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Welsh Health Specialised
Services Committee (WHSSC)

Specialised Services Policy:

CP23

Vagal Nerve Stimulation

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Approved by:	WHSSC Executive Board
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0.1	27 th June 2007	Amendments to text in section 4.4 performance management. Revisions to clarify access criteria	1.0
1.0	February 2014	Transferred onto new template, minor amendments made	1.1
1.1	March 2013	Ratified through Chair's Action on behalf of Management Group	2.0
2.0	June 2014	Amendments made following feedback received from Clinicians. Revisions to clarify access criteria & other minor amendments to bring the document up-to date with the latest national guidance.	2.1
2.1	August 2014	Ratified	3.0
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Consultation		
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Approvals		
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Distribution – <i>this document has been distributed to</i>			
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Policy Statement

<p>Background</p>	<p>Vagal nerve stimulation (VNS) is an adjunctive treatment for intractable epilepsy. VNS uses an implantable generator that sends electric impulses to the vagal nerve in the neck, via a lead implanted under the skin. The aim of treatment is to reduce the frequency and intensity of seizures.</p>
<p>Summary of Access Criteria</p>	<p>WHSSC will not consider referrals for VNS unless the patient has:</p> <ul style="list-style-type: none"> • Undergone thorough evaluation of their epilepsy to rule out non-epileptic conditions or a treatable epilepsy; <p>and</p> <ul style="list-style-type: none"> • Undergone a full and thorough series of investigations including MRI, EEG and other alternative treatments and changes of medication have been trialled; <p>and</p> <ul style="list-style-type: none"> • Been evaluated by an epilepsy surgery program to establish that resective surgery is not indicated; <p>and has the following:</p> <ul style="list-style-type: none"> • Medically refractory epilepsy, where the patient is not a suitable candidate for potentially curative surgical resections;
<p>Responsibilities</p>	<p>Referrals to the designated centres for VNS surgery are usually made by consultant neurologists and consultant neurosurgeons.</p> <p>VNS surgery is provided at the following centres:</p> <ul style="list-style-type: none"> • Royal Liverpool Children's NHS Trust; • Cardiff and Vale University Health Board; <p>and</p> <ul style="list-style-type: none"> • Walton Centre for NHS Foundation Trust. <p>Referrers should:</p> <ul style="list-style-type: none"> • Inform the patient that this treatment is not routinely funded outside the criteria in this policy; • Refer via the agreed pathway.

	<p>Clinician considering treatment should:</p> <ul style="list-style-type: none"> • Discuss all the alternative treatment with the patient; • Advise the patient of any side effect and risks of the potential treatment; • Inform the patient that VNS is not a curative therapy for their epilepsy • Inform the patient that treatment is not routinely funded outside of the criteria in the policy; and • Confirm that there is contractual agreement with WHSSC for the treatment. <p>In all other circumstances submit an IPFR.</p>

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1. Aim

1.1 Introduction

The document has been developed as the policy for the planning of Vagal Nerve Stimulation for Welsh patients. The policy applies to residents of all seven Health Boards in Wales.

The purpose of this document is to:

- Set out the circumstances under which patients will be able to access Vagal Nerve Stimulation services;
- Clarify the referral process; and
- Define the criteria that patients must meet in order to access treatment.

1.2 Relationship with other Policies and Service Specifications

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

- All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR).

2. Scope

2.1 Definition

Vagal nerve stimulation (VNS) is an adjunctive treatment for intractable epilepsy. It uses an implantable generator that sends electric impulses to the vagal 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.

The VNS implanted device consists of a titanium encased generator about the size of a pocket watch; a lithium battery to fuel the generator, with a battery life of approximately 6-8 years, (although this will vary according to generator type and settings and magnet usage.) a lead system with electrodes; an anchor tether to secure leads to the vagal nerve; and external magnets.

Seizures are paroxysmal (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 has the potential to reduce seizure frequency and severity and improve quality of life. Approximately one third of cases will receive significant benefit.

2.2 Codes

ICD-10 Codes

Code Category	Code	Description
ICD-10	G40	Epilepsy

OPCS 4 Codes

Code Category	Code	Description
OPCS 4	A33	Neurostimulation of cranial nerve

3. Access Criteria

3.1 Clinical Indications

The clinical indication for vagal nerve stimulation under this policy is intractable epilepsy.

