

Blue Cross and Blue Shield of Vermont and the Vermont Health Plan Prior Authorization Guidelines Xenical® (orlistat)

DESCRIPTION: Xenical® is a lipase inhibitor that inhibits the absorption of dietary fats from the stomach and small intestine.

INDICATION(S): Xenical® is indicated for the management of obesity in conjunction with a reduced calorie diet. Xenical® is also indicated to reduce the risk of weight regain after prior weight loss.

REASONS FOR PA: Cost Potential for misuse Toxicity

CRITERIA for APPROVAL:

1. Patient remains overweight despite weight reduction program including dietary modification and increased physical activity.
AND
2. Patient is enrolled in nutritional counseling.
AND
3. Patient is 12 years of age or older.
AND
4. Patient's initial body mass index (BMI) is $\geq 30 \text{ kg/m}^2$.
OR
5. Patient's initial body mass index (BMI) is $\geq 27 \text{ kg/m}^2$ and patient has other cardiovascular risk factors.

Note: $\text{BMI} = \frac{\text{Weight (lb)} \times 705}{\text{Height (in)}^2}$ or $\frac{\text{Weight (kg)}}{\text{Height (m)}^2}$

REASONS for DENIAL of BENEFIT:

1. Patient has a known hypersensitivity to Xenical® or any of its components.
2. Patient has chronic malabsorption syndrome or cholestasis.
3. Patient has an organic cause of obesity, such as hypothyroidism.
4. Patient has a major eating disorder (anorexia nervosa or bulimia nervosa).
5. Patient does not meet above criteria.

RENEWAL CRITERIA: Review of first 3 months demonstrates weight loss (first renewal) or review of previous 6 months of therapy demonstrates additional weight loss or maintenance of lost weight (subsequent renewals).

BENEFIT APPROVAL: Initial approval for a period of 3 months with a quantity limit of 90 capsules/30 days. Renewal approval period: 6 months. Lifetime maximum of two years.

References:

1. Xenical® (orlistat) Prescribing Information. Roche Pharmaceuticals, Nutley, NJ. December 2004.