinical experiences. A recently published article of a multi-center survey among ASBP members, studied varied combinations of sympathomimetics and SSRI and other antidepressants (excluding monoamine oxidase inhibitors MAOI's) and found not one documented case of the feared serotonin syndrome from combining the medications.[36] Such use is consistent with the FDA policy as elucidated in the Physicians Desk Reference:

> "The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may choose to prescribe it for uses or in treatment regimes or patient populations that are not included in approved labeling. The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling."

- **Barrier: Many physicians, because of a lack of treatment guidelines and the existence of outdated and/or antiquated federal and or state laws, fear regulatory retaliation if they prescribe anorectic medications.**

Comment: Unfortunately, fear of confrontation with regulatory agencies is often a barrier to the appropriate use of controlled drugs. Since the introduction of the original *Anorectic Usage Guidelines* in 1990 and in light of recent medical and scientific research and opinion, several state medical regulatory agencies have changed previously outdated and antiquated policies overly restricting or banning anorectic medications. The ASBP is proud to have been the first major organization to advocate for the patient to both the medical community and state regulatory agencies regarding modern day pharmacological treatment of obesity. In producing this set of peer-reviewed guidelines, ASBP hopes to continue to educate those involved in the treatment of obesity and those involved in the regulation of obesity evaluation and management.

- **Barrier: There has been a failure to recognize that adverse metabolic conditions may develop with even small amounts of fat gain or abnormalities in fat cell function.**

Comment: BMI, although a reasonable epidemiologic measurement tool, does not measure any specific metabolic abnormality. Therefore BMI alone may not be the best tool for deciding appropriate weight loss therapy. The potential benefits of weight control or weight maintenance, including the use of antiobesity agents should be considered appropriate at any weight where metabolic or other conditions pose present or future health risks to an individual.

Bays, et.al.[3] document that in some individuals, excess fat related metabolic diseases (EFRMD) may occur in individuals who are overfat and in individuals with normal fat amounts but abnormally functioning fat, but still within ranges considered to be normal weight. Anti-obesity agents may play an important role in usage in these individuals.

Obesity and the metabolic conditions associated with obesity should be viewed as a disease spectrum. To preclude the treatment of overweight or the metabolic abnormalities associated with abnormal functioning adipose tissue with any means available could be compared to not treating hypertension to prevent ischemic heart disease or congestive heart failure. Therefore, using BMI alone as qualifying criteria

for treatment would restrict treatment from many individuals who would otherwise benefit from it.

As noted previously there is a tendency for untreated overweight individuals to gain one and a half to three pounds or more a year until senility is reached, after which there may be some spontaneous weight loss. Hence, the prevention of weight gain may be warranted particularly if the patient has co-morbidities or if the patient's close relatives tend to develop diabetes mellitus and/or to become significantly more obese as they age.

- **Barrier: The positive psychological effect of weight loss and maintenance as an additional benefit of anorectic usage is often overlooked or ignored.**

Comment: The Lasik procedure is used so that patients with otherwise perfectly good eyes can discard their glasses. Botox is used repeatedly over time to temporarily erase skin wrinkles. Plastic surgeons perform cosmetic surgery or liposuction. Human growth hormone has been approved for repeated injections into short children to modestly increase height. None of these procedures is without risk. None of these procedures reduce health risks. Yet all are considered ethical treatments because they add to the quality of life. Similarly, helping modestly overweight patients attain and maintain a more cosmetically pleasing weight may appropriately, in and of itself, be considered a clinical response.

Over the past several decades obesity has moved from being considered a problem of gluttony to that of being an illness or a disease. It is now time to consider that it is not just a health problem but also a cosmetic problem worthy of being addressed on that basis.

.

Overweight and Obesity
Evaluation and Management Guidelines

The American Society of Bariatric Physicians Guidelines on Overweight and Obesity Evaluation and Management (approved 2009) replace the Anorectic Usage Guidelines statement on the use of Schedule II, III & IV controlled anorectics in the treatment of obese patients as approved by the ASBP Board of Trustees in 1990, and revised October 17, 1996, December 4, 1998, October 4, 2000, and January 30, 2004.

These guidelines on overweight and obesity evaluation and management replace and supersede any and all previous ASBP position statements and/or guidelines on the use of Schedule II, III & IV controlled anorectics in the treatment of obese patients. These guidelines are not intended to endorse the use of controlled substances, but rather to recognize appropriate use of these medications as part of a comprehensive bariatric program. Obesity is a chronic condition that may be controlled but is rarely cured. For most patients, optimal results will not be achieved on a short-term basis. Long-term treatment and follow-up of months to years may be required.

The bariatrician must not rely on these guidelines, or on any other guidelines to provide an infallible blueprint for patient treatment. It is not the intent of these guidelines to limit the bariatrician's right to alter the therapy based on the patient's condition, medical problems or therapeutic response. These guidelines are not intended to provide specific requirements to be followed by the treating bariatrician.

