



**GIG**  
CYMRU  
**NHS**  
WALES

Pwyllgor Gwasanaethau Iechyd  
Arbenigol Cymru (PGIAC)  
Welsh Health Specialised  
Services Committee (WHSSC)

## **Specialised Services Commissioning Policy: CP35**

### **Cochlear Implant for children and adults with severe to profound deafness**

*May 2020  
Version 5.00*

**Document information**

<b>Document purpose</b>	Policy
<b>Document name</b>	Cochlear implant for children and adults with severe to profound deafness
<b>Author</b>	Welsh Health Specialised Services Committee
<b>Date first published</b>	May 2007
<b>Date first revised</b>	August 2014
<b>Revision Date</b>	May 2020
<b>Commissioning Team</b>	Women and Children's
<b>Target audience</b>	Chief Executives, Medical Directors, Directors of Finance, Specialist Care Centres, Health Boards, NHS Trusts Consultant Ear ,Nose and Throat, Audiology, Audiovestibular Physician, Directors of Primary Care, Director of Nursing and Quality
<b>Description</b>	NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy
<b>Document No</b>	CP35
<b>Review Date</b>	2023

## Contents

<b>Policy Statement</b> .....	4
Disclaimer .....	4
1. Introduction .....	5
1.1 Plain Language Summary .....	5
1.2 Aims and Objectives .....	5
1.3 Epidemiology .....	6
1.4 Current Treatment.....	6
1.5 Proposed Treatment .....	6
1.6 What NHS Wales has decided.....	6
1.7 Relationship with other documents .....	7
2. Criteria for Commissioning .....	8
2.1 Assessment for Cochlear Implant .....	8
2.2 Inclusion Criteria .....	8
2.3 Cochlear Treatment Options .....	8
2.4 Exclusion Criteria .....	9
2.5 Continuation of Treatment.....	9
2.6 Acceptance Criteria.....	9
2.7 Patient Pathway (Annex i) .....	9
2.8 Designated Centres .....	10
2.9 Exceptions.....	11
2.10 Clinical Outcome and Quality Measures .....	11
2.11 Responsibilities .....	12
3. Evidence .....	13
3.1 References .....	13
3.2 Date of Review.....	13
4. Equality Impact and Assessment.....	14
5. Putting Things Right: Raising a Concern.....	15
5.1 Raising a Concern.....	15
5.2 Individual Patient Funding Request (IPFR) .....	15
Annex i Patient Pathway.....	16
Annex ii Checklist.....	19
Annex iii Codes.....	21
Annex iv Abbreviations and Glossary .....	22

## **Policy Statement**

Welsh Health Specialised Services Committee (WHSSC) will commission cochlear implants for children and adults with severe to profound deafness in accordance with the revised criteria outlined in this document.

In creating this document WHSSC has reviewed this clinical condition and the options for its treatment. It has considered the place of cochlear implants in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy has been developed based on the revised threshold for accessing cochlear implant(s) which has been reduced from 90dBHL to 80dBHL at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3000 Hz and 4,000 Hz), as per the revised NICE Technology Appraisal Guidance on Cochlear implants for children and adults with severe to profound deafness (TA566)<sup>1</sup>.

## **Disclaimer**

WHSSC 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.

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

---

<sup>1</sup> [Overview | Cochlear implants for children and adults with severe to profound deafness | Guidance | NICE](#)

## 1. Introduction

This policy has been developed as the revised Policy for the planning and delivery of cochlear implants for children and adults with severe to profound deafness resident in Wales. This service will only be commissioned by the Welsh Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

### 1.1 Plain Language Summary

Hearing loss affects over 10 million people across the United Kingdom. It can lead to significant health and mental health issues<sup>2</sup>.

Severe to profound deafness is defined as hearing only sounds that are louder than 80 dB HL (pure-tone audiometric threshold equal to or greater than 80 dB HL) at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids<sup>2</sup>.

A cochlear implant is an implanted electronic hearing device designed to produce useful hearing sensations to a person with severe to profound nerve deafness by electrically stimulating nerves inside the inner ear.

