

CRITERIA FOR CONSIDERATION OF VAGUS NERVE STIMULATION (VNS) AS A TREATMENT FOR CHRONIC, REFRACTORY DEPRESSION.

The following **minimum** inclusion criteria are provided as a guide only.

Please also see Information Leaflet.

N.B. it is not expected that referrers will have experience in the use of the Antidepressant Treatment History Form (ATHF; Sackeim, 2001).

INCLUSION CRITERIA

1. The patient has a primary diagnosis of depression of **at least** moderate severity according to ICD-10.
2. The patient's current episode of depression is of **at least** two years duration, or, the patient has a history of recurrent depression (at least four lifetime episodes, including the current, treatment-refractory, episode).
3. The patient has not experienced an acceptable clinical response despite treatment with **at least** four confirmed, '*adequate*' antidepressant medications from different pharmacological groupings during the current episode of depression. The treatment categories include: tricyclic antidepressants (TCA's); selective serotonin reuptake inhibitors (SSRIs); monoamine oxidase inhibitors (MAOIs); bupropion; venlafaxine; mirtazapine; trazodone; and reboxetine. ECT may also have been tried and failed. '*Adequate*' treatment is defined as an ARR¹ score of 3 or more on the Antidepressant Treatment History Form (ATHF).
4. The patient has a history of treatment by psychological treatment methods (preferably Cognitive Behavioural Therapy - CBT) that did not result in significant clinical improvement.
5. The patient must be able to comply with all pre- and post-implantation assessment and clinical review requirements. This would normally mean frequent visits to Dundee in the weeks following device implantation, with further reviews in the 12-24 months after surgery.
6. The patient has to be able to provide signed, informed consent.
7. The suitability of the proposed treatment and capacity to provide informed consent are independently verified by a designated medical practitioner appointed by the Mental Welfare Commission for Scotland.

¹ Antidepressant Resistance Rating

EXCLUSION CRITERIA

1. A primary diagnosis other than depression.

(N.B. - Axis II comorbidity (i.e. a personality disorder or personality difficulties) is not necessarily a contraindication, but it should not be the primary diagnosis, and if difficulties are extensive the individual is unlikely to be suitable for VNS).

2. The patient has other (progressive) neurological disease (e.g. multiple sclerosis, Parkinson's disease, stroke, etc.), or has had a cervical fracture that makes implantation of the VNS stimulator difficult.
3. Inability to tolerate a general anaesthetic – if a patient has a history of myocardial infarction, cardiac arrhythmia, or has significant cardiovascular or respiratory disease (such as COPD).
4. The patient has significant current problems with alcohol or substance misuse. Individuals with a history of substance misuse in the previous 12 months are unlikely to be suitable.
5. The patient has a history of significant head injury, or neurovascular disease, or previous neurosurgery.
6. The patient has had a previous unilateral or bilateral cervical vagotomy.
7. The patient has active peptic ulceration.
8. The patient has a cardiac pacemaker, implantable defibrillator, or some other kind of implantable stimulator. TENS machines are not usually a problem and are not a contraindication.
9. Since patients with VNS are unable to undergo MRI scanning or bipolar diathermy, any individual who is likely to require these is unsuitable.

REFERENCES

- Sackeim, H. A. (2001)** The definition and meaning of treatment-resistant depression. *Journal of Clinical Psychiatry*, **62 (Suppl 16)**, 10-17.