# LPT Guidelines on Vagus Nerve Stimulation (VNS) Therapy
# Date of Review March 2023

**Background**

Vagus Nerve Stimulation (VNS) is a therapy that delivers pulses of electrical stimulation to the left cervical vagus nerve to adjust neurotransmitters in the brain that can lead to a clinical response or remission in patients with treatment-resistant depression (TRD).

Implantation of VNS is a one-off procedure, is minimally invasive, and is performed as a day case procedure by a suitably trained Neuro, ENT or Vascular Surgeon.

Stimulation is delivered by a 'pacemaker-like' pulse generator which is implanted via a small surgical incision in the patient's upper left chest wall (see picture). A second small incision is made on the left side of the neck, and a stimulation electrode is wrapped around the vagus nerve, then tunnelled under the skin and attached to the pulse generator. Once activated, the patient will receive automatic stimulation of the vagus nerve, normally with a stimulation 'duty cycle' of 30 seconds every five minutes.

Patients will be seen by the LPT team responsible for VNS after the surgical procedure has been completed, for dosing and stimulation parameter adjustments and all other routine ongoing VNS care.

The generator remains in place until such a time as the battery is depleted which, on normal settings, is expected to be after approximately 7-9 years of therapy delivery. At that time, if the patient has been a responder to the therapy, a generator replacement would be undertaken. The generator replacement surgery is a much quicker procedure and again can be performed as a day case.

**LPT Guidelines:**

The local guidance for the use of VNS for treatment resistant depression is as follows:

VNS Therapy will be offered to patients who are deemed to be within a treatment resistant or treatment intolerant major depressive episode and whom meet the eligibility criteria. Initially patients with resistant and/or complex mood disorders will be referred for a second opinion with in LPT to a clinician who has expertise in managing such patients and who has been trained in assessment for, and management of VNS Therapy. Once suitability for VNS has been confirmed patients will be referred to surgery.

The specific pathway is described below and is summarised in the patient flowchart following the pathway.

**Eligibility criteria**

**Patients who may be considered for VNS Therapy can be from any of the following groups (Note, the patient does not have to meet criteria in all domains and** these requirements may be waived if there is a recognised contraindication, or the patient has declined or been intolerant of the one or more of the treatments.**:**
. Patients will be assessed as potentially suitable for adjunctive VNS therapy if they remain at least moderately depressed despite multiple alternative evidence-based therapeutic trials. These should include;

- At least two trials of structured, evidence-supported psychological therapy;
- At least four adequate trials of antidepressants;
- At least two adequate trials of an evidence-based augmentation/combination agent given with an antidepressant;
- Atrial of ECT (at least 8 treatments and ideally bilaterally).

- Requiring maintenance ECT to maintain response or remission from major depressive episodes.

- Requiring the current course of ECT due to relapse of a major depressive episode following a successful course of ECT within the previous 12 months.

- Treatment-refractory depression and poor response to, or inability to tolerate, the current course of ECT.

- Multiple admissions and/or an admission over 3 months for a major depressive episode

**LPT VNS Patient Pathway**

- Suitable patients with capacity and willingness to provide written informed consent are referred for VNS surgery following baseline measurements. The patient's consultant

psychiatrist will complete the referral forms and remain responsible for liaising with LPT colleagues and the VNS implant centre.

- The Consultant Psychiatrist responsible for the patient will refer the patient for a second opinion within LPT by Consultant colleagues who has expertise in managing such resistant cases and training in VNS.