Cochlear implant systems consist of internal and external components. A microphone and sound processor are worn externally behind the ear. The sound processor is connected to a transmitter coil, which is worn on the side of the head. Data from the transmitter coil are passed to a receiver–stimulator package that is implanted into a surgically fashioned depression in the mastoid bone. The receiver–stimulator translates the data into electrical pulses that are delivered to an array of electrodes. These are placed surgically within the cochlea. The electrodes stimulate spiral ganglion cells that innervate fibres of the auditory nerve. The activation of electrodes provides a sensation of hearing, but does not restore hearing.

### 1.2 Aims and Objectives

This policy aims to define the commissioning position of WHSSC on the use of cochlear implants for people with severe to profound deafness.

The objectives of this policy are to:

- ensure commissioning for the use of cochlear implants is evidence based;
- ensure equitable access to cochlear implants;
- define criteria for people with severe to profound deafness to access treatment, and
- improve outcomes for people with severe to profound deafness.

---

<sup>2</sup> [Overview | Cochlear implants for children and adults with severe to profound deafness | Guidance | NICE](#)

### **1.3 Epidemiology**

Approximately 370 children in England and 20 children in Wales are born with permanent severe to profound deafness each year. Around 90% of these children have 2 parents who can hear. About 1 in every 1,000 children is severely or profoundly deaf at 3 years old. This rises to 2 in every 1,000 children aged 9 to 16 years.

There are approximately 613,000 people older than 16 years with severe to profound deafness in England and Wales. In the UK around 3% of people older than 50 and 8% of those older than 70 years have severe to profound hearing loss.

Approximately 40% of children who are deaf and 45% of people younger than 60 years who are deaf have additional difficulties, such as other physical disabilities<sup>3</sup>.

### **1.4 Current Treatment**

The first and preferred way of correcting hearing loss is to use a regular hearing aid/aids as advised by your or your child's audiologist. These devices work by simply making the sound louder in the ear.

For some patients, these acoustic hearing aids will not work or they are not suitable. This may be due to the shape and size of the ear or due to other medical problems with the ear.

Currently, cochlear implants are available for patients with inner ear or mixed hearing conditions resulting in severe to profound deafness. Where severe to profound deafness is defined, as hearing only sounds that are louder than 90 dB HL at frequencies of 2, 3 and 4 kHz unaided.

### **1.5 Proposed Treatment**

It is proposed the threshold for accessing cochlear implant be reduced from 90dBHL to 80dBHL at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz), as per the revised NICE Technology Appraisal Guidance on [Cochlear implants for children and adults with severe to profound deafness \(TA566\)](#).

### **1.6 What NHS Wales has decided**

WHSSC has carefully reviewed the evidence of cochlear implants for children and adults with severe to profound deafness, NICE, Technology Appraisal Guidance [Cochlear implants for children and adults with severe to profound deafness \(TA566\)](#). We have concluded that there is enough

---

<sup>3</sup> [Overview | Cochlear implants for children and adults with severe to profound deafness | Guidance | NICE](#)

evidence to fund the use of cochlear implants, within the criteria set out in section 2.1.

### **1.7 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).
- **National Institute of Health and Care Excellence (NICE) guidance**
  - Cochlear implants for children and adults with severe to profound deafness. NICE Technology Appraisal Guidance (TA566., March 2019. <https://www.nice.org.uk/guidance/TA566>
- **Other published documents**
  - British Cochlear Implant Group Quality standards (2018). <https://www.b cig.org.uk/bcig-revised-quality-standard-now-available/qs-update-2018-pdf-final/>

## 2. Criteria for Commissioning

The Welsh Health Specialised Services Committee approve funding of cochlear implants for adults and children with severe to profound deafness which includes the assessment, surgical implantation, rehabilitation and maintenance of implants, in-line with the revised criteria identified in the policy.

### 2.1 Assessment for Cochlear Implant

The clinical indication for assessment is where children or adults do not gain adequate benefit from acoustic hearing aids for at least 3 months (unless contraindicated or inappropriate).

Children and adults should only be considered for cochlear implantation after an assessment by the cochlear multidisciplinary team.

Paediatric and adult cases are eligible for cochlear implantation if all the following criteria is met:

- The patient meets all of the agreed audiological, physical and psychological criteria outlined in the relevant national Guidelines (e.g. BCIG<sup>4</sup> and NICE<sup>5</sup>).
- The patient should be fit for general anaesthesia.
- Parental and/or patient understanding of the expectations and agreement to the long-term commitment of a cochlear implant.

