GIG CYMRU NHS WALES
Cyd-bwyllgor Comisiynu
Joint Commissioning Committee

VAGUS NERVE STIMULATION FOR ADULTS, YOUNG PERSONS AND CHILDREN

Commissioning Policy: CP23

May 2024
Version: 5.0

Document information	
Document purpose	Commissioning Policy
Document name	Vagus Nerve Stimulation for Adults, Young Persons and Children
Author	NHS Wales Joint Commissioning Committee
Publication date	May 2024
Commissioning Team	Neurosciences and Long-Term Conditions
Target audience	Chief Executives, Medical Directors, Directors of Finance, Paediatric Neurologists, Paediatric Neurosurgeons, Consultant Neurologists and Consultant Neurosurgeons, Director of Nursing
Description	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
Document No	CP23
Review Date	2027

Contents

Policy Statement

NHS Wales Joint Commissioning Committee (NWJCC) will commission Vagus Nerve Stimulation (VNS) for people of all ages with intractable epilepsy in accordance with the criteria outlined in this document.

In creating this document NWJCC has reviewed the requirements and standards of care that are expected to deliver this service.

Welsh Language

NWJCC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the Welsh Language Act (1993), the Welsh Language (Wales) Measure 2011 and the Welsh Language Standards (No.7) Regulations 2018.

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this, NWJCC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

NWJCC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the NWJCC commitment

Disclaimer

NWJCC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

NWJCC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This policy has been developed for the planning and delivery of Vagus Nerve Stimulation (VNS) surgery for adults, young persons and children resident in Wales. NICE Clinical Practice Guideline for the management of epilepsies[1] states that VNS is indicated for use as an adjunctive therapy for refractory epilepsy in children, young people and adults.

This service will only be commissioned by the NHS Wales Joint Commissioning Committee (NWJCC) and applies to residents of all seven Health Boards in Wales.

1.1 Background

Epilepsy is a neurological condition characterised by recurrent epileptic seizures unprovoked by any immediately identifiable cause. Seizures are sudden recurrent attacks (recurring like spasms) disorders of the central nervous system characterised by abnormal electrical activity of cerebral neurons. There are many different types of seizures, that can present with or without warning and can present as sudden disturbance of consciousness, behaviour, emotion, motor, sensory or autonomic function with or without loss of consciousness.

VNS is an adjunctive treatment for intractable epilepsy. VNS involves implantation of a battery-powered pulse generator under the skin usually of the upper left chest. The implantable generator sends electric impulses to the vagus nerve in the neck, via a lead implanted under the skin, in order to reduce the frequency and intensity of seizures. It can also be activated at onset or during seizures externally by swiping the generator site with a magnet.

VNS has the potential to reduce seizure frequency and severity and improve quality of life. Approximately one third of cases will receive significant benefit. For the comparison of VNS with best medical practice to best medical practice alone, a clinically important benefit of VNS combined with best medical practice was found for quality of life and proportion of people with a greater than 50% decrease in seizure frequency at one year.

1.2 Aims and Objectives

This policy aims to define the commissioning position of NWJCC on the use of VNS for people with intractable epilepsy.

The objectives of this policy are to:

- ensure commissioning for the use of VNS is evidence based

---

[1] https://www.nice.org.uk/guidance/ng217

- ensure equitable access to the VNS Service
- define criteria for people with intractable epilepsy to access treatment
- improve outcomes for people with intractable epilepsy
- clarify the referral process.

1.3 Epidemiology

Epilepsy is one of the most common serious neurological conditions in the world. Epilepsy affects around 630,000 people in the UK. Around 87 people are diagnosed with epilepsy in the UK every day2. About 5% to 30% of people with epilepsy have medically refractory complex partial seizures3. In Wales approximately 11 in 1,000, have Epilepsy4.

1.4 What NHS Wales has decided

NWJCC will fund the provision of VNS for residents of all seven Health Boards in Wales within the criteria set out in se3ction 2.1 of this policy.