Because of the Schedule II anorectics' potential for street abuse and the acceptable Schedule III & IV alternatives, the ASBP feels that there is currently no indication for the use of the federally regulated Schedule II anorectics in any obesity treatment program. When properly used as part of treatment for obesity, and not as a sole treatment for obesity, Schedule III & IV anorectic drugs (anorectics) can often be useful in helping patients to lose weight and to maintain a reduced weight. The Schedule III and IV anorectics by definition have a low-level of risk and little potential for addiction or psychological dependence when carefully prescribed by a physician in a properly supervised medical practice.

The bariatrician should weigh the benefits and risks of any treatment modality or medication used. Significant sources of information to direct therapeutic interventions include but are not limited to published clinical trials in medical literature; presentations at medical meetings; recommendations of respected independent university-based reviewers and colleagues; practice-based, carefully evaluated clinical experience derived from treating other patients; anorectic labeling and textbook information. All of these sources can provide information, but no single source should be used to the exclusion of others. Unfortunately, the information contained in standard textbooks is often out of date. In addition, it should be noted that while anorectic labeling may be helpful, it is

simply another source of information that often does not reflect the latest published data. Labeling is a legal document developed by lawyers from the Food and Drug Administration and the manufacturer of the medication. Therefore, while ostensibly based on reliable data, often legal issues supersede medical and scientific issues. ASBP advises all practitioners to be fully aware of local and state medical and pharmacy boards and federal regulations involving the treatment of obesity.

These guidelines provide suggestions for the work-up and follow-up of the bariatric patient. They are not intended to replace, and indeed cannot replace, the bariatrician's judgment regarding a particular patient's treatment. Neither are they intended to represent legal requirements for providing good medical practice. The bariatrician is the one most capable of determining what is or is not appropriate for an individual patient.

A. Initial patient work-up

The course of treatment should be based on the patient's history, appropriately completed physical examination, laboratory work and other testing as indicated.

1. *History*

   A history of each patient should be taken and recorded. It should include an evaluation of dietary status, a weight history and a history of mental status. Whenever this is a self-fill-in or computerized history, or one taken by assistants, the bariatrician should personally evaluate significant positive responses and make appropriate notations.

   Items considered appropriate for medical history should be obtained and document and may include but are not limited to:

   - Patient's and caregivers' stage of readiness to change
   - Past medical and surgical history
   - Co-morbid medical conditions
   - Social history
   - Mental health history
   - Review of systems
   - Weight history
   - Dietary history
   - Substance abuse history
   - Family structure
   - Prior eating disorders
   - Focused family history related to obesity
   - Present physical activity level
   - Food and drug allergies and intolerances
   - Current supplement consumption
   - Current medications
   - Past medication known to affect weight
   - Prior prescribed medications for weight loss
   - Current primary care provider
   - Source of referral
   - Patient's goals

A. Initial patient work-up (continued)

2. *Physical examination*
   Items considered appropriate for physical exam should be examined or obtained and documented and may include but are not limited to:
   - General appearance
   - Height
   - Weight
   - Blood pressure
   - Pulse
   - Head and neck exam
   - Thyroid exam
   - Lung exam
   - Cardiovascular exam
   - Abdominal exam
   - Abdominal circumference
   - BMI
   - Extremity exam
   - General neurologic exam
   - Body composition testing of some type (examples: waist to hip ratio, bio-impedance, infra red, Dexa-scanning)

A. Initial patient work-up (continued)

3. *Diagnostic studies*
   When prior medical records can be obtained indicating any of the diagnostic studies have recently been completed, the bariatrician may avoid unnecessary duplication by performing only those exams needed to complete the bariatric work-up.

   a. Laboratory work
      Items considered appropriate for initial laboratory testing may include but are not limited to:
      - Comprehensive metabolic profile including basic chemistries including glucose, lipid profile, CBC and liver function testing
      - Thyroid functions including TSH and free T4

   b. Electrocardiogram
      ECG is required if there is reasonable evidence of present or past significant cardiac disease. In addition, the potential value of an ECG should be considered if coronary heart risk factors are present, e.g. hypertension, hyperglycemia, dyslipidemias, metabolic syndrome or a strong family history of cardiac disease. A personal history of syncope unexplained or a family history of unexplained death under age 40 may indicate a risk for prolonged Qtc syndrome, and in this situation an ECG should strongly be considered.

   c. Other optional tests
      Items considered appropriate for optional testing may include but are not limited to:
      - A fasting and/or two-hour insulin test
      - Two- or three-hour Glucose tolerance testing with insulin levels
      - Hemoglobin A1c
      - Vitamin D level
      - Advanced lipid testing
      - B12 level
      - RBC Folate level
      - 24-hour urinary cortisol or other form of cortisol testing
      - Prolactin level
      - Cardiac stress testing
      - Sleep apnea study
      - Physical fitness testing
      - Advance psychological testing
      - Echocardiogram

A. Initial patient work-up (continued)

4. *Initial patient management*

Education may be done individually or in a group setting, and may be done by appropriate clinic staff as determined by the clinic supervising MD.

