



February 2015

**Naltrexone/bupropion 8mg/90mg (Mysimba®) for weight management in obese patients in combination with a reduced-calorie diet and physical activity**

The GMMMG New Therapies Subgroup discussed the above drug at its meeting on 17<sup>th</sup> February 2015. The recommendation of this subgroup is as follows:\*

The New Therapies Subgroup of the GMMMG considered the use of Naltrexone/bupropion 8mg/90mg (Mysimba®) in combination with a reduced-calorie diet and physical activity, for people with a body mass index (BMI  $\geq$  30Kg/m<sup>2</sup>, or a BMI  $\geq$  27Kg/m<sup>2</sup> and at least one weight-related complication.

**The group does not recommend the use of Mysimba® for the above indication.**

Whilst data from clinical trials shows a 5% reduction in bodyweight with the licensed dose of Mysimba®, against placebo, the group noted that the EMA guidelines stipulate that a clinically significant reduction in body weight would be at least a 10% reduction in body weight. It has also not been established whether the initial weight loss advantages seen can be sustained over the long term. Further longer term safety and efficacy data is required before Mysimba® can be recommended for use.

According to set criteria Mysimba® was deemed to be a low priority for funding.

Review date: February 2016

\* Unless superseded by NICE guidance or substantial and significant new evidence becomes available.

▼ Newly marketed drugs and vaccines are intensively monitored for a minimum of two years, in order to confirm the risk / benefit profile of the product. Healthcare professionals are encouraged to report all suspected adverse drug reactions regardless of the severity of the reaction.

## Further information / commissioning implications for CCGs

There is currently only one licensed drug to aid weight loss in the UK, orlistat.  
[Note: there has been no Primary Care prescribing of the centrally acting appetite suppressants dexfenfluramine, fenfluramine, diethypropion, phentermine and sibutramine in the last 3 months, all of which have had their marketing authorisations withdrawn.]

Guidance on the use of orlistat for obesity is now contained in NICE Clinical Guideline 189 [Obesity: identification, assessment and management of overweight and obesity in children, young people and adults <http://www.nice.org.uk/guidance/cg189> ]

### Recommendation

The recommendation deems this preparation a low priority for funding. Although there is existing prescribing of both components, neither would be used alone to aid weight loss.

The NHS price is currently unknown.

### Future commissioning implications

There are not expected to be any significant future financial or commissioning implications.

### Formulary and Interface considerations

As not yet launched, the drug has not been considered by Greater Manchester Formulary Sub Group. However, once launched, it will be assessed for the Do Not Prescribe list by NTS. For that reason, it will also not be assigned a RAG status.

### Summary of impact

The recommendation will be reviewed once the product has been launched and the price known. However, unless there is significant new clinical evidence, the recommendation is unlikely to change and therefore impact will be minimal.

**SUPERSEDED BY NICE**