1.5 Relationship with other documents

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

- **NHS Wales Joint Commissioning Committee policies and service specifications**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).
  - Adult Neurosurgery Service Specification https://whssc.nhs.wales/commissioning/whssc-policies/neurosciences/adult-neurosurgery-service-specification-cp178-february-2023/
  - Children's Epilepsy Surgery Services
  - https://whssc.nhs.wales/commissioning/whssc-policies/paediatric-services/paediatric-epilepsy-commissioning-policy-cp174-september-2022/

- **National Institute of Health and Care Excellence (NICE) guidance**

---

[2] https://www.epilepsy.org.uk/info/what-is-epilepsy
[3] https://www.nice.org.uk/guidance/ipg50
[4] https://epilepsy.wales/

  - Epilepsies in children, young people and adults NICE guideline [NG217] https://www.nice.org.uk/guidance/ng217/resources

- **Relevant NHS England policies**
  - Children's Epilepsy Surgery Service (CESS) (E09), January 2018
  - Clinical Commissioning Policy: Vagal Nerve Stimulation for Epilepsy Vagal-nerve-stimulation-for-epilepsy.pdf (england.nhs.uk)

2. Service Delivery

The NHS Wales Joint Commissioning Committee will commission Vagus Nerve Stimulation for people of all ages and resident in Wales, in-line with the criteria identified in this policy.

2.1 Inclusion Criteria

VNS is commissioned for adults, young people and children who meet all the criteria as indicated below, as appropriate to their clinical circumstances.

2.1.1 Medically Refractory Focal-Onset Seizures

The patient has medically refractory focal-onset seizures. Medically refractory means seizures that occur in spite of well tolerated standard doses of antiseizure medications that cannot be treated with therapeutic levels of anti-epileptic drugs because of intolerable adverse side effects.

2.1.2 Medically Refractory Generalised Seizures

The patient has medically refractory generalised seizures. Medically refractory means seizures that occur in spite of therapeutic levels of anti-epileptic drugs or seizures that cannot be treated with therapeutic levels of anti-epileptic drugs because of intolerable adverse side effects.

NWJCC consider referrals for VNS if the patient has:

- undergone thorough evaluation of their epilepsy to rule out non-epileptic conditions or medically treatable epilepsy
- Undergone a full and thorough series of investigations including MRI, EEG and other alternative treatments and changes of medication have been trialled
- The patient has been evaluated by an epilepsy surgery program to establish that resective surgery is not indicated
- Has complex partial seizures OR recurrent life-threatening status epilepticus[5]
- Failure of adequate trials of 2 tolerated and appropriately chosen and used antiseizure medication schedules[6]

2.2 Exclusion Criteria

NWJCC will not consider referrals for VNS where the decision on treatment modality has been based on patient preference.

NWJCC **will not** consider referrals for VNS for the following conditions:

---

[5] https://www.england.nhs.uk/wp-content/uploads/2013/04/d04-P-d.pdf

[6] https://www.nice.org.uk/guidance/ng217/chapter/terms-used-in-this-guideline#drug-resistant-epilepsy

- indications that do not meet the above criteria
- treatment of patients with seizures other than focal-onset seizures or medically refractory generalised seizures
- patients who can be treated successfully with anti-epileptic drugs and/or with a ketogenic diet
- treatment of patients with depression
- treatment of essential tremor
- treatment of headaches
- treatment of hiccoughs
- cognitive impairment associated with Alzheimer ’s disease; and
- bulimia or other related eating disorders.

2.3 Continuation of Treatment

Healthcare professionals are expected to review a patient’s health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

At any time, additional stimulation can be applied or the device turned off. If no improvement to a patient’s health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.4 Acceptance Criteria

The service outlined in this policy is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Patient Pathway (Annex i)

All patients are required to go through the patient pathway described in the policy as a mandatory requirement prior to VNS provision. Follow up and programming is completed and actioned by the referring clinician and epilepsy nurses.

2.6 Designated Centre

Royal Liverpool Children's NHS Trust
Alder Hey Children’s NHS Foundation Trust
Eaton Road
Liverpool
L12 2AP

Cardiff and Vale University Health Board
Heath Park
Cardiff
CF14 4XW
Walton Centre NHS Foundation Trust
Lower Lane
Fazakerley
Liverpool
L9 7LJ

University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Edgbaston
Birmingham
B15 2GW

Manchester University NHS Foundation Trust (MFT)
Manchester Royal Infirmary
Oxford Road
Manchester
M13 9WL

2.7 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Individual Patient Funding Requests

2.8 Clinical Outcome and Quality Measures

VNS should only be performed in an experienced specialist centre willing to publish its results and use established clinically relevant patient outcomes.
The Provider must work to written quality standards and provide monitoring information to NWJCC. Providers are expected to submit the following information:

- Service Activity (including the number of Vagus Nerve Stimulators)
- Waiting Times

- Clinical Statistics
- Patient Reported Outcome Measures (PROMS).
- Patient Reported Experience Measures (PREMS).

