NHS England

SCHEDULE 2 – THE SERVICES

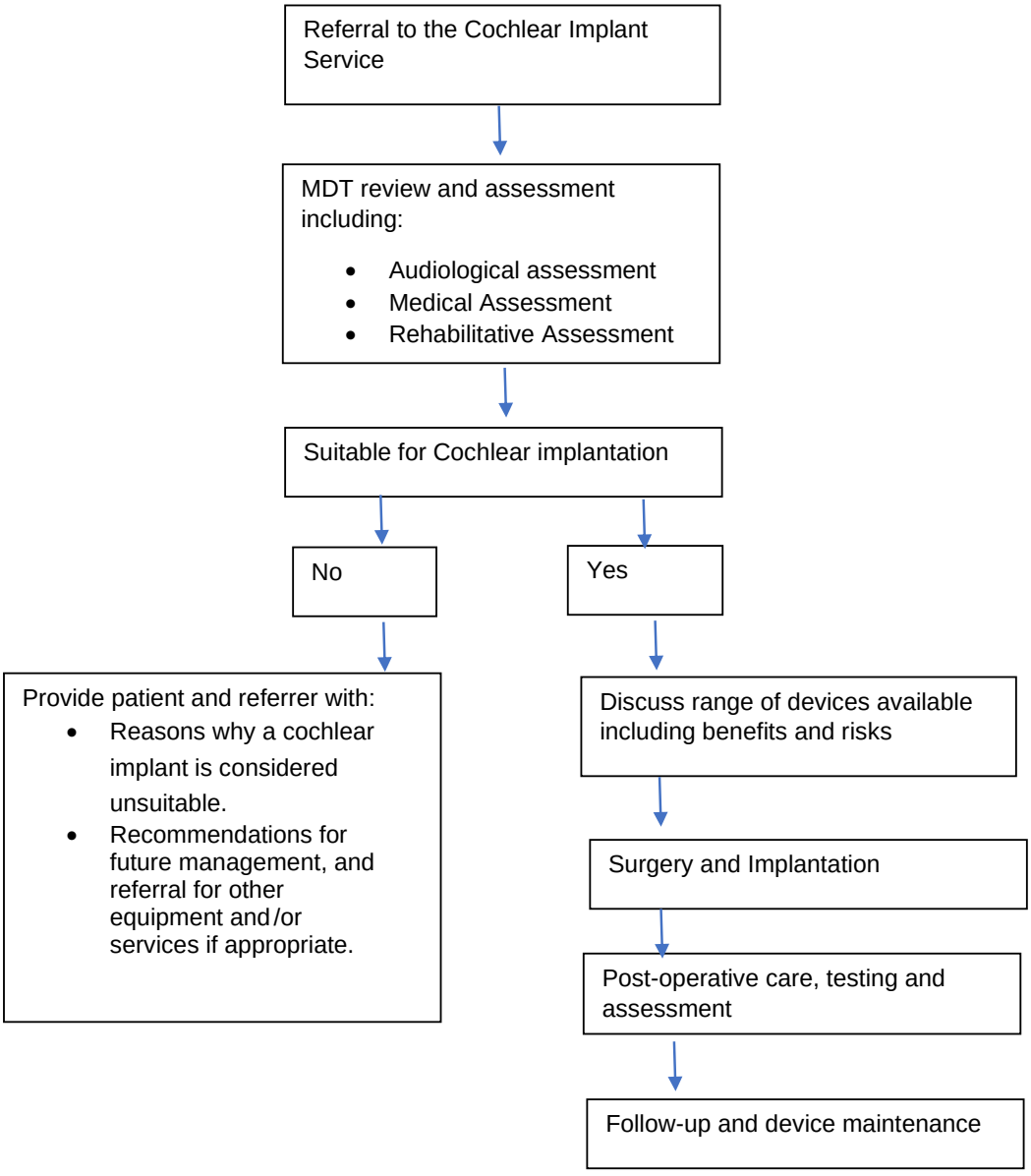
A. Service Specifications

1. Service name	**Cochlear implantation services (adults and children)**
2. Service specification number	D09/S/A – 230503S
3. Date published	22nd May 2023
4. Accountable Commissioner	NHS England NHS commissioning » Trauma (england.nhs.uk)

