National Institute for Health and Care Excellence

Single Technology Appraisal (STA)

Naltrexone-bupropion (prolonged release) for managing overweight and obesity

Response to consultee and commentator comments on the draft scope

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	GlaxoSmithKline (GSK)	The background information is accurate and appropriate	Comment noted. No action required.
	Royal college of physicians (RCP)	Overall this combination treatment seems to offer better weight loss than orlistat and with a different adverse effect profile. It therefore represents a new option for patients with obesity.	Comment noted. No action required.
	Diabetes UK	The background information is accurate	Comment noted. No action required.
The technology/ intervention	Diabetes UK	*'Is the description of the technology or technologies accurate?'* Yes	Comment noted. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
Population	Diabetes UK	Given that the NICE Public Health Guidance 46 suggest the use of lower BMI cut threshold for certain ethnic minority groups, it would be useful to reword the population to reflect this. We suggest the population to be 'Adults who have a BMI of • ≥30kg/m2 (obese) • ≥ 27kg/m2 to <30kg/m2 (overweight) in the presence of one or more weight-related co-morbidities, or from Black, Asian or other ethnic minority group'	
Comparators	GSK	Since orlistat is the only authorised medicine for obesity treatment in the UK, it is an appropriate comparator. However, it is recommended that only the prescription dose, 120mg orlistat, be used for the following reasons: • Only the 120mg prescription dose is approved for long term use; 60mg orlistat is only approved for short term use • The indication for orlistat 60mg is limited to weight loss whereas the 120 mg dose is indicated for the treatment of obese patients, which includes weight loss, maintenance and improvement in weight-related risk factors • 60mg orlistat is over the counter and although it provides 80-85% of the efficacy of the 120mg dose, if orlistat is being used as a comparator to a prescription drug, the higher dose is a more appropriate option.	Comment noted. We agree that 120mg of orlistat is the most appropriate dose as a comparator.
	RCP	The comparators seem reasonable but there is no direct head to head comparison with orlistat. Most of the trials with orlistat were conducted over 20 years ago, so caution should be exercised when making indirect comparisons; this is particularly true for conditions such as diabetes where background standard therapy (for glucose and lipids especially) may be very different now.	

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Outcomes	GSK	In addition to the outcome measures listed, the following might be considered as surrogate end points: • Total fat mass and % body fat • Estimates of visceral adipose tissue	Comment noted. Outcomes listed in the scope are not to be all encompassing, but to list those most appropriate to cover effect of disease, treatment and quality-of-life. As such, we would expect any other outcomes not listed to be presented alongside those listed.
	RCP	In terms of outcomes the main ones where there are data have been included in the draft scope. There may well also be reductions in conditions such as sleep apnoea and pain from arthritis and low mood – these may be only partly captured by changes in quality of life measures.	
Other considerations	RCP	There is very little data on some ethnic groups (particularly people from Asia) within the trials with Naltrexone-Bupropion, so it may not be possible to make any firm conclusions for that group.	
	Diabetes UK	Consider evidence for possible co-prescribing with weight loss drugs and possible drug interactions especially in people with Type 2 diabetes Consider evidence of the use of Naltrexone-bupropion (prolonged release) following obesity surgery	

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Innovation	Diabetes UK	*'Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?'* Yes *'Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?'* Yes, more support to people to help them lose weight is welcome. This will go a long way in reducing the rising numbers of Type 2 diabetes and other obesity-related conditions *'Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits'* The Public Health England evidence review for the National Diabetes Prevention Programme .	Comment noted. No action required.