3.2 Criteria for Treatment

WHSSC will not consider referrals for VNS unless the patient has:

- Undergone thorough evaluation of their epilepsy to rule out non-epileptic conditions or treatable epilepsy;
- and
- Undergone a full and thorough series of investigations including MRI, EEG and other alternative treatments and changes of medication have been trialled;
- and
- Been evaluated by an epilepsy surgery program to establish that resective surgery is not indicated.

and has Irretractable epilepsy

3.3 Referral Pathway

Referrals to the designated centres for VNS surgery are made by consultant neurologists and consultant neurosurgeons.

VNS Surgery is provided at the following centres:

- Royal Liverpool Children's NHS Trust;
- Cardiff and Vale University Health Board; and
- Walton Centre for NHS Foundation Trust.

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

3.4 Exclusions

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

WHSSC will not consider referrals for VNS for the following conditions:

- Indications that do not meet the above criteria;
- Patients successfully treated with anti-epileptic drugs;
- Treatment of 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.

3.5 Exceptions

If the patient does not meet the criteria for treatment, but the referring clinician believes that there are exceptional grounds for treatment an Individual Patient Funding Request (IPFR) can be made to WHSS under the All Wales Policy for Making Decisions on Individual Patient Funding Requests (IPFR).

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

Guidance on the IPFR process is available at www.whssc.wales.nhs.uk

3.6 Responsibilities

Referrals to the designated centres for VNS surgery are usually made by consultant neurologists and consultant neurosurgeons.

VNS is provided at the following centres:

- Royal Liverpool Children's NHS Trust;
- Cardiff and Vale University Health Board; and
- Walton Centre for NHS Foundation Trust.

Referrers should:

- Inform the patient that this treatment is not routinely funded outside the criteria in this policy; and
- Refer via the agreed pathway.

Clinician considering treatment should:

- Discuss all the alternative treatment with the patient;
- Advise the patient of any side effect and risks of the potential treatment;
- Inform the patient that this is not curative surgery

- Inform the patient that treatment is not routinely funded outside of the criteria in the policy; and
- Confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR should be submitted.

4. Putting Things Right: 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:

- When a patient or their representative is unhappy with the decision that the patient does not meet the criteria for treatment further information can be provided demonstrating exceptionality. The request will then be considered by the All Wales IPFR Panel.
- If the patient or their representative is not happy with the decision of the All Wales IPFR Panel the patient and/or their representative has a right to ask for this decision to be reviewed. The grounds for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated. The review should be undertaken, by the patient's Local Health Board;
- When 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 WHSSC.