5.	**Population and/or geography to be served**
5.1	**Population Covered** Cochlear implantation services are commissioned for children and adults with severe to profound deafness in England in line with NICE technology appraisal guidance (TA566). Cochlear implantation is a process that involves the surgical implantation of an electrode array into the cochlea to provide direct electrical stimulation of the auditory nerve. A microphone, transmitter coil and sound processor unit worn on the side of the head transmits to the internal receiver-stimulator package. The resulting electrical stimulation of the auditory nerve provides auditory sensation but does not restore normal hearing. 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. 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: • 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. 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

<table>
<tr><td></td><td>80 dB HL) at 2 or more frequencies (500 Hz, 1,000 Hz, 2,000 Hz, 3,000 Hz and 4,000 Hz) bilaterally without acoustic hearing aids.
Adequate benefit from acoustic hearing aids is defined in the NICE guidance (TA566) as:
for adults, 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.</td></tr>
<tr><td>5.2</td><td>Minimum population size
It is expected that the planning population for this service should be 3-5 million.</td></tr>
<tr><td>6.</td><td>Service aims and outcomes</td></tr>
<tr><td>6.1</td><td>Service aims
The aim of a cochlear implantation service is to improve access to sound and hearing related quality of life for those who meet the criteria as defined in section 5.1.
Hearing related quality of life includes the domains of access to:
Environmental and other sounds .
Spoken language (understanding, use and speech intelligibility).
Integration (social, educational, employment).
Well-being (listening effort, health, psychological status, cognition).
The service will deliver the aim by:
Providing equitable access for all eligible children and adults.
Providing a service which is clinically and cost effective.
Providing appropriate long-term support and aftercare.
Additional aim for children:
To promote the normal development of auditory awareness and comprehension.</td></tr>
<tr><td>6.2</td><td>Outcomes
<u>NHS Outcomes Framework Domains & Indicators</u><table><tr><td>Domain 1</td><td>Preventing people from dying prematurely</td></tr><tr><td>Domain 2</td><td>Enhancing quality of life for people with long-term conditions</td></tr><tr><td>Domain 3</td><td>Helping people to recover from episodes of ill-health or following injury</td></tr><tr><td>Domain 4</td><td>Ensuring people have a positive experience of care</td></tr><tr><td>Domain 5</td><td>Treating and caring for people in safe environment and protecting them from avoidable harm</td></tr></table></td></tr>
</table>

	<table><tr><th colspan="3">Clinical Outcomes - quantitative data</th></tr><tr><td>% of patients with improvement in hearing as measured by implant aided sound field testing assessed 12 months after implant surgery.</td><td>National Hearing Implant Registry</td><td>Domain 2</td></tr><tr><td>% of patients with consistent and reliable use of their cochlear implant</td><td>National Hearing Implant Registry</td><td>Domain 2</td></tr><tr><td>% of children with improvement in the Categories of Auditory Processing (CAP) testing score assessed 12 months after implant surgery</td><td>National Hearing Implant Registry</td><td>Domain 2</td></tr></table> Quality Metrics: The service will complete/upload data for all listed quality metrics to the national specialised Services Quality Dashboard (SSQD). The full version of the quality metrics and their descriptions including the numerators and denominators can be accessed at https://www.england.nhs.uk/commissioning/spec-services/npc-crg/spec-dashboards/ <u>Service defined outcomes/outputs</u> Providers are expected to meet the quality standards for age-appropriate services as set out in the British Cochlear Implant Group Quality Standard (2023) for Cochlear implant services for children, young people and adults. The service will engage in audit and monitoring of service outcomes, including complying with data requirements of the National Hearing Implant Registry (NHIR) and appropriate external organisations, such as the MHRA.
7.	**Service description**
7.1	Cochlear implant services are commissioned for children and adults with severe to profound deafness in England in line with NICE technology appraisal guidance (TA566) from centres as outlined in section 7.8. The service includes assessment, surgical implantation, rehabilitation and ongoing care and maintenance. The service is delivered by a multidisciplinary team of specialist professionals with expertise in otology (surgical and nursing), clinical science (Audiological Scientists and/or Clinical Physicists), clinical physiology (Audiologists and/or Hearing Therapists) and rehabilitation (Speech and Language Therapists and/or Teachers of the Deaf and/or Hearing Therapists and/or Auditory Verbal Therapists). The service is required to have appropriate transition arrangements in place for children moving into adult services.

