

## The Clinical and Economic Aspects of Obesity Management: A Managed Care Perspective

*Faculty Question-and-Answer Session*

### Pharmacotherapy

*Question: At what point during pharmacotherapy treatment for obesity would one determine that the case is a therapeutic failure? Is this decision individualized per patient or is there a general rule of thumb to use in daily practice?*

*Answer (Dr. Kushner):* Data from clinical trials indicate that weight loss of at least four pounds, regardless of baseline weight, during the first month of treatment is predictive of extended pharmacotherapy success. However, in my clinic I routinely put patients on a 3-month trial because I feel it unfair to expect an individual to change lifestyle within 1 month. If a 5% weight loss occurs within 3 months of intensive pharmacotherapy, it is likely that prolonged therapy will be effective. If not, we start to look for the psychological reasons the patient may be unable to lose weight and pharmacotherapy is discontinued.

*Question: So far sibutramine shows no evidence of causing valvular heart disease, but has it been studied to the extent the other serotonin agents have?*

*Answer (Dr. Kushner):* Drugs associated with valvular heart disease like dexfenfluramine work as both a serotonin releasing agent and a serotonin reuptake inhibitor while sibutramine's serotonergic action is only as a reuptake inhibitor. No additional serotonin is being produced. Other similar drugs, namely the

selective serotonin reuptake inhibitors commonly used for depression, have never shown evidence of valvular heart disease. No increased incidence of valvular heart disease with sibutramine [2.3% (3/132 patients)] have been found in clinical studies.

*Question: Are there parameters in place to ensure the appropriate use of the new agents coming to the market?*

*Answer (Dr. Brownell):* Yes. The indications for these drugs are being written so they are only to be prescribed for patients with a body mass index of  $\geq 30$  kg/m<sup>2</sup> or  $\geq 27$  kg/m<sup>2</sup> in the presence of comorbid conditions. In the absence of comorbidities, a greater degree of obesity will be needed for the drugs to be indicated. I think these guidelines will be very helpful to prescribing physicians.

*Question: Has the combination of fluoxetine and phentermine for weight loss been studied and is there any justification for using this combination based on the mechanisms of action of both drugs?*

*Answer (Dr. Kushner):* The combination makes theoretical sense; however, since fluoxetine alone does not produce weight loss in everyone when used alone, it probably is working on the serotonin receptors that are not directly linked to the hypothalamus and appetite control. It does work quite well on the

serotonin receptors linked to feelings of depression. Although there is some pharmacological support for fluoxetine use in obesity, I doubt whether fluoxetine and phentermine would be the right combination. I personally think it inappropriate to unleash this combination on the general public when it hasn't been tested, particularly in light of the political sensitivity surrounding the fenfluramine and phentermine combination. On the other hand, there has been a study done showing that fluoxetine and phentermine are more effective than placebo for weight loss but not as effective as the fenfluramine and phentermine combination. That is where the research along this line remains and should remain until there is further data.

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— Kelly D. Brownell, PhD

*Question: Are there certain drugs used to treat the comorbidities of obesity that actually cause weight gain, thereby contributing to the original problem? It seems the medical professionals could benefit from understanding these potential drug effects.*

*Answer (Dr. Kushner):* Diabetes as a comorbidity of obesity immediately comes to mind. The use of insulin and sulfonylureas cause weight gain, while metformin and troglidazone probably do not. Certainly, anyone taking corticosteroids for any reason may have additional weight gain as would patients taking tricyclic antidepressants.

*Answer (Dr. Brownell):* I agree that medical professionals need to keep these drugs in mind. I think that in the literature, there are increasing uses of tables listing medications that may cause weight gain. Keeping up with the literature may be a starting point.

### Treatment Concept

*Question: If the goal of modest weight loss is 10% from baseline, is there any value in resetting the baseline down the road? For example, if a patient has maintained the initial 10% loss for a year, is it reasonable to reset the baseline to the new, maintained weight and try to lose another 10%?*

*Answer (Dr. Brownell):* That tactic would be right on target. With most patients, we don't initially focus on losing 10% of their weight because it is too intimidating. Instead, we concentrate on short-term goals of five, maybe 10 pounds, and keep resetting new goals until 10% is reached.

Continuing from 10% would simply progress the short-term goal process. However, if the patient doesn't feel they can go beyond the initial weight loss, we then focus on maintenance rather than risking weight regain.

*Question: In your experience, what percentage of patients actually remained compliant with lifestyle modification over a period of time? My experience with other programs such as those for gastrointestinal disease and smoking cessation has been that participants tend to comply with lifestyle change recommendations at the start but that compliance rate declines with time.*

*Answer (Dr. Brownell):* There is no question that lifestyle change is difficult to continue over the long term. In most trials, retention, or compliance rates, have been good, but healthcare professionals must go out of their way to make

it so. Positive reinforcement is essential, and tactics such as having patients pay a deposit at the beginning, which is only returned at the end of the program if they have attended required follow-ups and assessments, are often helpful. I would have to say that continual positive reinforcement of the beneficial effects of their weight loss is the most important factor in compliance.