### 2.2 Inclusion Criteria

Patients with inner or mixed loss conditions resulting in severe to profound deafness defined as 80dBHL at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz).

### 2.3 Cochlear Treatment Options

#### Unilateral cochlear implantation

Unilateral cochlear implantation is recommended as an option for people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids.

Adequate benefit is defined for this guidance as:

- a phoneme score of 50% or greater on the Arthur Boothroyd word test presented at 70 dBA
- for children, speech, language and listening skills appropriate to age, developmental stage and cognitive ability<sup>5</sup>.

---

<sup>4</sup> <https://www.bciq.org.uk/wp-content/uploads/2018/05/QS-update-2018-PDF-final.pdf>

<sup>5</sup> [Overview | Cochlear implants for children and adults with severe to profound deafness | Guidance | NICE](#)



## **Simultaneous bilateral cochlear implantation**

Simultaneous bilateral cochlear implantation is recommended as an option for the following groups of people with severe to profound deafness who do not receive adequate benefit from acoustic hearing aids (as defined above):

- Children
- Adults who are blind or who have other disabilities that increase their reliance on auditory stimuli as a primary sensory mechanism for spatial awareness.

## **Sequential bilateral cochlear implantation**

Sequential cochlear implantation is not recommended as an option for people with severe to profound deafness. NICE Technology Appraisal Guidance on [Cochlear implants for children and adults with severe to profound deafness \(TA566\)](#).

### **2.4 Exclusion Criteria**

There are no exclusion criteria. Individuals who meet the access criteria will be assessed by the Cochlear Implant Programme team for cochlear implantation.

### **2.5 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.

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.

### **2.6 Acceptance Criteria**

The service outlined in this specification 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.

### **2.7 Patient Pathway (Annex i)**

People who meet the criteria for cochlear implants are referred to one of the approved cochlear implant centres in England and Wales (see section 2.8).

Patients will receive a multidisciplinary assessment to determine whether they are suitable for cochlear implantation. Both audiological hearing and functional hearing are assessed as part of the multidisciplinary assessment,

as well as other factors such as fitness for surgery, structure of the cochlea, the presence of a functioning auditory nerve and the likely ability of the person to derive benefit from the stimuli produced by the cochlear implant system. As part of the assessment children and adults should also have had a valid trial of an acoustic hearing aid for at least 3 months (unless contraindicated or inappropriate).

Referrals to approved centres (see section 2.8) are made by either:

- an Ear, Nose and Throat (ENT) specialist
- an Audiovestibular Physician
- an Audiologist
- a Paediatrician

Population referral routes are confirmed below.

### **North Wales (including North Powys)**

Adult referrals should be made to:

- North Wales Cochlear Implant Programme at Betsi Cadwaladr University Health Board (Glan Clwyd Hospital).

Paediatric referrals should be referred to WHSSC IPFR team for Prior Approval. Following approval referral and treatment to:

- Manchester Cochlear Implant Programme at Central Manchester University Hospitals NHS Foundation Trust.

### **Mid & West and South Wales**

Adult and paediatric referrals should be made to:

- South Wales Cochlear Implant Programme at both Cardiff and Vale University Health Board and

## **2.8 Designated Centres**

- **North Wales**

Ysbyty Glan Clwyd  
Betsi Cadwalader University Health Board  
Sarn Lane  
Bodelwyddan

Royal Manchester Childrens Hospital  
Central Manchester University Hospital NHS Foundation  
Oxford Rd  
Manchester  
M13 9WL

- **South Wales**

University Hospital of Wales and Noah's Ark Children's Hospital for Wales  
Cardiff and Vale University Health Board  
Heath Park Way  
Cardiff  
CF14 4XW

## **2.9 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: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

## **2.10 Clinical Outcome and Quality Measures**

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

All providers should meet the minimum standards detailed in the [British Cochlear Implant Group \(2018\) Quality Standards: Cochlear Implant Services for Adults and Children](#).

