

## Informed Consent for a Low Calorie Diet/Appetite Suppressant

**Patient Name (print):** \_\_\_\_\_ **Date of Birth:** \_\_\_\_\_

**Appetite Suppressants:** At the time of the writing of this consent form, there are 5 branded appetite suppressants on the market. These medications include Belviq, Contrave, Qsymia, Saxenda, and Xenical. Non-branded medications include diethylpropion, phendimetrazine, and phentermine. In addition, there are medications that are not appetite suppressants but which may be used to augment your weight loss efforts. Your provider may assist you with your decision in what is appropriate for yourself. Considerations may include the particular nature of the behavioral problem that is being treated, the cost of the medications, the expected length of the prescription time period, and relative and absolute contraindications from one medication that would favor another. At all times, the risk of your current health condition should be weighed against the risk/reward of using an appetite suppressant. You are not required to use an appetite suppressant to lose weight but results are typically better with one.

Appetite suppressants, such as phentermine, have package labeling which recommends the use of the medication for obese individuals, for time periods of up to 12 weeks, and at the dosage indicated in the labeling. Recently, national societies such as the Endocrine Society and the Obesity Medicine Association have issued position papers advocating for the longer term (> 12 weeks) use of phentermine as the risk/benefit analysis appears to favor the longer term usage. ‡, i, iv

**Guidelines for Anorectic Usage:** We adhere to guidelines for anorectic usage as stated by a variety of organizations such as the Obesity Medicine Association (OMA), AACE/ACE and the Endocrine Society. Pharmacotherapy generally is used as an adjunct to behavioral modification to reduce food intake and increase physical activity. Pharmacotherapy is indicated for the purpose of treating the disease of obesity<sup>i</sup> which has a variety of definitions, preventing the relapse of obesity and to treat and lessen the risk of complications of weight related conditions. Indications for initiation and continuation of anorectics include:

- BMI ≥ 30 (Caucasians) and ≥ 27 in certain ethnic populations in normal healthy individuals\*<sup>iii</sup>
- BMI ≥ 27 in individuals with co-morbidities (DM, HTN, insulin/leptin resistance, vascular disease, hyperlipidemia, asthma, cancer, GERD, OSA, kidney disease, osteoarthritis, gallstones, PCOS, psoriasis, acrochordon, acanthosis nigricans, or other related conditions)<sup>\*, iii</sup>
- BMI ≥ 25 with the above listed comorbidities and certain ethnic populations ≥ 23 with the above listed conditions<sup>†</sup>
- Current weight > 120% of a long standing healthy weight maintained after the age of 18<sup>ii</sup>
- Body fat ≥32% in females and ≥25% in males (obesity)\*
- Waist circumference ≥ 31" or ≥ 35" in women and ≥ 37" or ≥ 40" in men (increased and high risk) \*<sup>†</sup>
- Waist circumference in certain ethnic populations\*<sup>†</sup>:
  - Asians, Central and South American ≥ 31" in women and ≥ 35" in men
  - Europids, Middle Eastern ≥ 31" in women and ≥ 37" in men
- Any co-morbid condition that is aggravated by weight\*
  - Fat mass disease such as: hypertension, shortness of breath, impaired mobility, low self-esteem, body image dissatisfaction, decreased work productivity, negative self or external perceptions and others.
  - Sick fat disease such as: atherogenic dyslipidemia, increased triglycerides, insulin resistance, fatty liver, asthma, osteoarthritis, PCOS, hirsutism, low testosterone, intimacy problems, impaired fertility, prevention of cancer, sleep disorders, and others.
- Prevention of weight regain in a person who has previously lost weight<sup>i, iv, ‡</sup>
- Weight loss for occupational needs\*
- Prevention of weight gain in a person who has a familial/genetic predisposition to obesity, cancer, or other obesity related conditions\*

\* Obesity as defined by the OMA's Obesity Algorithm

† AACE/ACE Clinical Practice Guidelines.

