Criteria-for-Use Checklist for Orlistat (Xenical)

VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel

The following criteria-for-use are based on current medical evidence, existing clinical practice guidelines and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient situation.

Note: The MOVE program is scheduled to launch nationally in January 2006. Until a facility has a MOVE program, these criteria should be applied as is feasible.

Orlistat is approved for the management of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a calorie deficit diet. Patients who meet or continue to meet the criteria-for-use and whose prescriber has completed a non-formulary request form can be dispensed orlistat.

Criteria-for-Use for Initial 90 Day Supply	*Response*
☐ The patient is enrolled in a MOVE program or similar VA multidisciplinary weight loss program ☐ The patient has demonstrated the ability to comply with a low-fat diet ☐ The patient's BMI is: Greater than or equal to 30 kg/m^2 OR Greater than or equal to 27 kg/m^2 with the presence of other co-morbid conditions affected by being over weight or obese such as controlled hypertension, diabetes, and dyslipidemia. ☐ The patient has no contraindications to orlistat including hypersensitivity and with chronic malabsorption syndrome or cholestasis. ☐ The patient is taking or receives a prescription for a multivitamin	☐ Yes ☐ No Patients who fail to meet all these criteria are ineligible for treatment with orlistat.
Criteria for Initial 90 Day Refill	
☐ The patient has attended follow-up appointments. Initial follow-up is to be in 2 to 4 weeks after starting orlistat, the monthly for 3 months. The patient is to be weighed at each follow-up visit. ☐ After 12 weeks, the patient has lost at least 5% of their body weight or an average of $\geq$1 lb. per week. ☐ The patient is not experiencing intolerable side effects. ☐ The patient wishes to continue orlistat. ☐ The patient has no contraindications to orlistat including hypersensitivity and with chronic malabsorption syndrome or cholestasis.	☐ Yes ☐ No Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued.

Criteria for Refills every 6 months	
☐ The patient has maintained 67% of their initial weight loss to date or has continued to lose weight. ☐ The patient has attended follow-up visits every 3 months. ☐ The patient is not experiencing intolerable side effects. ☐ The patient wishes to continue orlistat. ☐ The patient has no contraindications to orlistat including hypersensitivity and with chronic malabsorption syndrome or cholestasis. ☐ The patient has been taking orlistat for less than 4 years.	☐ Yes ☐ No Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued. Four years is the maximum duration of treatment.