Outcomes which should be presented at the annual WHSSC cochlear audit day include:

- Speech perception measures. Arthur Boothroyd (AB) word & phoneme outcome measures, this test measures the percentage of whole words and phonemes correctly recognised from a list of monosyllabic words without lip reading. The teams record pre and post implant scores.
- Bamford Kowal and Bench, (BKB) sentence score. The BKB sentence test measures the percentage of words correctly recognised in unfamiliar sentences without lip reading. The teams are required to record a pre and post implant score for adult patients.
- Patient reported outcome measures. Format as agreed at All Wales Audit.

- Categories of Auditory Performance (CAP). Paediatric outcomes are measured using the CAP which is an assessment against a category ranging from 0 (being worst) to 7 (being best). The teams record this measure before implant and then at 3 months, 6 months, 12 months, 24 months and 36 months post implant.
- Speech Intelligibility Rating (SIR). Paediatric outcomes are also measured using the SIR which is an assessment against criteria ranging from 1 (being worst) to 5 (being best). The teams record this measure before implant and then at 3 months, 6 months, 12 months, 24 months and 36 months post implant.
- Categories of Expressive performance (COEP). Paediatric outcomes are also measured using COEP which is an assessment against a category ranging from 1 (being worst) to 6 (being best).
- Rates of device failure, explants and serious complications.

The 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 and for children, teenagers and young adults.

### **2.11 Responsibilities**

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 options with the patient;
- advise the patient of any side effects and risks of the potential treatment
- 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 must be submitted.

### **3. Evidence**

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

#### **3.1 References**

- British Cochlear Implant Group (2018) Quality Standards: Cochlear Implant Services for Children and Adults.  
<https://www.bcig.org.uk/wp-content/uploads/2016/05/BCIG-Quality-Standard-2016.pdf>
- Cochlear implants for children and adults with severe to profound deafness. NICE Technology Appraisal Guidance (TA566), March 2019. [Overview | Cochlear implants for children and adults with severe to profound deafness | Guidance | NICE](#)

#### **3.2 Date of Review**

This document is scheduled for review before 2023 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 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 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: Raising a Concern**

### **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 WHSSC.

### **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.

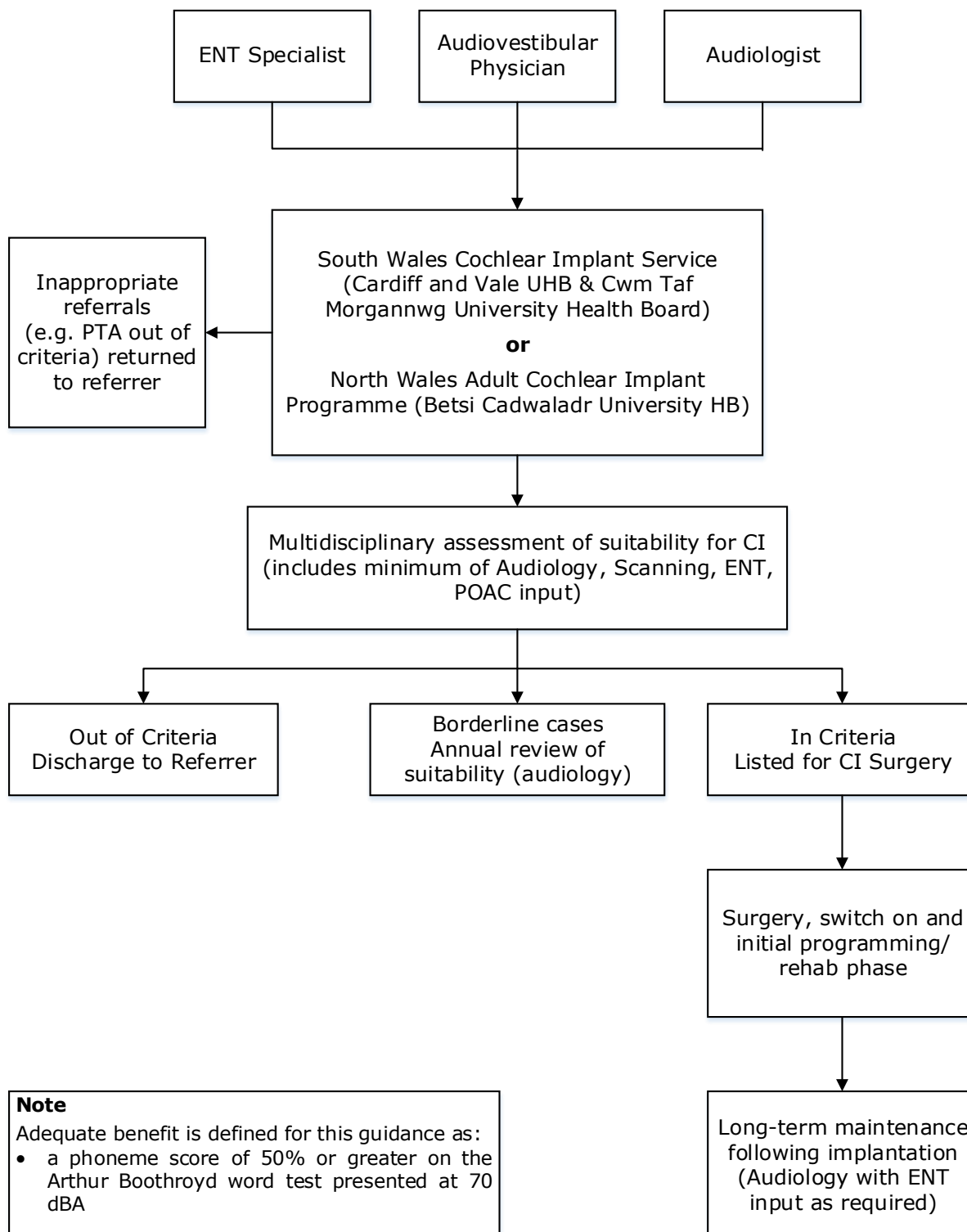
If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent 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 an IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