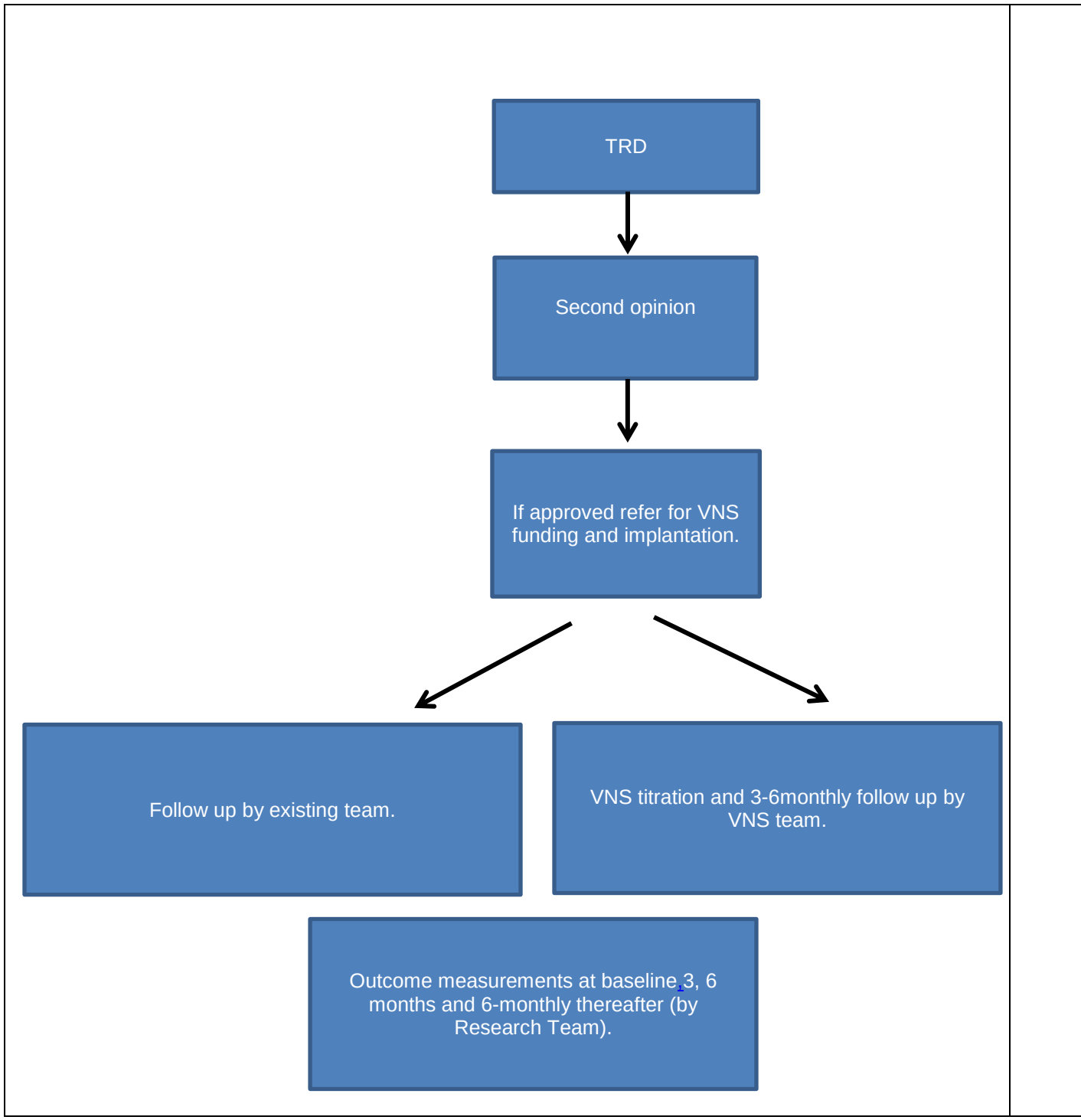
- Once the patient has been deemed suitable for VNS the Consultant Psychiatrist makes a referral to VNS implant centre such as Nottingham/Sheffield/Manchester using the tertiary referral form (Appendix 2).

- The Consultant Psychiatrist responsible for the patient's ongoing clinical care will retain overall responsibility for the patient's treatment as usual and follow-up in secondary care, while the surgeon implanting VNS and the LPT VNS trained psychiatrist will follow-up and dose the VNS, in a shared care manner.

- Following VNS surgery, patients will be reviewed by LPT expert trained in VNS 4-6 times over the first 1-2 months to achieve optimum stimulation settings. He will follow such patients every 3 months for 12 months and every 6 months thereafter.

- The consultant psychiatrist will be responsible for completing all the outcome measures as required periodically (3, 6, 9, 12 and 6-monthly thereafter) ie. Clinical Global Impression scale (CGI), Warwick-Edinburgh Mental Well-being Scale (WEMWBS), Montgomery-Asberg Depression Rating Scale (MADRS) and Hamilton Anxiety Scale. Those patients who will be consenting for the Life Restore study, the scales will be completed by the VNS leads in conjunction with the LPT Research Team. Life Restore is a 5 year multinational longitudinal study looking at the prognosis in patients with VNS implant for depression.

- In long-term follow-up, patients wishing to discontinue VNS Therapy (e.g. poor tolerability, poor effectiveness after an adequate trial) will have the stimulator switched off. Those for whom no future reinstatement of VNS Therapy is considered desirable or likely will be, if the patient so wishes, referred for removal (minor surgery) of the pulse generator in the upper left chest wall. The electrode around the vagus nerve is left in situ in perpetuity.


TRD
Second opinion
If approved refer for VNS funding and implantation.
Follow up by existing team.
VNS titration and 3-6monthly follow up by VNS team.
Outcome measurements at baseline, 3, 6 months and 6-monthly thereafter (by Research Team).