The Designated Centre should enable the patient’s, carer’s and advocate’s informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

Mandatory compliance is required by all Designated Centres with this Policy, including 100% provision of required data.

2.9 Responsibilities

Referrers should:

- inform the patient and/or their parent or guardian that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinicians considering treatment should:

- discuss all alternative treatments with the patient and/or their parent or guardian;
- advise the patient and/or their parent or guardian of any side effects and risks of the potential treatment
- inform the patient and/or their parent or guardian that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with NWJCC for the treatment.

In all other circumstances an IPFR must be submitted.

3. Evidence

NWJCC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

The evidence to support the recommendations within the policy are derived and have been directly adapted from the documents listed below. An updated evidence review has been commissioned by NWJCC to inform the next update of this commissioning policy

3.1 References

NWJCC policies and service specifications

- Deep Brain Stimulation Commissioning Policy (CP28), August 2020.
- Vagal Nerve Stimulation Commissioning Policy (CP23), August 2014.
- Specialised Neuropsychiatry Rehabilitation Commissioning Policy (CP128), February 2018.
- Specialised Neurological Rehabilitation Commissioning Policy (CP140), February 2018.

National Institute of Health and Care Excellence (NICE) guidance

- Epilepsies in children, young people and adults NICE guideline [NG217] https://www.nice.org.uk/guidance/ng217/resources

Relevant NHS England policies

- Clinical Commissioning Policy: Vagal Nerve Stimulation for Epilepsy Vagal-nerve-stimulation-for-epilepsy.pdf (england.nhs.uk)

3.2 Date of Review

This document is scheduled for review before March 2027 where we will check if any new evidence is available. If no new evidence or intervention is available the review date will be progressed.

If an update is carried out the policy will remain extant until the revised policy is published.

4. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable NHS Wales Joint Commissioning Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

5. Putting Things Right:

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to NWJCC.