Items considered appropriate for initial patient management may include but are not limited to:

- Review history, physical findings and laboratory data
- Establish and document a diagnosis list or problem list
- Obtain written informed consent
- Determine need for additional testing
- Determine age-appropriate goals for weight loss and review patient's own goals
- Provide a nutritional plan (see patient counseling dietary therapy below)
- Recommend a food diary
- Identify appropriateness for medication therapy
- Educate regarding:
    - Appropriate eating habits
    - Exercise
    - Behavioral modification
    - Complications of overweight and obesity.
    - Benefits, risks and possible side effects of medication if used
    - Role of vitamins, minerals, and hormone balance
- Discuss and document surgical options when appropriate.
- Establish initial follow-up schedule

Patient Counseling

a. Dietary therapy

ASBP recognizes that multiple studies exist of the advantages and disadvantages of different nutritional weight loss plans.[37,38,39] These types of nutritional therapy may include any combination of macronutrient guidelines, including controlled calorie, controlled fat, controlled carb, adequate protein and any combination of fixed meal plan programs and free choice meal planning. **It is unlikely that one diet is optimal for all overweight and obese people. Dietary guidance should be individualized to allow for specific food preferences and individual approaches to reducing energy intake.**

Dietary needs may change as the patient loses weight. Several options of plans might be made available to the patient. In 2007 the American Diabetes Association included a low carb diet as appropriate along with controlled calorie diets in working with diabetics.[40]

b. Exercise therapy

The importance of physical activity and weight loss maintenance is well documented.[41,42] ASBP recognizes there is no definite recommendation that works for all people and the exercise advice should be individualized to the likes and needs of each individual patient. However, ASBP recognizes the American College of Sports Medicine's advice that people should participate in approximately 30 or more minutes of physical activity on most days of the week.[42]

c. Maintenance, relapse prevention, and treatment counseling

Any bariatric program must include a maintenance plan for long-term weight management. Strategies for life-long weight maintenance include counseling for the patient, ideas, actions and therapeutic involvement to prevent regain. An intervention plan must be in place when relapse and weight gain occurs. The long-term nature of obesity should be emphasized to any patient at the start of any weight loss program.

d. Medications and other therapeutic modalities (see section B)

A. Initial patient work-up (continued)

5. *Ongoing patient management*
   Items considered appropriate for ongoing patient management should be evaluated and documented and may include but are not limited to:
   - Progress of weight loss or maintenance of loss
   - Changes in eating behaviors
   - Changes in activity level
   - Effectiveness of pharmacotherapy
   - Monitor for side effects of medications
   - Monitor for side effects of weight loss
   - Monitor for needed changes in routine medicines affected by weight loss
   - Develop a long-term monitoring and relapse prevention and intervention program
   - Review food diaries when indicated
   - Reassess patient's long term goals and objectives
   - Establish regular follow-up schedule

   a. Interval between visits
      Following the initial visit, patients should be seen by the bariatrician at reasonable intervals. The frequency of these visits may vary from bariatrician to bariatrician and from patient to patient within a single practice. The most common frequency of return bariatric visits in the U.S. is four weeks for patients receiving anorectics. With more severe calorie-restricted, carbohydrate-restricted, or ketogenic diets, the visit interval may be shorter.

      Regardless of the interval between patient visits, the therapy of a patient receiving anorectics requires active involvement by the bariatrician, including reasonable availability between patient visits both during weight loss and during maintenance.

   b. Ongoing services
      The patient should be weighed and have pulse rate and blood pressure checked on follow-up visits, all of which may be performed by a qualified assistant or nurse. The bariatrician should inquire about and evaluate potential medical problems or side effects of the treatment program and/or the anorectics and give appropriate medical counsel or treatment. Physiologic parameters, which could be affected by anorectic use, should be assessed from time to time by the bariatrician, and appropriate notations should be made in the patient's records by the bariatrician. Notations in the records by the nurses or assistants may also be appropriate.

      Bariatrics is the practice of medicine by physicians relating to the treatment of obesity and associated conditions and requires direct doctor-patient contact, even though it is legal in some states to delegate the initial exam and follow-up visits to the nursing staff. At a minimum, treatment should include direct

physician contact at the time of initiating therapy and follow-up by a qualified physician at reasonable intervals thereafter consistent with local standards of care. If follow-up visits are delegated to legally recognized physician extenders, the supervising bariatrician should be available for consultation regarding the patients.

In addition, the patient should receive counseling from the bariatrician and/or the nurses or assistants as indicated regarding the nutritional, behavioral, exercise components and psychological aspects of the treatment program.

c. Laboratory follow-up

Some bariatricians assume a primary care role for the patient while others limit their care more narrowly to the obesity-related issues. Either style is appropriate as long as the patient is clear about the limits of the doctor-patient relationship. Generally, those patients in extended treatment whose laboratory tests have been normal should have these tests repeated at twelve-month intervals. Abnormal values may require more frequent monitoring or referral for follow-up. If the patient has laboratory testing done by an outside laboratory or physician, the bariatrician should record the results in the patient's record when results are made available.