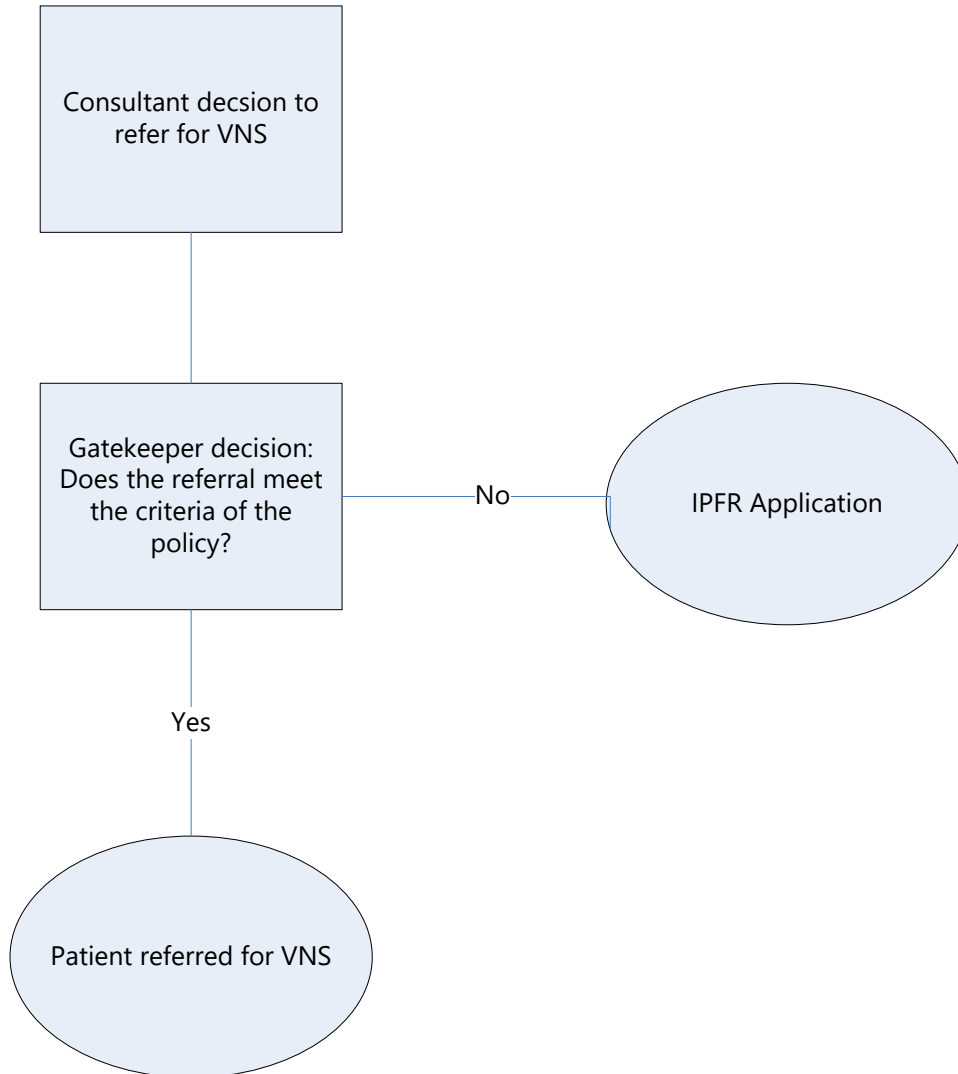
5. Equality Impact and Assessment

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 Welsh Health Specialised Services 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 that the policy is robust and that there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

Annex (i)

Adult Referral Pathway



Annex (ii) Checklist

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The following checklist should be completed and retained as evidence of policy compliance by the receiving centre. It is expected that this evidence will be provided at the point of invoicing by the receiving centre.

- i) Where the patient meets the criteria **AND** the procedure is included in the contract **AND** the referral is received by an agreed centre, the form should be completed and retained by the receiving centre for audit purposes.
- ii) The patient meets the criteria **AND** is received at an agreed centre, but the procedure is not included in the contract. The checklist must be completed and submitted to WHSSC for prior approval to treatment.
- iii) The patient meets the criteria but wishes to be referred to a non contracted provider. An Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration.
- iv) The patient does not meet criteria, but there is evidence of exceptionality. An Individual Patient Funding Request (IPFR) Form must be completed and submitted to WHSSC for consideration for treatment.

To be completed by the referring gatekeeper or treating clinician

The following checklist should be completed for **all patients to whom the policy applies**, before treatment, by the responsible clinician.

Please complete the appropriate boxes:

Patient NHS No:			
Patient is Welsh Resident	Post Code		
Patient is English Resident	GP Code:		
		Yes	No
Patient meets following access criteria for treatment:			
<ul style="list-style-type: none"> Undergone thorough evaluation of their epilepsy to rule out non-epileptic conditions or treatable epilepsy AND 			
<ul style="list-style-type: none"> Undergone a full and thorough series of investigations including MRI, EEG and other alternative treatments and changes of medication have been trialled AND 			
<ul style="list-style-type: none"> Been evaluated by an epilepsy surgery program to establish that resective surgery is not indicated AND 			
<ul style="list-style-type: none"> Medically refractory epilepsy 			
Patient wishes to be referred to non-contracted provider			
<i>An Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment. The form must clearly demonstrate why funding should be provided as an exception. The form can be found at http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&id=181455</i>			
Patient does not meet access criteria but is exceptional			
<i>An Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment. The form must clearly demonstrate why funding should be provided as an exception. The form can be found at http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&id=181455</i>			

Name: _____ **Designation:** _____

Signature: _____ **Date:** _____

	Name (printed):	Signature:	Date:	Yes	No
Authorised by TRM Gatekeeper					
Authorised by Patient Care Team?					

Authorised by agreed other? (Please state whom)					
Patient Care Team/IPFR TRM Reference number:					