‡ Endocrine Society Clinical Practice Guideline

i – OMA position statement on anti-obesity medications – 3/2015

ii – ASBP Overweight and Obesity Evaluation and Management guidelines – 2009

iii – FDA guidelines for anti-obesity medications

iv – OMA, pharmacotherapy position statement 2016

**Off Label Prescribing...** A provider is not required to use the medication as the labeling suggests. This is called off label prescribing and is specifically provided for by the FDA. I have found appetite suppressants and other non-anorectic type medications to be helpful for periods exceeding 12 weeks and at doses larger than those suggested in the labeling. The indications for these usages are based on my experience, the experience of my colleagues, and guidelines from the various medical societies. Such usage has not been as systematically studied as that suggested in the labeling and it is possible, as with most other medications, that there could be serious side effects. I believe the probability of such side effects is outweighed by the benefit of the appetite suppressant for the given dose and indication. However, you must decide if you are willing to accept the risks of side effects, even if they might be serious, for the possible help the appetite suppressants and other non-anorectic type medications may give.

**Dispensing and Furnishing:** An appetite suppressant or other weight loss related medication may be prescribed and dispensed within the office. I understand that I have a choice in where I may obtain my prescription and that I may obtain it at a pharmacy of my choice.

\_\_\_\_\_ - By initialing here I agree that I have been given a choice in where I may obtain my medication.

**Responsibility...** It is my responsibility to follow dosing instructions carefully and to report promptly any medical problem(s) that may be related to my weight control program. In general, medications will not be prescribed without an office visit. One time, short term exceptions can be decided on a case by case basis. We reserve the right to refuse such an exception to anyone. Abuse of this policy can result in dismissal from the clinic. Diversion of medications to individuals other than myself is grounds for dismissal. Random urine drug testing may be done.

**Purpose...** I understand the purpose of this treatment is to assist me in my desire to achieve and maintain a healthy weight. My continuing to receive appetite suppressants will be dependent on my progress in weight reduction and weight maintenance.

**Drug Testing:** If you are drug tested as part of your employment or for another purpose, and you are prescribed a stimulant medication, you may test positive for methamphetamines. If needed, you may be given a doctor's note to state you are taking a medication to aid in weight loss.

**Alternatives:** There are multiple ways to decrease body weight and maintain a healthy weight. A reduced calorie diet or a protein sparing modified fast and regular exercise without the use of appetite suppressants could help, even though I may be hungrier and the weight loss may not be as great.

**Risk of Proposed Treatment...**The use of anorectic medications, involves some risk. Risks are higher for dosages that exceed the recommended labeling. Common side effects of stimulant type medications include: **insomnia, palpitations, dry mouth, headaches, psychological problems, medication allergies, short term high blood pressure, and dependence** (exceedingly rare). Blood pressure can become more elevated when taken with pseudoephedrine, an over the counter cold medicine. Rare, but serious risks include **primary pulmonary hypertension and valvular heart disease**. These side effects were observed rarely with fenfluramine and have a very rare occurrence with other appetite suppressants but have not been found to have a direct association. These risks could be slightly higher with Belviq (Lorcaserin), a weight loss medication that is similar to fenfluramine. Medications containing topiramate can increase the risk of cleft palate in a developing fetus. Medications containing liraglutide (Saxenda) can increase risk of thyroid cancers and pancreatitis. These and other possible risks could, on rare occasion, be serious or fatal.

**Your role:** Your success depends upon your commitment to fulfilling your obligations during treatment. You should be willing to:

- Provide honest and complete answers to questions about your health, weight, eating, and lifestyle patterns.
- Devote the time needed to complete and comply with the course of treatment as prescribed.
- Attend your appointments regularly and follow your diet and exercise prescription.
- Obtain blood/diagnostic tests which your physician may deem necessary during your treatment.
- Advise the clinic staff of ANY concerns, problems, complaints, symptoms, or questions even if you may think it is not terribly important. This affords the best chance of intervening before a problem becomes serious.

