

## Criteria-for-Use Checklist for Sibutramine (Meridia)

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 and the Sibutramine Registry is under construction. Until a facility has a MOVE program and the registry is completed, these criteria should be applied as is feasible.**

Sibutramine 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, whose prescriber has completed a non-formulary request form, and who have been enrolled in the sibutramine registry can be dispensed sibutramine.

<i>Criteria-for-Use for Initial 30 Day Supply</i>	<i>Response</i>
<ul style="list-style-type: none"> <li><input type="checkbox"/> The patient is enrolled in a MOVE program or similar VA multidisciplinary weight loss program</li> <li><input type="checkbox"/> The patient's BMI is:  <ul style="list-style-type: none"> <li>Greater than or equal to 30 kg/m<sup>2</sup> OR</li> <li>Greater than or equal to 27 kg/m<sup>2</sup> with the presence of other co-morbid conditions affected by being over weight or obese such as controlled hypertension, diabetes, and dyslipidemia.</li> </ul> </li> <li><input type="checkbox"/> The patient has no contraindications to sibutramine including: <ul style="list-style-type: none"> <li>○ Hypersensitivity to sibutramine</li> <li>○ Not currently taking nor has taken a MAOI, SSRI, SNRI, a triptan or other medication that affects serotonin, or pseudoephedrine in the past 2-weeks.</li> <li>○ Anorexia or bulimia nervosa</li> <li>○ Uncontrolled hypertension (&gt;145/90)</li> <li>○ A history of coronary artery disease</li> <li>○ A history of heart failure</li> <li>○ A history of arrhythmia</li> <li>○ A history of stroke</li> <li>○ A history of narrow angle glaucoma</li> </ul> </li> <li><input type="checkbox"/> The patient has been enrolled in the sibutramine safety registry by the pharmacy.</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> No</li> </ul> <p>Patients who fail to meet all these criteria are ineligible for treatment with sibutramine.</p>

<i>Criteria for First Refill</i>	
<ul style="list-style-type: none"> <li><input type="checkbox"/> The patient has attended all safety follow-up appointments (at least one visit for BP, HR, and weight measurements within weeks 1 or 2 of treatment).</li> <li><input type="checkbox"/> The patient's resting systolic or diastolic blood pressure has <u>not</u> been elevated by more than 10 mm Hg or greater than 145/90 on two or more consecutive appointments.</li> <li><input type="checkbox"/> The patient's resting heart rate has <u>not</u> increased by more than 10 beats per minute on two or more consecutive appointments.</li> <li><input type="checkbox"/> After 4 weeks on a dose of sibutramine 10 mg per day the patient has lost at least 4 pounds. <i>(If the patient has lost less than 4 pounds, the dose of sibutramine can be increased to 15 mg per day and reassessed in another 4 weeks.)</i></li> <li><input type="checkbox"/> The patient is not experiencing intolerable side effects.</li> <li><input type="checkbox"/> The patient has not contraindications to sibutramine. See initial 30 days.</li> <li><input type="checkbox"/> The patient wishes to continue sibutramine</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> No</li> </ul> <p>Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued.</p>
<i>Criteria for Refills Every 30 Days x 4 months</i>	
<ul style="list-style-type: none"> <li><input type="checkbox"/> The patient has maintained their initial weight loss or has continued to lose weight.</li> <li><input type="checkbox"/> The patient has had at least one BP and HR measurement charted.</li> <li><input type="checkbox"/> The patient's resting systolic or diastolic blood pressure has <u>not</u> been elevated by more than 10 mm Hg or greater than 145/90 on two or more consecutive appointments.</li> <li><input type="checkbox"/> The patient's resting heart rate has <u>not</u> increased by more than 10 beats per minute on two or more consecutive appointments</li> <li><input type="checkbox"/> The patient has attended monthly safety follow-up appointments for BP, HR and weight.</li> <li><input type="checkbox"/> The patient is not experiencing intolerable side effects.</li> <li><input type="checkbox"/> The patient wishes to continue sibutramine.</li> <li><input type="checkbox"/> The patient has not contraindications to sibutramine.</li> <li><input type="checkbox"/> The patient has been taking sibutramine for less than 2 years.</li> <li><input type="checkbox"/></li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> No</li> </ul> <p>Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued.</p>

<i>Criteria for Continuation at 6 Months</i>	
<ul style="list-style-type: none"> <li><input type="checkbox"/> The patient has lost at least 5% of their initial body weight or an average of 1 lb. per week.</li> <li><input type="checkbox"/> The patient's resting systolic or diastolic blood pressure has <u>not</u> been elevated by more than 10 mm Hg or greater than 145/90 on two or more consecutive appointments.</li> <li><input type="checkbox"/> The patient's resting heart rate has <u>not</u> increased by more than 10 beats per minute on two or more consecutive appointments</li> <li><input type="checkbox"/> The patient has attended monthly safety follow-up appointments (BP, HR and weight recorded)</li> <li><input type="checkbox"/> The patient is not experiencing intolerable side effects.</li> <li><input type="checkbox"/> The patient wishes to continue sibutramine.</li> <li><input type="checkbox"/> The patient has not contraindications to sibutramine.</li> <li><input type="checkbox"/> The patient has been taking sibutramine for less than 2 years.</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> No</li> </ul> <p>If the patient meets all of these criteria, they are eligible to continue sibutramine for a maximum of 2 years (total) with refills every 90 days.</p>
<i>Criteria for Refills Every 90 Days After 6 Months</i>	
<ul style="list-style-type: none"> <li><input type="checkbox"/> The patient has maintained at least 67% of their maximum weight loss to date.</li> <li><input type="checkbox"/> The patient's resting systolic or diastolic blood pressure has <u>not</u> been elevated by more than 10 mm Hg or greater than 145/90 on two or more consecutive appointments.</li> <li><input type="checkbox"/> The patient's resting heart rate has <u>not</u> increased by more than 10 beats per minute on two or more consecutive appointments</li> <li><input type="checkbox"/> The patient has attended monthly safety follow-up appointments (BP, HR and weight recorded)</li> <li><input type="checkbox"/> The patient is not experiencing intolerable side effects.</li> <li><input type="checkbox"/> The patient wishes to continue sibutramine.</li> <li><input type="checkbox"/> The patient has not contraindications to sibutramine.</li> <li><input type="checkbox"/> The patient has been taking sibutramine for less than 2 years.</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Yes</li> <li><input type="checkbox"/> No</li> </ul> <p>Patients who fail to meet any one of these criteria should have their treatment plan re-evaluated or the medication discontinued.</p>