B. Medications and other therapeutic modalities

The bariatrician should weigh the potential benefits and risks of any medication or modality used. Significant sources of information include these ASBP OOEM guidelines, journal articles, experiences of colleagues, textbooks, and personal education training and experience. Each of these sources may provide valuable information, and no single source should be used to the exclusion of others.

When appropriate, the bariatrician should provide information on the benefits and risks of the proposed treatment modalities to be used and should inquire as to the patient's understanding of the benefits and risks.

When medications are dispensed, they should be packaged and labeled in accordance with applicable laws and statutes, and appropriate records should be kept.

1. *Informed Consent*

   Although the risks associated with the use of anorectics in a prudent manner for weight reduction and weight maintenance are very low, these risks have been more thoroughly evaluated in the dosages and for time periods indicated in the anorectic labeling. Although the probability of psychological dependence is low when anorectics are used in medical weight reduction and maintenance programs appropriately supervised by bariatricians, there should be an awareness of this possibility and the patient should be monitored accordingly, especially when anorectics are used in higher doses and/or on a long-term basis. Monitoring for non-therapeutic use, diversion to unsupervised individuals, and observation for signs of psychological and physical dependence should be ongoing.

   When the anorectics are used in doses exceeding labeled recommendations and suggested treatment time periods and/or in combination therapy, it is suggested that the bariatrician inform the patient that the anorectics are being used in an "off-label" manner, and as such the risks associated with this type of usage have been less systematically evaluated and thus, may be increased over the risks seen with usage in compliance with labeled suggestions. A suggested form of notification to the patient could be through a consent form prepared in cooperation with the bariatrician's professional legal advisors. Such consent form, if used, should be signed by the patient and should indicate the patient's awareness of alternative therapies, possible increased risks associated with off-label use of the anorectics and the patient's explicit decision to proceed with the proposed treatment plan.

B. Medications and other therapeutic modalities (continued)

2. *Initiation of anorectic medication therapy*
   At the time of this update, there are no universally accepted minimum criteria for appropriate usage of anorectic agents. The scientific and medical community is well aware that there are multiple factors contributing to obesity, as well as several physiologic parameters, which have been shown to contribute to increased health risks (morbidity and mortality). Such parameters may include ideal body weight (Metropolitan tables), BMI, percent body fat, visceral fat distribution, waist circumference, and/or waist-to-hip ratio. These should be taken into account by the bariatrician and patient considering anorectic agent therapy.[43,44] It is recognized that BMIs may appear high in athletic individuals who are not obese and low in individuals with a low lean body mass (sarcopenia). Therefore, BMI must be combined with clinical correlation.

   It is important to realize that the minimum age of treatment with medication is unknown. Unfortunately, adolescent and childhood obesity has increased dramatically in the U.S. since the 1960s. Adult-related obesity conditions are now commonly diagnosed in adolescence. Therefore, it is up to the individual medical provider to determine a safe age to begin use of anorectic medication in children and adolescents based upon careful historical and physical examination and review of individual patient risks and benefits of such intervention.

   a. Initial parameters
      The ASBP recognizes that there are several acceptable anorectic agent usage criteria for patients including but not limited to at least one of the following parameters:
      - BMI ≥ 30.0 in a normal, otherwise healthy individual
      - BMI ≥ 27.0 in an individual with associated co-morbidities (e.g. type II diabetes, hypertension, abnormal glucose tolerance, atherosclerosis, cardiovascular disease, stroke, hyperlipidemia, hypercholesterolemia, osteoarthritis, gall bladder disease, breast cancer, or sleep apnea)
      - Current body weight ≥ 120 percent of a well documented, long-standing, healthy weight that the patient maintained after age 18
      - Body Fat ≥ 30 percent in females
      - Body Fat ≥ 25 percent in males
      - Waist-hip ratio or waist circumference such that the individual is known to be at increased cardiovascular and/or co-morbidity risk because of abdominal visceral fat
      - Presence of a co-morbid condition or conditions aggravated by the patient's excessive adiposity

      Anorectic agent use may also be appropriate in a number of other situations including but not limited to:
      - Prevention of regain in a person who has lost weight,
      - Occupational needs for maintaining a low body weight,

- Prevention of weight gain in patients with a familial/genetic predisposition to obesity and associated co-morbidities.

b. Dosages
Since there are significant differences in response by various patients to medications, including the anorectics, initial doses should be conservative and should be increased step wise, if and only if needed, and provided there are no significant adverse side effects related to the anorectics.

