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**Agomelatine for the
treatment of major
depressive episodes
(terminated appraisal)**

Advice

NICE is unable to recommend the use in the NHS of agomelatine for the treatment of major depressive episodes because no evidence submission was received from the manufacturer or sponsor of the technology.

Background

The manufacturer of agomelatine (Servier) has informed NICE that it would not be making an evidence submission for the appraisal of agomelatine for the treatment of major depressive episodes. Servier drew attention to the fact that NICE guidelines for England and Wales recommend generic selective serotonin reuptake inhibitors (SSRIs) as first-line treatment followed by a different SSRI or a better tolerated newer-generation agent as second-line treatment. The manufacturer noted that the majority of the clinical trial evidence for agomelatine was as a first-line treatment and furthermore was not against the full range of comparators in the scope. The manufacturer stated that this precluded the development of an economic case that would address the NICE decision problem and maintain the requisite level of certainty.

NICE has therefore terminated this single technology appraisal.

Information

NHS organisations should take into account the reasons why the manufacturer did not make an evidence submission when considering whether or not to recommend local use of agomelatine for the treatment of major depressive episodes in adults. If, after doing this, organisations still wish to consider the use of agomelatine for the treatment of major depressive episodes in adults, they should follow the advice set out in 'Good practice guidance on managing the introduction of new healthcare interventions and links to NICE technology appraisal guidance'

(www.dh.gov.uk/en/DH_064983), which outlines the approach that should be adopted in circumstances where NICE guidance is unavailable.

NICE will review the position at any point if the manufacturer indicates that it wishes to make a full submission.

Related NICE guidance

For information about NICE guidance that has been issued or is in development, see the website (www.nice.org.uk)

Published

- Common mental health disorders. NICE clinical guideline 123 (2011). Available from www.nice.org.uk/guidance/CG123
- Depression with chronic physical health problems. NICE clinical guideline 91 (2009). Available from www.nice.org.uk/guidance/CG91
- Depression in adults (update). NICE clinical guideline 90 (2009). Available from www.nice.org.uk/guidance/CG90
- Vagus nerve stimulation for treatment-resistant depression. NICE interventional procedure guidance 330 (2009). Available from www.nice.org.uk/guidance/IPG330
- Transcranial magnetic stimulation for severe depression. NICE interventional procedure guidance 242 (2007). Available from www.nice.org.uk/guidance/IPG242
- Bipolar disorder. NICE clinical guideline 38 (2006). Available from www.nice.org.uk/guidance/CG38
- Depression in children and young people. NICE clinical guideline 28 (2005). Available from www.nice.org.uk/guidance/CG28

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