

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

Lorcaserin hydrochloride for the treatment of obesity and overweight

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of lorcaserin hydrochloride within its licensed indication for the treatment of adults who are obese and the treatment of adults who are overweight who have at least one obesity related co-morbidity.

Background

Obesity is a chronic condition characterised by increased body fat, which poses a significant risk to health. The most common method for measuring obesity is body mass index (BMI) which is calculated as the ratio of weight to height squared. In adults of European family origin, overweight is typically defined by a BMI of 25 kg/m² to 29 kg/m² and obesity by a BMI of 30 kg/m² or more (an appropriate adjustment of BMI for other ethnic groups is necessary). People with obesity are at increased risk of developing cardiovascular disease, type-2 diabetes, atherosclerosis (the presence of fatty deposits in the arteries), hypertension and dyslipidaemia (abnormal levels of fats in the blood). In 2010, almost two-thirds of adults in England were classed as being overweight or obese and almost a quarter of adults were obese.

Current treatment of obesity includes dietary and lifestyle advice, pharmacological treatments, and surgical intervention. NICE has produced several public health guidance documents which address weight management. NICE clinical guideline 43 for the prevention, identification, assessment and management of overweight and obesity in adults and children recommends that drug therapy with orlistat should only be considered after dietary, exercise and behavioural approaches have been started and evaluated. The clinical guideline also recommends that surgical intervention (bariatric surgery) is considered as a first-line option for adults with a BMI of more than 50 kg/m². For adults with BMI of more than 40 kg/m² or BMI of more than 35 kg/m² with other significant obesity-related disease (such as type II diabetes) it is recommended that surgery is considered only after all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate weight loss for at least 6 months.

The technology

Lorcaserin hydrochloride (brand name to be confirmed, Arena Pharmaceuticals) selectively stimulates the serotonin 2C (5-HT_{2C}) receptor, which is located in the hypothalamus, the area of the brain associated with regulation of satiety and metabolism. Lorcaserin hydrochloride is administered orally. It is intended for use in combination with behaviour modification.

Lorcaserin hydrochloride does not have a UK marketing authorisation. It has been studied in three trials examining its effect in combination with behaviour modification, compared with placebo. Two trials were in overweight adults (BMI 27 to 29.9 kg/m²) with at least one co-morbid condition (hypertension, dyslipidemia, cardiovascular disease, glucose intolerance or sleep apnoea) and in obese adults (BMI 30 to 45 kg/m²) with or without at least one comorbid condition. One trial was in overweight and obese adults (BMI 27 to 40 kg/m²) with type 2 diabetes.

Intervention(s)	Lorcaserin hydrochloride in combination with behaviour modification.
Population(s)	<ul style="list-style-type: none"> • Obese adults • Overweight adults with at least one comorbid condition.
Comparators	<ul style="list-style-type: none"> • Orlistat (high dose and low dose preparations) in combination with behaviour modification
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • weight loss • waist circumference • development of type II diabetes • cardiovascular events • mortality • adverse effects of treatment • health-related quality of life • change in concomitant medication <p>Where information on clinical endpoints is unavailable, consideration may be given to surrogate end-points such as:</p> <ul style="list-style-type: none"> • glycated haemoglobin (HbA1c) • cholesterol levels and lipid profiles (including LDL and HDL) • blood pressure • insulin resistance

Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
Other considerations	<p>If the evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"> • type II diabetes • impaired glucose tolerance <p>Guidance will only be issued in accordance with the marketing authorisation.</p> <p>If evidence allows, consideration should be given to the appropriate adjustment of BMI for older people and for people of certain ethnic groups.</p>
Related NICE recommendations	<p>Related Technology Appraisals</p> <p>Suspended Technology Appraisal 'Phentermine with topiramate for the treatment of obesity and overweight' Date of issue to be confirmed</p> <p>Related Clinical Guidelines</p> <p>Clinical Guideline 43, December 2006. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. Partial review in preparation. Earliest anticipated publication date tbc.</p> <p>Related Public Health Guidance</p> <p>Public Health Guidance 2, March 2006. Four commonly used methods to increase physical activity. Review decision date: March 2013.</p> <p>Public Health Guidance 8, January 2008. Physical activity and the environment. Review decision date: February 2014.</p> <p>Public Health Guidance 13, May 2008. Promoting physical activity in the workplace. Review decision date: July 2014.</p> <p>Public Health Guidance 27, July 2010. Dietary interventions and physical activity interventions for</p>

	<p>weight management before, during and after pregnancy. Review decision date: July 2013.</p> <p>Public Health Guidance 42, November 2012. Obesity – working with local communities. Review decision date tbc</p> <p>Public Health Guidance in preparation: BMI and waist circumference – black and minority ethnic groups. Earliest anticipated date of publication: June 2013.</p> <p>Public Health Guidance in preparation: Overweight and obese adults - lifestyle weight management. Earliest anticipated date of publication: October 2013.</p>
--	---