Dosages suggested on anorectic labeling are primarily based on information obtained from the relatively short-term studies done prior to their approval by the FDA. As such, these dosages may not be appropriate for longer-term therapy. If a clinical response is obtained, it may be appropriate to increase the dose of anorectic medication over time. The bariatrician must determine the magnitude of increased dosages on an individual basis. Bariatricians utilizing dosages in excess of labeled dosages and/or for periods exceeding labeled suggestions and/or using anorectic agents in combination with one another or in combination with other medications are under an additional duty to carefully monitor the patient's progress and potential problems and to continue weighing the benefits and risks associated with the increased dosage and/or longer treatment periods. The decision to use any medication in a specific way should be appropriately documented in the patient's medical record.

c. Use of anorectic medications in obese patients having associated medical conditions
Certain medical problems often associated with obesity, such as diabetes, hypertension and most serum lipid abnormalities, usually respond favorably to weight loss. The anorectics may be useful in helping patients with these conditions achieve meaningful weight loss. *The NIH guidelines for usage of medicines for weight loss use the presence of co- as indication to use medicines at a lower beginning weight.*[43] As noted by Albert Stunkard, M.D., Professor of Psychiatry, University of Pennsylvania:

> "There are strong positive indications for the long term use of appetite suppressants. Many obese, hypertensive and diabetic patients can control their conditions by weight loss. Unfortunately, however, many of them cannot lose weight by diet alone. As a result, they are forced to rely on long term use of medication to control their hypertension, diabetes, and other conditions. If these patients must receive long term medication, they may well be better off on appetite suppressants than on the usual remedies."

The ASBP suggests that the bariatrician carefully weigh the benefits and risks of using anorectics with these patients and if the choice is made to use them, recommends the following:

- Diabetes
  The anorectics may be of value in helping obese patients with diabetes achieve and maintain a meaningful weight loss. Reductions in food intake, carbohydrate intake, and in body weight may reduce the need for insulin and/or hypoglycemic agents. The bariatrician should be alert to these possible changes and their management. The patient should be counseled accordingly. *This condition requires closer monitoring and must include counseling on the prevention and risks of hypoglycemic reactions as well as appropriate medication adjustment by either the bariatrician or primary care physician. Clear communication between these physicians regarding who is responsible for monitoring medication response and changing dosage is required.*

- Serum dyslipidemias
  Obese patients with dyslipidemias are best treated with appropriate dietary changes and weight reduction. The anorectics may well be of value in helping these patients to achieve appropriate dietary changes, weight reduction and weight maintenance.

- Hypertension
  Sympathomimetic amine anorectic-induced hypertension has never been described in the peer-reviewed medical literature. Although there is a widely-held opinion that sympathomimetic amine anorectics induce increases in blood pressure, yet no evidence to support this hypothesis has ever been published. In fact, data from clinical trials with phentermine and diethylpropion indicate that blood pressure falls as patients lose weight just as blood pressure falls in patients who lose weight without pharmacotherapy.

  In considering anorectics in obese patients, bariatricians should be aware of the JNC 7 blood pressure diagnostic categories: optimal or normal BP 119/79 or less; prehypertension BP 120-139/80-89; hypertension BP $\geq$ 140/90; Stage I hypertension BP 140-159/90-99; Stage II hypertension BP $\geq$ 160/100. Typically blood pressures in obese patients with pre-hypertension and hypertension fall if they lose weight. Anorectics may be used safely in obese patients with optimal BP or pre-hypertension. They may also be safely used in patients with either stage I or stage II hypertension on anti-hypertensive medication provided the blood pressure is in control and at or below 140/90 when an anorectic is prescribed. Caution should be exercised in prescribing a sympathomimetic amine anorectic to patients with untreated hypertension. Bariatricians should consider either waiting for weight loss to lower blood pressure or prescribing a diuretic first to lower blood pressure and then adding an anorectic when blood pressure is at or below 140/90. Hypertensive patients on anti-hypertensive medication who omit their medication on the day of examination can be expected to have a blood pressure > 140/90.

Anorectics may be prescribed in such patients with the admonition that they must take their blood pressure medication daily, monitor their own blood pressure and omit the anorectic if their BP is > 140/90. These cautions are suggested more to protect the bariatrician from criticism and censure rather than to protect the patient since there is no evidence that sympathomimetic amine anorectants in therapeutic doses affect blood pressure or any other cardiovascular parameter.

- Cardiovascular disease
  Although there is no evidence anorectics have any effect on cardiac status, many physicians assume otherwise. To protect themselves against criticism or censure, bariatricians should exercise caution in prescribing anorectics in patients with known cardiovascular disease, monitor such patients carefully, and obtain cardiology consultation when appropriate.

  If a pre-treatment ECG is obtained, the Qtc should be evaluated. It had previously been propagated among bariatric practitioners that the upper limit Qtc for anorectic therapy was 440 msec. However, extensive review of medical literature and discussions among practitioners have proven that using Qtc 440 msec is not justifiable or supported in the medical literature. Although a PubMed search does not document any connection between anorectic usage and prolongation of Qtc, an acceptable approach that could be supported includes:

QTC INTERVALS

	1 to 15 yrs.	**Men**	**Women**
Normal	0.44 sec	<0.43 sec	<0.45 sec
Borderline	0.44 to 0.46 sec	0.43 to 0.45 sec	0.45 to 0.47 sec
Prolonged (upper 1%)	>0.46 sec	>0.45 sec	>0.47 sec

If normal, no contraindications.