	The service will provide support to all patients, including those with complex and special needs, and ensure access to further appropriate services and care for these patients as necessary. When appropriate, suitable communication support must be provided to permit equal access for deaf patients e.g. BSL interpreters, speech to text.
7.2	**Pathways** **Summary patient pathway** 

7.2	**Referral**
	The service will accept referrals from:
	• GP.
	• Audiology Service (NHS or private).
	• Ear, Nose and Throat (ENT) Service.
	• Paediatrician.
	• Audiological physicians.
	• Speech and Language Therapists.
	• Teachers of the deaf.
	• Neurology.
	
	Written or electronic referrals should be made to the cochlear implantation service providing evidence of:
	• Unaided hearing level in both ears at frequencies between 0.5 and 8 kHz (for babies and young children this may not be possible to assess fully prior to referral).
	• Where possible, evidence of a hearing aid trial of at least 6 weeks or a reason as to why this is contraindicated or inappropriate.
	
	Assessment
	All patients will undergo comprehensive assessment by a specialist multi-disciplinary team to assess suitability for cochlear implantation.
	
	When considering the assessment of adequacy of acoustic hearing aids, the multidisciplinary team assessment will include all or some of the following:
	• Audiological assessments
	  ○ otoscopy, age-appropriate behavioural hearing assessment, evaluate middle ear function, objective hearing assessments, hearing aid evaluation, aided speech perception testing, balance function testing as required, adhering to relevant and up to date test protocols.
	  ○ Testing may need to be adapted to take account of a person's disabilities (such as physical and cognitive impairments), or linguistic or other communication difficulties, to ensure equality of access.
	  ○ If it is not possible to administer tests in a language in which a person is sufficiently fluent for the tests to be appropriate, other methods of assessment will be considered, for example the Auditory Speech Sounds Evaluation (ASSE) or other non-language-biased tests.
	• Patient/family/carer understanding and expectations of implantation and informed consent.
	• Medical assessments

- Clinical history, physical examination, fitness for surgery, suitability of cochlear for implantation, radiological evaluation via MRI +/- CT imaging.

- Speech, language and communication assessment
  - Speech and language skills, functional listening, quality of life, ability to participate in rehabilitation programme, developmental level of child, availability of support and liaison with local services.
  - Interaction and communication skills.
- Psychological Services
  - Cochlear implantation teams should know how to refer to and access local mental health and psychological services (for adults and children), if required.
- Information and signposting
  - patients who may be candidates for implantation and their families/carers as appropriate, will receive information about voluntary services and support groups including the opportunity to have contact with deaf patients of a similar age (and their families for paediatric patients) who are users of cochlear implants.
  - Patients will be offered written information to help them to make informed decisions about their healthcare, at appropriate points within the assessment to ensure they have realistic expectations of cochlear implantation.

Following assessment, all cases will be discussed in a multi-disciplinary team (MDT) including representatives of all core members of the team.

Where the outcome of the assessment is that the patient could benefit from a cochlear implantation, the range of devices available and their specifications will be discussed, and device choice confirmed through discussion between the patient and the clinical team.

A full discussion of the benefits and risks of cochlear implantation will be undertaken by the team including the surgeon and appropriate consent obtained.

If the outcome of the assessment, following MDT discussion, demonstrates that the patient would not benefit from a cochlear implantation, a report to the referring clinician with copies to the patient, their GP and to any other relevant professionals should be provided and should include:

- Reasons why a cochlear implantation is considered unsuitable.
- Recommendations for future management, and referral for other equipment and/or services if appropriate.
- Opportunity for the patient and/or the family to discuss the outcome of the assessment.

Surgery and implantation

- The operation must be completed by an experienced otologist (completing a minimum of 10 cases annually) in line with British Cochlear Implant Group Quality Standard (2023) for Cochlear implant services for children, young people and adults.
- Electrode placement should be confirmed through imaging and/or electrophysiology. This could be performed intraoperatively or during early post-operative follow-up.
- Surgical facilities must afford appropriate NHS standards of safety, accessibility, cleanliness, privacy and dignity and also take into account communication needs of deaf patients.
- The facilities should also comply with British Cochlear Implant Group Quality Standard (2023) for Cochlear implant services for children, young people and adults.