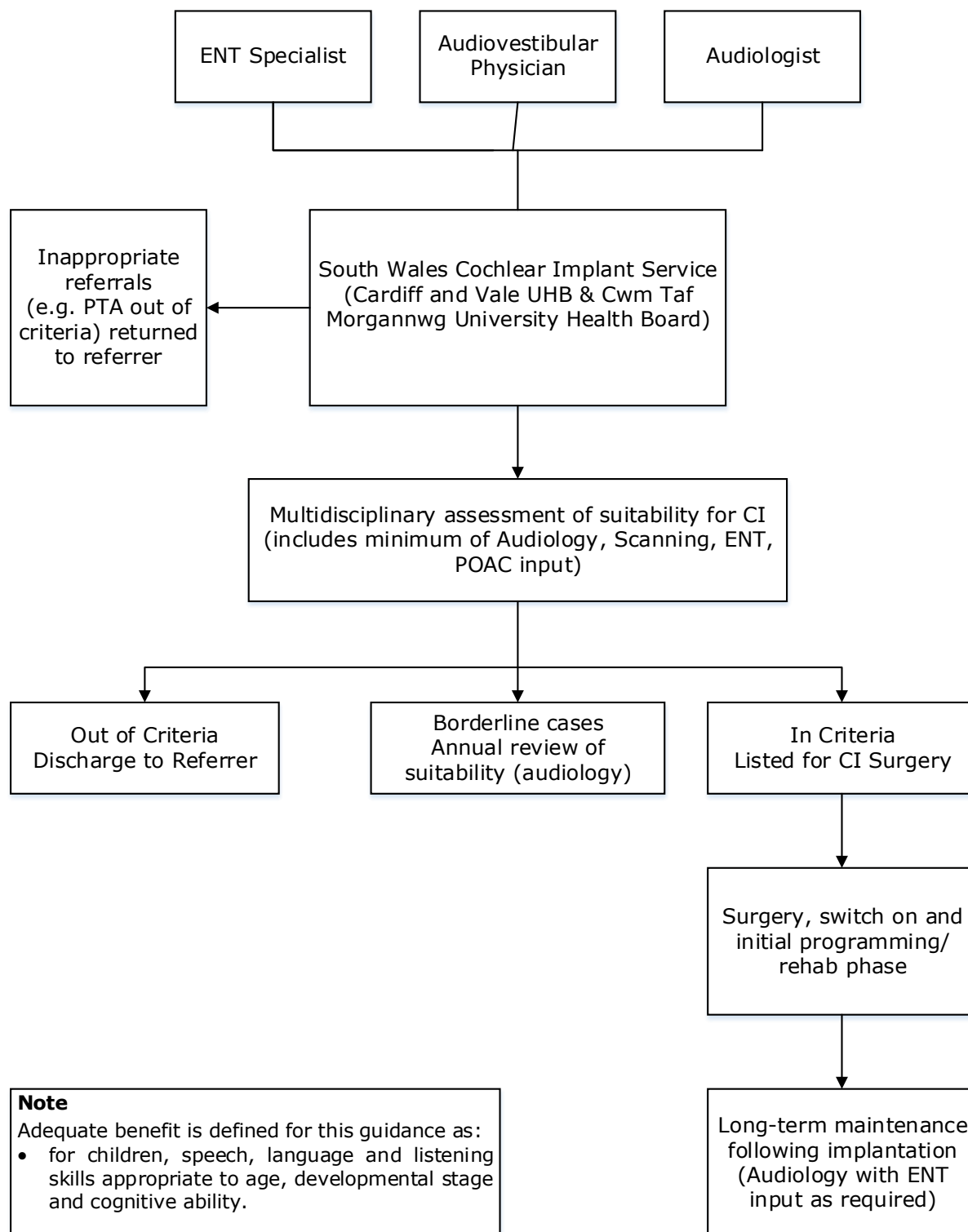
## Annex i Patient Pathway

### Adult Patients

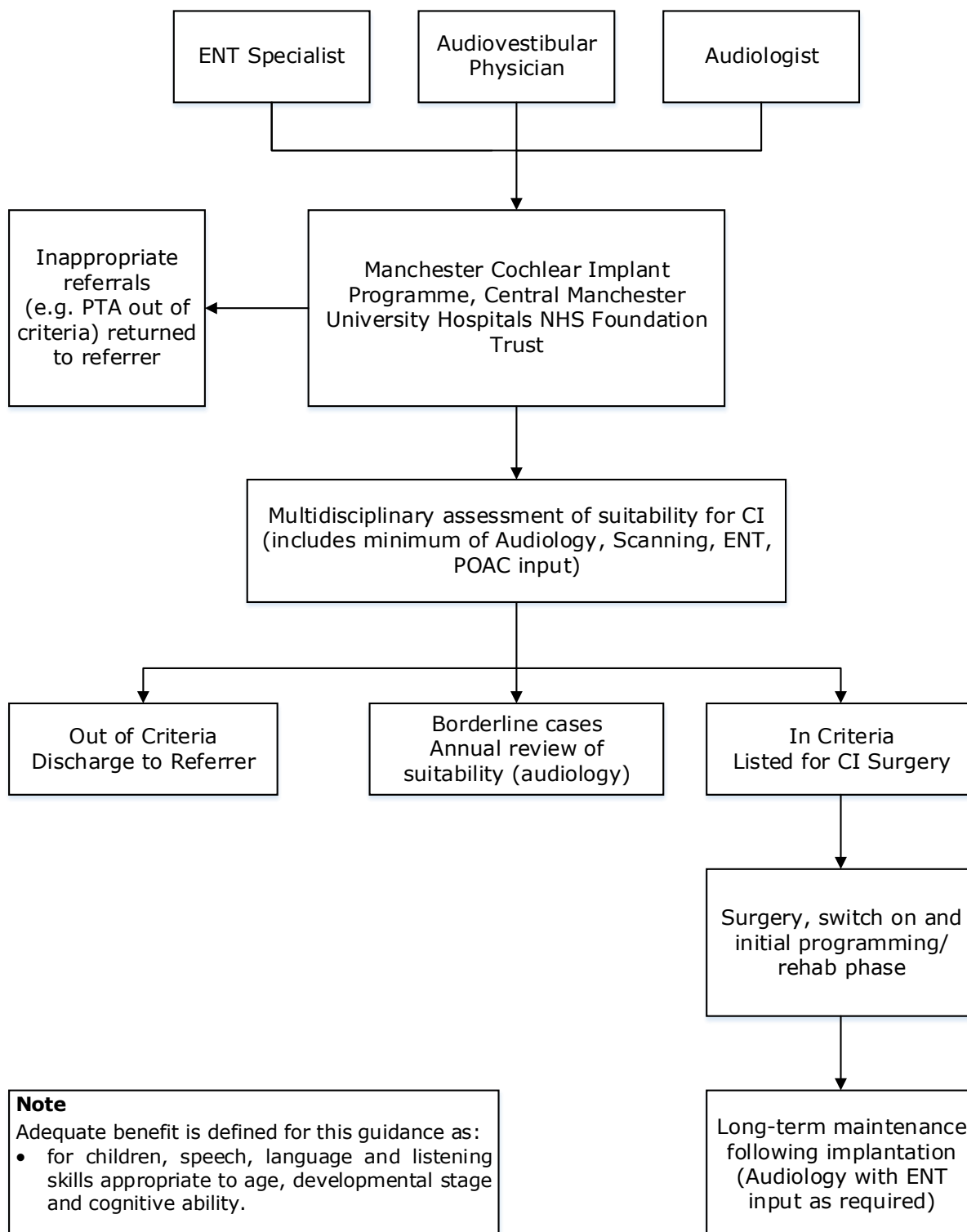




## Paediatric Patients (South Wales)



## Paediatric Patients North Wales



## **Annex ii Checklist**

### **Commissioning Policy CP35: Cochlear Implants**

The following checklist should be completed for every patient to whom the policy applies:

- 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.
- 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.
- 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.
- 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.

## Checklist for Cochlear Implants (Commissioning Policy CP35)

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 registered with NHS Wales GP	GP Code:	
	<b>Yes</b>	<b>No</b>
Patient meets following access criteria for treatment:		
Severe to profound hearing loss bilaterally averaging > 80dBHL at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz and 4,000 Hz)		
Radiological examination has excluded retro cochlear pathologies and cerebral defects		
Patient should be fit for anaesthesia and surgery		
Patient must have an understanding of the expectations and agreement to the long term commitment		
Patient wishes to be referred to non-contracted provider		
