**MERIDIA®, XENICAL® UTILIZATION MANAGEMENT CRITERIA**

<table>
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<th>DRUG CLASS:</th>
<th>Obesity</th>
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| BRAND NAME: | Meridia® (sibutramine), HICL = J8AN  
|           | Xenical® (orlistat), HICL = D5AA |

**FDA INDICATIONS:** The management of obesity including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. Indicated for obese patients with an initial body mass index (BMI) ≥ 30 kg/m² or ≥ 27 kg/m² in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

**INITIAL COVERAGE AUTHORIZATION CRITERIA:**

1. Member is: ≥ 12 years for Xenical® and ≥ 16 years for Meridia®

2. Patient has a BMI ≥ 30 kg/m² OR a BMI ≥ 27 kg/m² and at least one of the following apply:
   - [ ] Patient has two or more cardiovascular risk factors (LDL > 160; HDL < 40; hypertension; smoking; impaired fasting glucose; family history of premature CHD (CHD in male first degree relative < 55 years; CHD in female first degree relative < 65 years); Age (male ≥ 45 years or female ≥ 55 years or postmenopausal)
   - [ ] Waist circumference > 40 inches in men or > 35 inches in women
   - [ ] Patient has one or more obesity-related co-morbidities (established CHD, other atherosclerotic diseases, type 2 diabetes, obstructive sleep apnea)

*Member will be invited to join the Member Health Partnerships program, continuation of therapy will be dependent on enrollment in the weight module of this program.

**COVERAGE AUTHORIZATION FOR CONTINUATION OF THERAPY:**

1. After 6 months of initial therapy, an additional 6 months will be approved if the member has lost at least 5% of their initial body weight and continues to be enrolled in the weight module of the Member Health Partnerships program.

2. After each year of therapy, an additional 12 months of therapy will be approved if the member has maintained a weight loss of at least 5% of their initial body weight and has no contraindications to the prescribed drug.

**RATIONALE:**

- Meridia® and Xenical® are indicated for a very specific patient population. Use of these medications should be restricted to use by these individuals only.

**WARNINGS / PRECAUTIONS:**

**Meridia®**

- Substantial increase in blood pressure and/or pulse rate in some patients, regular monitoring of blood pressure and/or pulse rate is required.
- Meridia® should not be used in patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke.
- Potential interaction with Monoamine Oxidase Inhibitors

**Xenical®**

- Gastrointestinal events may increase when Xenical® is taken with a diet high in fat (> 30% total daily calories from fat). The daily intake of fat should be distributed over three main meals.
- Reduction of some fat-soluble vitamins and beta-carotene. Patients should be strongly encouraged to take a multivitamin supplement.

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REFERENCES:

1. Product Information: Xenical (orlistat); Roche; January 2005.
2. Product Information: Meridia (sibutramine); Abbott; December 2004.
3. Product Information: Adipex (phentermine); Gate Pharmaceuticals; November 2000.
4. Product Information: Tenuate (diethylpropion); Aventis; February 1998.
5. Product Information: Didrex (benzphetamine); Pharmacia; April 2002.