*Question: Although this conference has not focused on surgical treatment for morbid obesity, I'd like to know what the appropriate criteria should be when deciding whether to recommend surgery for a patient.*

*Answer (Dr. Kushner):* First, body mass index should be at least 40 for surgery to be a consideration. Second, the patient should have a history of participating in weight management programs with only very temporary success followed by regaining any weight lost and more. Third, the patient will have at least one, but usually multiple, comorbidities or be at very high risk of developing those comorbidities, such as when there is a family history of diabetes. The next requirement is that there is no significant psychopathology including schizophrenia or bipolar illness and they must be psychologically able to comply with various assessments and follow-ups. Lastly, surgical candidates must understand what the surgery will involve and the dietary changes required, but most important, they must be at a point in their life when they view this step as a turning point.

*Question: Certainly, only a small percentage of patients who qualify for surgery undergo the procedure due to limited financing. Should you attempt using other modalities of obesity management with pharmacotherapy in these patients? Do they derive as much benefit from a 10% weight loss as do those who are less obese?*

*Answer (Dr. Kushner):* This issue hasn't been studied enough. All of the pharmacotherapy trials have included only moderately obese patients, and there have been no trials with the severely obese. In my practice, severely obese patients do not seem to receive the same benefit with appetite suppres-

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sants. Whether the reasons are biologic, genetic, metabolic, or involve the increased adipose mass, these patients are not responsive to the types of behavioral therapy we normally employ. It is very frustrating when surgery is denied to these patients. All you can do at that point is treat them for sleep apnea, diabetes, gastrointestinal reflux, and everything else they have. Denial of a procedure that can help them also leads to incredible frustration and depression for the patient. They often disappear from the program because they are so disillusioned.

*Question: Are there any guidelines for primary care physicians to assist them in diagnosing mild, moderate, and severe obesity and linking appropriate treatment approaches to those patients?*

*Answer (Dr. Kushner):* Shape Up America and the American Obesity Association, in a joint venture, have published guidelines available from either organization or on the Internet. They

separate categories of risk and outline treatment modalities.

### Obesity Costs

**Question:** *Are the companies manufacturing agents for obesity assisting in the long-term epidemiological studies involving the benefits of weight loss? Such data would make the decision process much easier for health plans when they are considering whether to reimburse.*

**Answer (Ms. Wolf):** Yes. There are already many long-term epidemiological studies that have evaluated the impact of obesity on comorbid conditions (Nurses' Health Study, Framingham). Some new research, being funded by NIH as well as pharmaceutical companies, is evaluating the benefits of weight loss along with the probabilities of developing a comorbidity, such as type 2 diabetes, or a constellation of comorbidities, such as type 2 diabetes, hypertension, and dyslipidemia with weight gain. We are just beginning to explore who may be good candidates for target interventions.

**Question:** *If over a 3-year period, patients with a body mass index of more than 25 caused \$2,200 more in health-care costs than patients not at risk, and if the best cost to affect a 1% reduction in body weight per year was \$70 with a direct cost of \$2, I calculate that the best we could do by giving long-term pharmacotherapy is to break even. This would be assuming that everyone achieving a 10% body weight loss with treatment moved into a body mass index category that was not at risk. Have any models been done to determine the costs of avoiding obesity or of maintaining patients in a nonrisk state?*

**Answer (Ms. Wolf):** No. Interventions aimed at prevention of weight gain are currently ongoing, but to my knowledge, direct costs and productivity costs are not being evaluated. The models so far have just looked at the cost of obesity. The model you are referring to projected the savings associated with a 10% weight loss, but it did not include the cost of treating obesity. As far as long-term savings associated with a 10% weight loss, we do not project that there will be a dramatic amount of savings. However, the situation is similar to coronary heart disease or diabetes. If you treat everyone with dyslipidemia, there will not be much savings. This strategy is not cost-effective. This is where targeting populations comes in; we need to develop risk-satisfaction models.

**Question:** *From information that was presented regarding employer groups viewing satisfaction with health plans as being based on cost, what would be the incentive for a health plan to increase its costs by treating obesity?*

**Answer (Dr. Burton):** Let me point out that the costs I presented were for women with a body mass index of 27.3 and men with a body mass index of 27.8. However, once you reach body mass index levels of 30 and higher, you will begin to see huge differences in cost. It is at this level of obesity that medications would probably be used. Therefore, the payback will be much more prominent in terms of both direct and indirect costs. It is the indirect costs of obesity, such as lost productivity, disability absences, and more long-term risk factors, that corporations will be interested in. When the increase in productivity is included in cost calculations regarding treatment payback, I believe employers will understand that the amount paid for these services becomes relatively small.