The patient will receive:

- Written information regarding care of the wound/ear and pain management post operatively.
- Written guidelines on what to do should medical/surgical problems arise.
- Advice regarding health and safety with a cochlear implant.
- Manufacturer safety guidelines.

The Cochlear implant device offered will:

- Have a proven track record for safety.
- Have UKCA approval.
- Conform to the recommendations of the Medical and Health Care Products Regulatory Agency Medical devices: how to comply with the legal requirements in Great Britain - GOV.UK (www.gov.uk)
- Comply with terms and conditions of the purchasing body.
- Have high quality clinical and technical support available from the manufacturer.
- Meet national purchasing requirements.

Post-operative management

- Medical check following implantation of surgical site and device placement.
- Initial activation and ongoing sound processor programming.
- Records of all programmes installed in the software, and of all tests performed by the multi-disciplinary team, must be kept.
- Progress with the cochlear implant will be monitored through at least three assessments in the first year and then again at routine contacts which should be offered in line with patient need.

	• Recognised and validated developmental age appropriate audiological and speech perception measures will be performed on at least two occasions in the first year. • Tests will include the patient's ability to hear sounds and speech, as well as assessment of quality of life. • The patient will have access to on-going audiological review, frequency based on individual patient need. This may be offered through the use of patient-initiated follow-up as outlined in Implementing patient initiated follow-up guidance for local health and care systems (2022). • Remote consultation and programming may be offered where appropriate. **Training and Outreach** • Sound awareness training in adults and development of listening skills in children. • Communication skills training in adults and development in children. • Listening and language skills development training and/or support as required. • Lip reading skills training. • Training and advice to patient (and carers if appropriate) on care and use of the implant. • Patients and/or carers will be trained by the service to carry out simple troubleshooting and maintenance such as visual inspection of external parts and subjective listening checks (where possible). • Advice to other organisations (for example, troubleshooting advice for local education, health and social care staff). **Device Maintenance** • On-going support and maintenance – including a comprehensive spares and repairs service. • For more complex maintenance needs, the cochlear implant service will provide information on how to contact the service and will make arrangements whereby external implant parts can be returned to the service during opening hours. • The service will aim to resolve repair and replacement issues within 2 working days. • Spares/replacements of external equipment (microphone, sound processor and transmitter) will be provided as required. • Replacement batteries will be available to implant users either from the cochlear implant service or the service may be able to arrange collection from a local audiology department. • Upgrade or provision of new sound processors, if clinically appropriate (on average at 5 yearly intervals), to ensure patient access to up-to-date

technology to optimise their hearing performance and subsequently outcome from the intervention.

Device policies

The service will have policies in place which cover the following:

- Device failure.
- Lost processor/s.
- Assistive Listening Devices.
- Upgrade of speech processor/s.
- Essential repairs, consumables, and spare parts.
- Non-Essential items e.g. decorative covers, holiday loaners and for repair or replacement of parts or devices if damage, loss or failure is determined to be due to inappropriate care, with appropriate provision for appeal.

Device Failure

- The service will provide re-implantation if required.
- Any device failures must be reported to the MHRA Adverse Incidents section and the company that supplied the implant.
- If device failure is clinically suspected, the patient must be offered an appointment within 7 working days to check the external and internal components of the implant device.

Transition and Transfer

- The service will follow the transfer of care pathway from/to another service (including transition paediatric to adult) in line with British Cochlear Implant Group Quality Standard (2023) for Cochlear implant services for children, young people and adults.
- All healthcare services are required to deliver developmentally appropriate healthcare to patients and families. Children and young people with ongoing healthcare needs may present direct to adult services or may be required to transition into adult services from children's services. Transition is defined as a 'purposeful and planned process of supporting young people to move from children's to adults' services'. Poor planning of transition and transfer can result in a loss in continuity of treatment, patients being lost to follow up, patient disengagement, poor self-management, and inequitable health outcomes for young people. It is therefore crucial that adult and children's NHS services, in line with what they are responsible for, plan, organise and implement transition support and care (for example, holding joint annual review meetings with the child/young person, their family/carers, the children's and adult service). This should ensure that young people are equal partners in planning and decision making and that their preferences and wishes are central throughout transition and transfer. NICE guidelines recommend that planning for transition into