**Risks Associated with Being Overweight:** People who are overweight or obese have greater tendencies toward: hypertension, diabetes /metabolic syndrome/insulin resistance, high cholesterol, asthma, GERD, fatigue, heart attack, stroke, peripheral vascular disease, abnormal cardiac rhythms, obstructive sleep apnea, pulmonary hypertension, migraines, arthritis, low back pain, depression, anxiety, decreased fertility, PCOS, various types of cancer and other problems. ***These risks/conditions can be reduced with weight loss of as little as 5 percent.*** If you are taking medications for obesity related condition, dosages may need to be adjusted as your diet progresses.

**Unknown Side Effects:** The possibility always exists in medicine that the combination of a disease with methods employed for its treatment may lead to previously unobserved or unexpected effects, including death. Should one or more of these conditions occur, additional medical or surgical treatment may be necessary.

**Common Side Effects:** During a low calorie diet, common side effects can be: *a reduced metabolic rate, increased urination, dizziness, sensitivity to cold, a slower heart rate, dry skin, fatigue, diarrhea, constipation, bad breath, dry or brittle hair, hair loss, muscle cramps, or menstrual changes.* These responses are temporary and resolve when calories are increased after the period of weight loss.

**Gallstones:** Overweight people develop gallstones at a rate higher than normal weight individuals. As body weight and age increase, so do the chances of developing gallstones. These chances double for women, women using estrogen, and smokers. Losing weight, especially rapidly, may increase the chance of forming/developing stones or having complications of existing stones within the gallbladder. Should symptoms develop, commonly a right upper abdominal pain, or if you know or suspect that you have gallstones, let your provider know immediately. Gall stones may need a medication to treat the stones or surgery to remove the gallbladder. Less commonly, they may be associated with more serious complications or even death.

**Pancreatitis:** An inflammation/infection of the pancreas, may be associated with gallstones and/or obstruction in the bile ducts. The symptoms of pancreatitis are typically pain in the left upper abdominal area. Pancreatitis may be precipitated by binge-eating or consuming a large meal after a period of dieting. Also associated with pancreatitis are long term abuse of alcohol and the use of certain medications and increased age. Pancreatitis requires treatment and may be associated with more serious complications including death.

**Pregnancy:** If you become pregnant, report this to your health care professional and physician immediately. Your calorie restricted diet must be stopped promptly to avoid further weight loss and potential damage to a developing fetus. Anorectic medications used to facilitate weight loss are contraindicated during pregnancy. ***You must take precautions to avoid becoming pregnant during the course of weight loss.*** Your health care provider may help by prescribing birth control pills, referring for IUD placement or discussing other methods of birth control.

**The risk of weight re-gain:** Obesity is a chronic condition, and the majority of overweight individuals who lose weight have a tendency to regain all or some of it over time. Factors which favor maintaining a healthy body weight include regular exercise, adherence to a healthy diet, and having a coping strategy for weight regain before it occurs. Successful treatment may take months or years.

**Sudden Death...**Patients with morbid obesity and serious health problems such as severe hypertension, heart disease, or diabetes, have a statistically higher chance of suffering sudden death when compared to normal weight people without these problems. **Rare instances of sudden death have occurred while obese patients were undergoing medically supervised weight reduction, though no cause and effect relationship with the diet has been established.** Other rare risks are primary pulmonary hypertension and valvular heart disease.

**Food Items...**Food items purchased in the office are non-returnable once purchased. "Warning: Food products sold in this office may contain lead which at certain levels is known by the state of California to cause cancer, reproductive harm or developmental harm." It is not possible for our suppliers to track all sources of lead in the production of the food including those that are naturally occurring in the soil.

**Your Rights and Responsibility...**You may leave treatment at any time. You have a responsibility to notify the physician that you are discontinuing treatment and to find another physician who is able to assume medical care for you after you leave treatment.

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**Consent – Low Calorie Diet/Appetite Suppressants:** I, the undersigned, have reviewed the above information with my health care professional, regarding reduced calorie diets and appetite suppressants and understand/agree that the potential benefits of weight loss outweigh the risks of the proposed therapy. I have had an opportunity to ask questions and have had them answered to my satisfaction.

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**Participant Signature**

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**Date**