

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

Vortioxetine for treating major depressive disorder

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of vortioxetine within its licensed indication for the treatment of major depressive disorder.

Background

Major depressive disorder is a broad and heterogeneous condition associated with a range of cognitive, behavioural, emotional, and physical symptoms. It is referred to by many synonymous terms, for example: clinical depression, major depression, unipolar depression, and depression. Major depressive disorder is characterised by low mood and/or loss of pleasure in most activities. The severity of the disorder may vary from mild to severe depending on both the number of symptoms and the degree of functional impairment. In severe disease, psychotic symptoms such as hallucination or delusion may be present. Major depressive disorder often has a remitting and relapsing course, and symptoms may persist between episodes.

In the UK, the prevalence of major depressive disorder is estimated to be between 5% and 10% of people seen in primary care settings and 10% to 14% of medical inpatients, although it may be underdiagnosed. Between 10% and 15% of older people have symptoms of depression. The risk of relapse is 50%, 70%, and 90% after the first, second, and third episodes of major depressive disorder respectively. The rate of major depressive disorder in women is twice as high as in men.

NICE clinical guideline 90 advocates a stepwise approach for the management of major depressive disorder. The routine use of antidepressants to treat mild major depressive disorder is not recommended except for people who have a past history of moderate or severe major depressive disorder or who have mild major depressive disorder that persists after other interventions. For people with moderate or severe depression, the guideline recommends a combination of antidepressant medication and a high-intensity psychological intervention (cognitive behavioural therapy or interpersonal psychotherapy). When an antidepressant is prescribed, it should normally be a generic selective serotonin reuptake inhibitor (SSRI). If the person with depression develops side effects or their condition has an inadequate response, switching to a different SSRI or a better tolerated newer-generation antidepressant may be considered. Subsequently an antidepressant of a different pharmacological class that may be less well tolerated may also be considered. Antidepressants may then be combined or augmented with other pharmacological treatments.

The technology

Vortioxetine (Brintellix, Lundbeck) is a multimodal antidepressant that is thought to exhibit its clinical effect through direct modulation of receptor activity and inhibition of the serotonin transporter.

Vortioxetine has a marketing authorisation in the UK for the treatment of major depressive episodes in adults.

Intervention(s)	Vortioxetine
Population(s)	Adults with major depressive disorder
Comparators	<ul style="list-style-type: none">• Selective serotonin reuptake inhibitors (for example citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, and sertraline)• Tricyclic antidepressants (for example clomipramine, doxepin, imipramine, lofepramine, nortriptyline, trimipramine, and amitriptyline)• Tricyclic-related antidepressants (for example mianserin and trazodone)• Serotonin and noradrenaline reuptake inhibitors (for example venlafaxine, duloxetine and levomilnacipran)• Other antidepressant drugs (for example agomelatine, mirtazapine, reboxetine and non-reversible mono-amine oxidase inhibitors [such as phenelzine])• Augmentation treatments (for example, with an antipsychotic such as quetiapine)

Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • response to treatment (including response rate and time to response) • relapse (including relapse rate and time from remission to relapse) • severity of depression • cognitive dysfunction • remission of symptoms • anxiety • sleep quality • hospitalisation • mortality • adverse effects of treatment (including adverse effects of treatment discontinuation) • health-related quality of life.
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 evidence allows the subgroup of people with moderate or severe major depressive disorder will be considered.</p> <p>If evidence allows the clinical and cost effectiveness of vortioxetine may be considered in different positions in the treatment pathway.</p> <p>Guidance will only be issued in accordance with the marketing authorisation.</p>
Related NICE recommendations and NICE Pathways	<p>Terminated Technology Appraisal No. 231, Jul 2011, 'Agomelatine for the treatment of major depressive episodes'.</p> <p>Related Guidelines:</p> <p>Clinical Guideline No. 90, Oct 2009, 'Depression: the treatment and management of depression in adults'</p>

	<p>Currently being updated, earliest anticipated date of publication May 2017.</p> <p>Clinical Guideline No. 91, Oct 2009, 'The treatment and management of depression in adults with chronic physical health problems' Review proposal date June 2015.</p> <p>Clinical Guideline No. 123, May 2011, 'Common mental health disorders: identification and pathways to care' Review proposal date May 2014.</p> <p>Related Quality Standards:</p> <p>Quality Standard No. 8, Mar 2011, 'Depression in adults quality standard'. Review date to be confirmed.</p> <p>Related NICE Pathways:</p> <p>NICE Pathway: Depression http://pathways.nice.org.uk/pathways/depression</p>
<p>Related National Policy</p>	<p>National Service Frameworks:</p> <p>Mental Health: modern standards and service models</p> <p>Older People</p> <p>Department of Health (2014) Mental health: priorities for change</p> <p>Department of Health (2013) Making mental health services more effective and accessible</p> <p>Welsh Government (2012) Together for Mental Health: A Strategy for Mental Health and Wellbeing in Wales</p> <p>Department of Health (2012) No health without mental health: implementation framework</p> <p>Department of Health (2011) The mental health strategy for England</p> <p>Department of Health (2009) New Horizons: A shared vision for mental health</p> <p>Department of Health (2007) Commissioning a brighter future: improving access to psychological therapies</p>