5.2 Individual Patient Funding Request (IPFR)

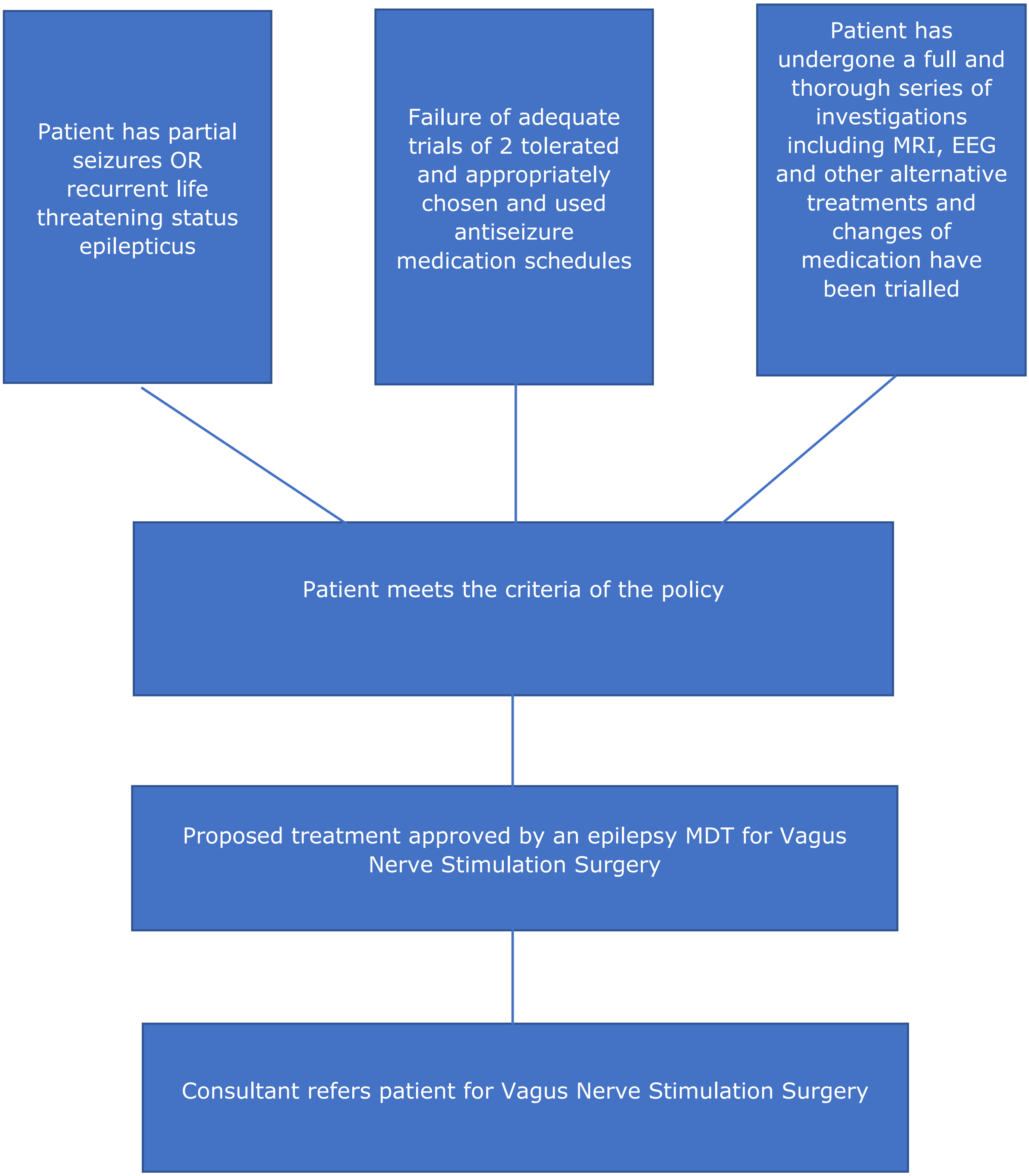
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Individual Patient Funding Requests

Annex i Patient Pathway



Patient has partial seizures OR recurrent life threatening status epilepticus

Failure of adequate trials of 2 tolerated and appropriately chosen and used antiseizure medication schedules

Patient has undergone a full and thorough series of investigations including MRI, EEG and other alternative treatments and changes of medication have been trialled

Patient meets the criteria of the policy

Proposed treatment approved by an epilepsy MDT for Vagus Nerve Stimulation Surgery

Consultant refers patient for Vagus Nerve Stimulation Surgery

Annex ii Codes

Code Category	Code	Description
ICD-10	G40	Epilepsy
OPCS 4	A33	Neurostimulation of cranial nerve
OPCS 4	A33.1	Implantation of cranial nerve neurostimulator

Annex iii Abbreviations and Glossary

Abbreviations

AWMSG	All Wales Medicines Strategy Group
IPFR	Individual Patient Funding Request
MDT	Multidisciplinary Team
NICE	National Institute Clinical Evidence
NWJCC –	NHS Wales Joint Commissioning Committee
PROMS	Patient Reported Outcome Measures
PREMS	Patient Reported Experience Measures (PREMS)
VNS	Vagus Nerve Stimulation

Glossary

Individual Patient Funding Request (IPFR)

An IPFR is a request to NHS Wales Joint Commissioning Committee (NWJCC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

NHS Wales Joint Commissioning Committee (NWJCC)

NWJCC is a joint committee of the seven local health boards in Wales. The purpose of NWJCC is to ensure that the population of Wales has fair and equitable access to the full range of Tertiary Services. NWJCC ensures that services within our portfolio are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.

Focal-Onset Seizures

Focal onset seizures start in, and affect, just one part of the brain, sometimes called the 'focus' of the seizures. It might affect a large part of one hemisphere or just a small area in one of the lobes.

Sometimes a focal onset seizure can spread to both sides of the brain (called a focal to bilateral tonic-clonic seizure). The focal onset seizure is then a warning, sometimes called an 'aura' that another seizure will happen.

Generalised Seizures

Generalised onset seizures affect both sides of the brain at once and happen without warning.
The person will be unconscious (except in myoclonic seizures), even if just for a few seconds and afterwards will not remember what happened during the seizure.