

## **Delaware Medicaid and Medical Assistance**

### **Request for Prior Authorization – Anti-Obesity Drug**

**Submit request via: Fax – 1-302-454-0224 or Website – WWW.DMAP.STATE.DE.US**

30% of the United States population is obese and 95% of obese people treated with exercise, diet and or behavior modification are unable to maintain their weight loss at 5-year follow-up.

Research is now producing acceptable adjunctive drugs for the treatment of obesity.

The Delaware Medical Assistance Program (DMAP) has the authority to provide coverage of this type of treatment for drugs covered under the Medicaid Program with the following restrictions since it is an optional service under the Medicaid Program. The DMAP, with consultation of the Drug Utilization Review Board, will determine the inclusion of any Food and Drug Administration (FDA) approved antiobesity therapy. Applicable guidelines for coverage of these products have been established and will be routinely reviewed.

The only drugs for the treatment of obesity that will be covered are those that are FDA approved as both safe and effective for continuous treatment of at least one-year duration. In order to receive such a covered antiobesity medication, a patient must meet both the general weight criteria and the specific criteria of at least one of the covered clinical conditions.

#### **General Requirements**

Obesity by itself is not a sufficient criteria but as a minimum requirement the Body Mass Index (BMI) must be > 27kg/sq.m.

#### **Covered Conditions**

Additionally the patient must have at least one of the following 3 covered co-morbid conditions; diabetes mellitus, mixed hyperlipidemia (low HDL, high TG>300) or hypertriglycerides (TG>300) and these specific dyslipidemia patients will be limited to those with pre-existing heart disease and/or two other cardiac disease risk factors,(Sibutramine will not be approved for any client with a history of coronary artery disease, congestive heart failure, arrhythmis or stroke) or obstructive sleep apnea. These conditions have been selected since they have fulfilled the coverage criteria of providing sufficient evidence that significant weight loss can produce a measurable, intended, beneficial effect on the underlying condition, and that the favorable effects outweigh the harmful effects, and that the medicine is cost-effective and comparable or complementary to other treatments for the condition. The conditions/illnesses to be covered may be expanded in the future if appropriate and sufficient evidence is submitted i.e. peer reviewed, well-controlled studies relating the intervention the intervention to health outcome.

#### **Restrictions**

1. The initial assessment must include a thorough history and physical exam.
2. The patient cannot have pulmonary hypertension and cannot be currently on MAOI, other weight loss medicines, serotenergic medicines, lithium, antidepressants,cough suppressants, tryptophan, sumatriptan,

- dihydroergotamine, other medicines used for the treatment of migraines and must avoid alcohol consumption.
3. The patient must have documentation of prior nutritional therapies and results, prior exercise programs and results, and prior behavior modification attempts and results.
  4. The patient must be placed on an appropriate calorie restricted diet and supervised by a qualified dietitian/nutritionist prior to seeking prior authorization. The patient must also be placed on a medically appropriate exercise program.
  5. Blood pressure must be stable, properly monitored and documented. Initial blood pressure must be below a systolic of 160 and a diastolic of 95.
  6. Patients must be at least 16 years old.
  7. Documentation that the client is not suffering from narrow angle glaucoma must be submitted.
  8. As more experience is gained with these medications, more clinical restrictions concerning use may be added.

### **Initial Prior Authorization**

If the patient meets these requirements then Prior Authorization will be granted for a 1-month trial of an authorized product at a standard dose. Weight loss must be documented during the first 30 days of therapy. If adequate weight loss has occurred, the medication will be dispensed in 30-day supplies and allow for no more than 90 days per authorization. In order for the authorization to be renewed after that period, the physician must provide documentation that a substantial, minimal amount of weight loss has occurred. The minimum will be 5% of the baseline weight. The patient must also meet their particular condition-specific requirements below. Prior authorization must be renewed every 3 months. If weight loss continues or is at least maintained then the Prior Authorization will be renewed as long as they meet the condition specific requirements also. However, if more than 50% of what has been lost is regained or if total weight loss from the baseline is ever <5% then the Prior Authorization for this or an essentially similar medicine as determined by the Delaware Medical Assistance Program may not be renewed for at least one year.

### **Condition Specific Requirements**

1. **Diabetes Mellitus:** At the time of the first prior authorization, a baseline hemoglobin A1C is required to be submitted. For renewal of antiobesity medications, there must be a significant improvement in the diabetes glucose control as demonstrated by the submitted hemoglobin A1C value (minimum equal to 0.1) or the maintenance of an excellent hemoglobin A1C value (less than 7.0%) with the concomitant reduction in dose or omission of diabetic medication (insulin/sulfonylureas, metformin, etc.). For future renewals, improved hemoglobin A1C values must be maintained.
2. **Dyslipidemias:** Patients with preexisting Coronary Artery Disease (CAD) or two or more CAD risk factors may be prior authorized for the anti-obesity medication if they have either a mixed type of hyperlipidemia (HDL<35 with TG>300) or hypertriglyceridemia (TG>300) and who satisfy the general weight criteria will be granted a trial 3 month period. (CAD or risk factors criteria will not apply when sibutramine is requested.) Future renewals at 3-month intervals, will be authorized if the physician provides evidence of a minimum 15% improvement in either or both the HDL/TG levels as compared to the baseline values before

treatment was initiated. As noted previously there must be the same evidence of the significant minimum weight loss and maintenance of such weight loss.

3. Obstructive Sleep Apnea: Any obstructive sleep apnea patient who meets the general weight criteria noted above may have a 3 month trial of antiobesity medication if the treating pulmonologist states a trial of medication is indicated. Renewals for a 3-month period will be authorized if the weight loss criteria are met and the pulmonologist can state a significant objective improvement has occurred.

Antiobesity Drug

**Authorization**

Client Name: \_\_\_\_\_ Date Of Birth: \_\_\_\_\_

Medicaid Number: \_\_\_\_\_

Practitioner Name: \_\_\_\_\_ Provider #: \_\_\_\_\_

Office Phone Number: \_\_\_\_\_ Office Fax #: \_\_\_\_\_

Diagnosis: \_\_\_\_\_

Previous weight loss attempt records included:    **Yes**    **No**

Laboratory values included and date :    **Yes**    **No**

Current weight : \_\_\_\_\_ BMI : \_\_\_\_\_

Proposed Regimen : \_\_\_\_\_

Date: \_\_\_\_\_

Additional Comments: \_\_\_\_\_

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