	adult services should start by age 13-14 years at the latest, or as developmentally appropriate and continue until the young person is embedded in adult services.
7.3	**Clinical Networks** There are no formal operational delivery networks (ODNs) for cochlear implantation services. All Providers will be required to participate in a networked model of care to enable services to be delivered as part of a co-ordinated, combined whole system approach.
7.4	**Essential Staff Groups** The multidisciplinary team should comprise a core team including: • Cochlear Implant Co-ordinator/Head of Service, • Clinical Scientist (Audiology/Clinical Physics) and/or Clinical Physiology (Audiology), • Rehabilitation Therapists (this may include the following - Speech and Language Therapist, Teacher of the Deaf, Hearing Therapist, Auditory Verbal Therapist, • Minimum of two experienced Otologists who should have received Fellowship training, or equivalent, in cochlear implantation. Access should also be available to the following health professionals: • Neuroradiologists, • Audiovestibular Physicians, • Geneticists, • Paediatricians, • Specialists in Older People's Medicine.
7.5	**Essential equipment and/or facilities** Cochlear implantation services should have the following facilities: • Age-appropriate inpatient and outpatient facilities. • Operating theatres. • Audiological testing will comply with British Society of Audiology Practice Guidance for The Acoustics of Sound Fields Audiometry in Clinical Audiology Applications (2019) • Facilities for patients should be accessible, safe, suitable, and family friendly for a deaf population (including for patients with additional comorbidities). • Outpatient settings should include the provision of visual or other devices to alert the patient that the clinician is ready to see them. Cochlear implantation centres should have the following equipment:

	• Electro-medical equipment necessary to deliver a safe and effective service. Equipment should be serviced on a regular basis and annual electromedical safety checks should be carried out. All equipment must be appropriately calibrated to current British and ISO standards, with calibration and service records appropriately retained.
7.6	**Interdependent Service Components – Links with other NHS services** The service has interdependencies with the following services: • NHS Audiology Service, • NHS New-born Hearing Screening Programme, • Social Services including Social Worker for the Deaf, • Occupational therapy, • Physiotherapy, • Psychology, • Mental Health Services for the Deaf (Adults and Children).
7.7	**Additional requirements** Not applicable
7.8	**Commissioned providers** **North East and Yorkshire** Bradford Teaching Hospitals NHS Foundation Trust Sheffield Teaching Hospitals NHS Foundation Trust* (non-surgical) South Tees Hospitals NHS Foundation Trust **North West** Manchester University NHS Foundation Trust **Midlands** Birmingham Women's and Childrens NHS Foundation Trust Nottingham University Hospitals NHS Foundation Trust University Hospitals Birmingham NHS Foundation Trust **East of England** Cambridge University Hospitals NHS Foundation Trust **London** Great Ormond Street Hospital for Children NHS Trust Guy's and St. Thomas' NHS Foundation Trust, London St. George's University Hospital NHS Foundation Trust, London University College London Hospitals NHS Foundation Trust **South East** Oxford University Hospitals NHS Foundation Trust

	University Hospital Southampton NHS Foundation Trust **South West** University Hospitals Bristol and Weston NHS Foundation Trust *Sheffield Teaching Hospitals NHS Foundation Trust works in partnership with other commissioned providers who deliver the surgical elements of the care pathway.
7.9	**Links to other key documents** NICE TAG 566 (2019) Cochlear implants for children and adults with severe to profound deafness British Cochlear Implant Group Quality Standard (2023) for Cochlear implant services for children, young people and adults.

Change form for published Specifications and Products developed by Clinical Reference Group (CRGs)

Product name: Service Specification - Cochlear implantation services (adults and children)

Publication number:

CRG Lead: National Clinical Lead for Specialised Ear Services / National Programme of Care Senior Manager - Trauma