If borderline

No hx of syncope or unexplained family sudden death < age 40

Evaluate and add supplement if appropriate: Potassium, Calcium and Magnesium prior to prescribing sympathomimetic anorectic agents.

POSITIVE Hx of syncope or unexplained family sudden death < age 40

Withhold sympathomimetic anorectic agents for the first month of therapy. Evaluate and add supplement if appropriate: Potassium, Calcium and Magnesium prior to prescribing sympathomimetic anorectic agents. Repeat ECG in one month and check for normalization.

If prolonged

No hx syncope unexplained family death < age 40

Delay prescribing sympathomimetic anorectic agents. Evaluate and add supplement if appropriate: Potassium, Calcium and Magnesium prior to prescribing sympathomimetic anorectic agents. Repeat ECG in one month

POSITIVE hx syncope or family sudden death

Withhold sympathomimetic anorectic agents and refer for cardiac workup.

References for Qtc

1. Findling RL, Biederman J, Wilens TE, et al. Short- and long-term cardiovascular effects of mixed amphetamine salts extended release in children. J Pediatr 2005;147:348-54.

2. Magnano AR, Talathoti NB, Hallur R, et al. Effect of acute cocaine administration on the QTc interval of habitual users. Am J Cardiol 2006;97:1244-6.

3. Haning W, Goebert D. Electrocardiographic abnormalities in methamphetamine abusers. Addiction (Abingdon, England) 2007;102 Suppl 1:70-5.

4. Hung YM, Chang JC. Weight-reducing regimen associated with polymorphic ventricular tachycardia. The American journal of emergency medicine 2006;24:714-6.

- Psychiatric Disorders

  The obese patient may be prone to depression. In such cases the anorectics may be helpful in the patient's weight loss program, which in turn may help with the depressive state. Patients with significant depressive symptoms should be considered for antidepressant therapy. If antidepressants or other psychiatric drugs are used concurrently with anorectics, the patient should be monitored for potential drug interactions and adverse effects.

B. Medications and other therapeutic modalities (continued)

3. *Continuation of anorectic medication therapy*
   The continuing use of anorectics should be based on the patient's response to treatment and on an ongoing beneficial benefit-to-risk ratio. Benefit is assumed if the patient is actively losing weight or maintaining an amount of loss associated with statistical reduction of associated risks (five to 10 percent of initial body weight has been shown to provide such benefit).[20] In addition, prevention of weight regain is an appropriate use of medications. In some patients an anorexiant drug may prevent weight gain without producing weight loss. The anorectic drug may be continued if the bariatrician and the patient agree an anorectic is beneficial in preventing weight gain. Bariatric care should be patient-centered; decisions regarding benefit/risks should always be decisions between the physician and the patient.

   As discussed previously in this document and supported by numerous studies and references, long-term sympathomimetic usage for weight loss and relapse prevention and intervention is justifiable and medically indicated.[11,12,14,15,19,20,22,24,26,28,32,33,34,35,36,]

   The AMA states in its 1995 policy and compendium, "the AMA reiterates that it is appropriate and legal for physicians to prescribe approved drugs for uses not included in their official labeling when they can be supported as rational and accepted medical practice."

   It is important that the patient not feel abandoned during any period of non-anorectic use. Other appropriate therapies may be indicated and on-going support should be continued.

4. *Health benefits associated with fat loss*
   Although ideally the bariatrician would like to have obese patients lose and maintain a normal weight, this frequently does not happen. However, the evidence is increasingly strong that significant health benefits may occur with a five to 10 percent weight loss that is maintained.[20] In addition, helping patients avoid the tendency to gradually increase weight while getting older may, in and of itself, be a significant health benefit. Also, even a modest weight loss is frequently associated with an increased sense of self worth.

Conclusions

The Overweight and Obesity Evaluation and Management Task Force of the ASBP respectfully submits this product of work following months of efforts and numerous contributions from the ASBP Board of Trustees for consideration for adoption as the ASBP Overweight and Obesity Evaluation and Management guidelines.

Disclaimer

These guidelines are an educational tool designed to assist practitioners in providing appropriate bariatric care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the ASBP cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology subsequent to the publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. It should be recognized; therefore, that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

References:

1. Danford, D., Fletcher, S.W. Methods for voluntary weight loss and control, National Institutes of Health Technology Assessment Conference. Annals of Internal Medicine Supplement, 119 (7pt2) 641-770 (1993).
2. National Institutes of Health. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. U.S. Department of Health and Human Services, NIH Publication No. 98-4083, (September 1998).
3. Bays H, Dujovne CA. Adiposopathy is a more rational treatment target for metabolic disease than obesity alone. Curr Atheroscler Rep 2006;8(2):144-56.
4. Bays H. Adiposopathy, metabolic syndrome, quantum physics, general relativity, chaos and the theory of everything. Expert Review of Cardiovascular Therapy 2005;3(3):393-404.
5. Bays H, Blonde L, Rosenson R. Adiposopathy: How do diet, exercise and weight loss drug therapies improve metabolic disease in overweight patients? Expert Review of Cardiovascular Therapy 2006;4(6):871-95.
6. Bays H, Rodbard HW, Schorr AB, Gonzalez-Campoy JM. Adiposopathy: Treating pathogenic adipose tissue to reduce cardiovascular risk. Current Treatment Options in Cardiovascular Medicine 2007;9:259-71.
7. Nurses health study reference of states and obesity Carey, V Walters E.E Colditz, G.A. Solomon, C G Willett Body Fat Distribution and risk of noninsulin diabetes mellitus in Women The Nurses Health Study Am J Epidemiology 1997: 145 (7) 614-9
8. BHRSS survey
9. Haddock CK, Poston WS, Dill PL, Foreyt JP, Ericsson M. Pharmacotherapy for obesity: a quantitative analysis of four decades of published randomized clinical trials. International Journal of Obesity and Related Metabolic Disorders 2002;26(2):262-73.
10. SAMHSA. Drug abuse warning report (DAWN). U.S. Department of Health and Human Services. (2006).
11. ASBP Poster Presentation Hendricks et.al.
12. Frank A. The long-term management of obesity with continuing pharmacotherapy. Obes Res 2004;12(11):1821-7.
13. JAMA January 8,2003 Vol 289 No. 2
14. Long-term pharmacotherapy in the management of obesity. National Task Force on the Prevention and Treatment of Obesity. JAMA 1996;276(23):1907-15.
15. Bray GA. Use and abuse of appetite-suppressant drugs in the treatment of obesity. Ann Intern Med 1993;119(7_Part_2):707-13.
16. NIH evidence report NO 98-4083. Sept 1998.National Institute of Health Chapter 4 treatment guidelines, page 86.
17. Rothman RB, Blough BE, Baumann MH. Dual dopamine/serotonin releasers as potential medications for stimulant and alcohol addictions. Aaps J 2007;9(1):E1-10.
18. Pi-Sunyer FX. Use of lifestyle changes treatment plans and drug therapy in controlling cardiovascular and metabolic risk factors. Obesity 2006;14(suppl_3):135S-42.

19. Radley DC, Finkelstein SN, Stafford RS. Off-label prescribing among office-based physicians. Arch Intern Med 2006;166(9):1021-6.
20. Goldstein, David J. (1992): Beneficial health effects of modest weight loss. *Int J of Obesity.* 16:397-415
21. Williamson, D.F. (1993); Descriptive epidemiology of body weight and weight change in U.S. adults. *Ann Intern Med.* 119:646-649
22. Weintraub, Michael & Bray, George A. (1989); Drug Treatment of Obesity. Medical Clinics of North America. 73:237-249.
23. Nutrition Today, Vol.19. #4, July/1984, Pg. 22; also see, *Am J Clin Nutri.* 39:152
24. Douglas, J.G. & Munro, J.F. (1982); Drug Treatment and Obesity. *Pharmac Ther.* 18:351-373.
25. Sullivan, A.C. & Comai, K. (1978); Pharmacological Treatment of Obesity. *Int J of Obesity.* 2:167-189
26. Goldstein, D.J. & Potvin, J.H. (1994); Long-term weight loss: the effect of pharmacologic agents. *Am J Clin Nutr.* 60(5):647-657
27. Bray, G.A. (1976); Drug therapy for the obese patients. In "*The obese Patient,*: pp.353-410. Philadelphia: W.B. Saunders
28. Weintraub M, et al (1992); Long term weight control: The National Heart, Lung and Blood Institute funded multimodal intervention. Clin Pharmacol Ther. 51(5):581-646.
29. Richard, Barbara W. & Lasagna, Louis (1988): Anorectic Drugs: Drug policy Making at the State Level. *J Clin Pharm.* 28:395-400
30. Griffiths, R.R., Brady J. V., Bradford, D.L. (1979): Predicting the abuse liability of drugs with animal drug self-administration procedures: Psychomotor stimulants and hallucinogens, in Thompson T. Dews PB, (eds). *Advances in behavioral pharmacology.* Vol. 2 New York: Acedemic Press: 163-208
31. Scoville, Barrett (1975); Review of amphetamine-like drugs by the Food and Drug Administration: Clinical data and value judgements, in Bray, GA (ed): Obesity in perspective. *DHEW Publ No. 9.* (NIH) 75-708, Bethesda, MD National Institutes of Health: 441-443.
32. NAASO Task Force (1995): Guidelines for the Approval and Use of Drugs to Treat Obesity. *Obes Res.* 3(5): 473-478
33. Stunkard, Albert J. (1982); Mini-review – Anorectic Agents Lower a Body Weight Set Point. *Life Sciences.* 30:2043-25055
34. Stunkard, Albert J.(1988); The Salmon Lecture, "Some Perspectives on Human Obesity: Treatment. *Bull NY Acad Med.* 64:924-940.
35. AMA Policy Compendium, 1995, 120.992. Prescription of Drugs: The AMA reiterates that it is appropriate and legal for physicians to prescribe approved drugs for uses not included in their official labeling when they can be supported as rational and accepted medical practice.
36. Rader, W. A., Steelman, G.M, Westman, E.C 2008 Clinical experience using appetite suppressants and SSRIs OK Journal article 101:8 180-181
37. Gardner CD, Kiazand A, Alhassan S, et al. Comparison of the Atkins, Zone, Ornish, and LEARN diets for change in weight and related risk factors among