<p><i>If the patient wishes to be referred to a non-contracted provider an Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment.</i></p> <p><i>The form must clearly demonstrate why funding should be provided on the basis of the patient benefit being greater than the rest of the population.</i></p> <p><i>The form can be found at</i>  <a href="http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&amp;iid=181455">http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&amp;iid=181455</a></p>		
Patient does not meet access criteria however would have significant clinical benefit from treatment		
<p><i>An Individual Patient Funding Request (IPFR) must be completed and submitted to WHSSC for approval prior to treatment.</i></p> <p><i>The form must clearly demonstrate how the patient will have significant clinical benefit from treatment. The form can be found at</i>  <a href="http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&amp;iid=181455">http://www.wales.nhs.uk/sites3/docopen.cfm?orgid=898&amp;iid=181455</a></p>		

## Annex iii Codes

### ICD-10 Codes

Code Category	Code	Description
ICD-10	H90.3	Sensorineural hearing loss, bilateral
ICD-10	H90.6	Mixed conductive and sensorineural hearing loss, bilateral
ICD-10	H90.5	Sensorineural hearing loss, bilateral (which includes congenital deafness)

### OPCS 4 Codes

Code Category	Code	Description
OPCS 4	D13	Attachment of Bone Anchored Hearing Prosthesis
OPCS 4	D16	Reconstruction of Ossicular Chain
OPCS 4	D24	Operation on Cochlea
OPCS 4	D241	Implantation of intracochlear prosthesis
OPCS 4	D242	Implantation of extra cochlear prosthesis
OPCS 4	D243	Attention to cochlear prosthesis
OPCS 4	D246	Removal of cochlear prosthesis

## **Annex iv Abbreviations and Glossary**

### **Abbreviations**

<b>AWMSG</b>	All Wales Medicines Strategy Group
<b>AB</b>	Arthur Boothroyd
<b>BCIG</b>	British Cochlear Implant Group
<b>BKB</b>	Bench, Kowal and Bamford
<b>CAP</b>	Categories of Auditory Performance
<b>COEP</b>	Categories of Expressive performance
<b>IPFR</b>	Individual Patient Funding Request
<b>SMC</b>	Scottish Medicines Consortium
<b>SIR</b>	Speech Intelligibility Rating
<b>WHSSC</b>	Welsh Health Specialised Services

### **Glossary**

#### **Bilateral**

Relating to both sides of the body.

#### **Individual Patient Funding Request (IPFR)**

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

#### **Welsh Health Specialised Services Committee (WHSSC)**

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services 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.

#### **Unilateral**

Relating to one side of the body.