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
Specialised Ear Surgery – Cochlear Implants	Cochlear implantation services (adults and children)	1.0 Service name	For consistency with PSS Manual	Specification Working Group.	November 2022
Incidence and prevalence data	Removed	(old template) National context	This is no longer required in the new template	Specification Working Group	November 2022
Reference to NICE TAG166	Updated to reference NICE TAG566	All applicable references and associated text.	Updated NICE guidance published in 2019	Specification Working Group	November 2022
Reference to the British Cochlear Implant Group (BCIG) quality standards (2009)	Updated to reference British Cochlear Implant Group (BCIG) quality standards (2023)	All applicable references and associated text.	Updated BCIG documents published in 2023	Specification Working Group	January 2023
Specialist ENT surgeon	Otologist	Throughout	More accurate description of the specialist ENT surgeon and to ensure consistency in the document. An Otologist is a specialist ENT surgeon with a sub-	Specification Working Group	November 2022

			specialty focus on the ear.		
The aim of a cochlear implant service is to improve the hearing and quality of life for those with high frequency functional severe to profound permanent deafness who do not gain adequate benefit from conventional well-fitted hearing aids and to promote understanding and the use of spoken language in children	The aim of a cochlear implant service is to improve access to sound and hearing related quality of life for those who meet the criteria as defined in section 5. Hearing related quality of life includes the domains of access to: • Environmental and other sounds • Spoken language (understanding, use and speech intelligibility) • Integration (social, educational, employment) • Well-being (listening effort, health, psychological status, cognition)	6.1 Aim of service	To better describe the service aim – access to 'sound' as well as improve hearing. Also provides detail of hearing related quality of life domains.	Specification Working Group. Reflects current service provision as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	December 2022 March 2023
Old Quality Indicators	New Quality Outcomes	6.2 Outcomes	To reflect new approach to assessing the quality of services. Quality indicators are removed from specifications as they are updated and only the quality outcomes relating to the service	Specification Working Group	February 2023 March 2023

			will be included within the specification.		
	Insertion of outline patient pathway flow diagram	7.2 Patient Pathway	Requirement of new template	Specification Working Group	February 2023
The service will accept referrals from: • GP • NHS or private Audiology Service • Ear, Nose and Throat (ENT) Service • Paediatrician	The service will accept referrals from: • GP • Audiology Service • Ear, Nose and Throat (ENT) Service • Paediatrician • Audiological physicians • Speech and Language Therapists • Teachers of the deaf • Neurology	7.2 Referral	Additional referral sources have been added to reflect current practice.	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	December 2022 March 2023
Written referrals	Written or electronic referrals	7.2 Referral	Electronic referrals are accepted	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	December 2022 March 2023
Audiological assessments: otoscopy, age-appropriate behavioural hearing assessment, objective hearing assessments	Audiological assessments: otoscopy, age-appropriate behavioural hearing assessment, evaluate middle ear function, objective hearing assessments.	7.2 Assessment	Additional assessment - evaluate middle ear function - included in the description. This assessment is usual clinical practice.	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned	December 2022 March 2023

	Testing may need to be adapted to take account of a person's disabilities (such as physical and cognitive impairments), or linguistic or other communication difficulties, to ensure equality of access. If it is not possible to administer tests in a language in which a person is sufficiently fluent for the tests to be appropriate, other methods of assessment will be considered, for example the Auditory Speech Sounds Evaluation (ASSE) or other non-language-biased tests.		Text regarding alternative / adapted testing should be taken in-to account if required.	Cochlear Implant Centres.	
If the outcome of the assessment, demonstrates that the patient would not benefit from a cochlear implant, the report to the referring clinician should include:	All cases will be discussed in a multi-disciplinary team (MDT) including representatives of all core members of the team. If the outcome of the assessment, following MDT discussion, demonstrates that the patient would not benefit from a cochlear implant, the report to the referring clinician with copies to the patient's GP and to any other relevant professionals should be provided and should	7.2 Assessment	Included additional text with the requirement for assessment to be discussed with the MDT and copy of assessment outcome to be copied to GP and other relevant professionals. This change reflects usual standard practice and does not result in any additional steps in the care pathway.	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	November 2022 March 2023

	include:		Copying documentation to the patient, GP and other relevant professionals is considered good practice.		
-	New inserted text: In this situation, the service will ensure that the patient and/or the family have the opportunity to discuss the outcome of the assessment.	7..2 Assessment	To ensure the patient/family can discuss the outcome of the assessment with the clinical team.	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	November 2022 March 2023
-	New inserted text: The range of devices available and their specifications will be discussed, and device choice confirmed through discussion between the patient and the implant team. A full discussion of the benefits and risks of cochlear implantation will be undertaken by the team including the surgeon and appropriate consent obtained.	7.2 Assessment	To ensure the patient/family can make an informed decision.	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	November 2022 March 2023