overweight premenopausal women: the A to Z Weight Loss Study: a randomized trial. JAMA 2007;297:969-977. [Erratum, JAMA 2007;298:178.]
38. Yancy WS Jr, Westman EC. et.al. A low-carbohydrate ketogenic diet versus a low-fat diet to treat obesity and hyperlipidemia: a randomized, controlled trial. Ann Intern Med 2004;140:769-777.
39. Sack, Frank, Bray, George, et.al.; Comparison of weight loss diets with different compositions of fat, protein, carbohydrates. 2009 NEJM 360:859-873
40. DIABETES CARE, VOLUME 31, SUPPLEMENT 1, JANUARY 2008Shape Up America and The American Obesity Association; Guidance for the Treatment of Adult Obesity, November, 1996.
41. Med. Sci. Sports Exerc., Vol. 39, No. 8, pp. 1423–1434,
42. 2007.Azar ST Zantout MS. Evaluation and treatment of obesity.J Med Liban. 2000 Sep-Oct; 48(5):310-4
43. National heart Lung and Blood Institute Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. September, 1998, NIH Publication No. 98-4083
44. Bray G. Evaluation of total and regional body composition. In: Bray GA, Bouchard C, James WPT, eds. Handbook of Obesity. New York-Basel: Marcel Dekker, Inc., 1998, 831-54.

Guideline Authors

The OOEM guidelines were developed by the OOEM task force. The guidelines were evaluated, amended, and revised a total of 17 times prior to achieving the final document. ASBP would like to thank the following for their contributions to these guidelines.

OOEM Task Force

Allen Rader, MD
Chairperson OOEM task force
2008-2009 Secretary/Treasurer
2006–2009 Board of Trustees
2007 Bariatrician of the Year
ABBM Diplomate
ASBP member

David Bryman, DO
ABBM Board of Directors
2008 Bariatrician of Year
ABBM Diplomate
ASBP member

Ed Hendricks, MD
2008–2010 Board of Trustees
2009 Bariatrician of Year
ABBM Diplomate
ASBP member

Richard Lindquist, MD
OOEM task force member
ASBP member

Larry Vickman, MD
OOEM task force member
ASBP member

ASBP Board of Trustees

James Bland, MD, JD
2009-2011 Chairman of the Board
2007-2009 President
2005-2007 President-Elect
2004-2005 Board of Trustees
2009 Dr. Vernon B. Astler Award
ABBM Diplomate

Larry Richardson, MD, FASBP
2009-2011 President
2007-2009 President-Elect
2006-2007 Vice President
2004-2005 Chairman of the Board
1999-2002 Chairman of the Board
1997-1999 President
1995-1997 President-Elect
1991-1995 Board of Trustees
1996 Bariatrician of the Year
ABBM Diplomate

Eric Westman, MD, MHS
2008-2010 Vice President
2009 Steelman-Seim Educator Award

Mary Vernon, MD, FAAFP, CMD, FASBP
2007-2009 Chairman of the Board
2005-2007 President
2004-2005 President-Elect
2003-2004 Vice President
2002-2003 Board of Trustees
2008 Dr. Vernon B. Astler Award
2005 Bariatrician of the Year
ABBM Diplomate

ASBP Board of Trustees (cont.)

Allen Rader, MD
Chairperson OOEM task force
2008-2009 Secretary/Treasurer
2006–2009 Board of Trustees
2007 Bariatrician of the Year
ABBM Diplomate

Deborah Horn, DO, MPH
2009-2010 Secretary / Treasurer
2007-2009 Board of Trustees
ABBM Diplomate

Ed Hendricks, MD
2008–2010 Board of Trustees
2009 Bariatrician of Year
ABBM Diplomate

John Kelly, MD
2002-2009 Board of Trustees
2004-2005 Vice President
2005 Dr. Vernon B. Astler Award
ABBM Diplomate

Eneida Roldan, MD, MPH, MBA, FASBP
2005-2009 Board of Trustees
2003 Raymond E. Dietz Award
2000 Bariatrician of Year
ABBM Diplomate

Lisa Salvati, MD, MPH, FACPM, FAAFP
2008–2010 Board of Trustees
1992-1994 Board of Trustees
1996 Raymond E. Dietz Award

Erin Snyder, MD, FAAFP
2006–2010 Board of Trustees
ABBM Diplomate