

Implanted vagus nerve stimulation for treatment-resistant depression

Interventional procedures guidance

Published: 12 August 2020

www.nice.org.uk/guidance/ipg679

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG330.

1 Recommendations

- 1.1 Evidence on the safety of implanted vagus nerve stimulation for treatment-resistant depression raises no major safety concerns, but there are frequent, well-recognised side effects. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE website.
- 1.2 Clinicians wishing to do implanted vagus nerve stimulation for treatment-resistant depression should:
 - Inform the clinical governance leads in their NHS trusts.
 - Give patients clear written information to support shared decision making, including NICE's information for the public.
 - Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
 - Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and is developing an audit tool (which is for use at local discretion).
- 1.3 NICE encourages further research into implanted vagus nerve stimulation for treatment-resistant depression, in the form of randomised controlled

trials with a placebo or sham stimulation arm. Studies should report details of patient selection. Outcomes should include validated depression rating scales, patient-reported quality of life, time to onset of effect and duration of effect, and any changes in concurrent treatments.

2 The condition, current treatments and procedure

The condition

- 2.1 Depression is characterised by low mood, loss of interest and enjoyment in life, and a range of associated emotional, cognitive, physical and behavioural symptoms. Depression is treatment-resistant when symptoms have not improved after at least 2 standard treatments.

Current treatments

- 2.2 The diagnosis and management of depression is described in the [NICE guideline for depression in adults](#) and the [NICE guideline for depression in children and young people](#). Standard treatment for depression includes antidepressants or psychological therapies (including cognitive behavioural therapies) or a combination of both. In severe depression when multiple treatments have failed, electroconvulsive therapy or other forms of neurostimulation are sometimes used.

The procedure

- 2.3 The aim of implanted vagus nerve stimulation for treatment-resistant depression is to reduce symptoms and improve mood by periodic stimulation of the vagus nerve.
- 2.4 The procedure is done using general or local anaesthesia. An incision is made on the left side of the neck and the left vagus nerve is identified. A stimulator electrode is put around the nerve and the leads of the electrode are guided under the skin to the left chest wall. They are

attached to a pulse generator unit, which is implanted into a subcutaneous pocket. The stimulator settings can be adjusted or turned off using an external (wireless) programming device.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 3 systematic reviews and/or meta-analyses, 2 randomised controlled trials (1 of which resulted in 2 publications), 2 non-randomised comparative studies, 2 case series and 1 single case report. It is presented in [table 2 of the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: depressive symptoms, quality of life, and reduction in other treatments and hospital admissions.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: device failure, infection, and worsening of mood symptoms including risk of suicidality.
- 3.4 One commentary from a patient who has had this procedure was discussed by the committee.

Committee comments

- 3.5 The committee noted that there is a high incidence of side effects associated with the procedure including voice change, cough and dyspnoea. The side effects generally decrease over time and the treatment is generally well tolerated.

- 3.6 The committee was informed that there may be a better response to this intervention if the patient's symptoms have responded to electroconvulsive therapy.
- 3.7 The committee noted that, in common with other therapies for depression, studies on this procedure show a placebo effect.
- 3.8 The committee was informed that, if needed, the patient can temporarily deactivate the device before requesting removal by a clinician.

ISBN: 978-1-4731-3836-0

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

Accreditation