-	Psychological Services • Cochlear implant teams should know how to refer to and access local mental health and psychological services (for adults and children), if required.	7.2 Assessment	To ensure service knowledge on referral and access to local mental health and psychology services (if required)	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	November 2022 March 2023
Rehabilitative Assessment	Speech, language, and communication assessment	7.2 Assessment	Improved description of the assessment – detail of the assessment is unchanged.	Specification Working Group following advice from informal stakeholder testing.	March 2023
Patient pathway – annual follow-up After the first year following implant surgery, the patient will have access to regular audiological review, typically annually.	After the first year following implant surgery, the patient will have access to audiological review, with frequency based on individual patient. This may be offered through the use of patient-initiated follow-up.	7.2 Follow-up	Wording to reflect increased flexibility of long-term patient follow-up to reflect individual patient need in line with NHS England guidance NHS England guidance B0801-implementing-patient-initiated-follow-up-guidance-1.pdf (england.nhs.uk)	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	November 2022 March 2023
The operation must be completed by an experienced otologist who has an adequate caseload to maintain surgical skills	The operation must be completed by an experienced otologist (completing a minimum of 10 cases annually)	7.2 Surgery & Implantation	The use of the term 'adequate' was considered ambiguous. The reference to 10 cases annually is in line with professional guidelines (BCIG) and is achieved by all	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned	November 2022 March 2023

			commissioned services.	Cochlear Implant Centres.	
British Cochlear Implant Group safety guidelines	Manufacturer safety guidelines	7.2 Surgery & Implantation	BCIG website points to the manufacturer guidelines, so statement is a more accurate description.	Specification Working Group	November 2022 March 2023
The Cochlear implant device offered will: • Have CE approval	The Cochlear implant device offered will: • Have UKCA approval	7.2 Surgery & Implantation	The approval/ regulation body has changed since the UK left the European Union.	Specification Working Group following advice from informal stakeholder testing.	March 2023
-	Electrode placement should be confirmed through imaging and/or electrophysiology	7.2 Post-operative testing and follow-up	This is standard practice but was omitted from the previous document	Specification Working Group, Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	November 2022 March 2023
Initial activation and programming of speech processor	Initial activation and ongoing sound processor programming	7.2 Post-operative testing and follow-up	This is an improved description and standard practice.	Specification Working Group	November 2022 March 2023
After the first year following implant surgery, the patient will be offered regular audiological review, typically annually. Flexibility for additional appointments will be available if required to adequately meet the needs of the patient.	The patient will have access to on-going audiological review, frequency based on individual patient need. This may be offered through the use of patient-initiated follow-up as outlined in Implementing patient initiated follow-up	7.2 Post-operative testing and follow-up	Revised wording to reflect follow-up frequency based on individual patient need and the use of patient-initiated follow-up in line with NHS England guidance NHS England guidance B0801-implementing-	Specification Working Group Confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	November 2022 March 2023

	guidance for local health and care systems (2022)		patient-initiated-follow-up-guidance-1.pdf (england.nhs.uk)		
Advice to other organisations e.g. trouble shooting advice for local staff	Advice to other organisations e.g. trouble shooting advice for local education, health and social care staff	7.2 Training and Outreach	Provides further detail	Specification Working Group	November 2022
Upgrade or provision of new sound processors on average at 5 yearly intervals, where available, in order to ensure patient access to up to date technology to maximise their hearing performance and subsequently outcome from the intervention.	Upgrade or provision of new sound processors, if clinically appropriate (on average at 5 yearly intervals), to ensure patient access to up to date technology to optimise their hearing performance and subsequently outcome from the intervention.	7.2 Device Maintenance	Rewording to emphasise that upgrades are available as clinically appropriate.	Specification Working Group	December 2022
Transfer of care pathway from/to another service	Transfer of care pathway from/to another service (including transition paediatric to adult) in line with British Cochlear Implant Group Quality Standards (2023) Plus standard Transition wording inserted.	7.2 Transition	To highlight importance and standards for transition	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	December 2022 March 2023
For more complex maintenance needs, the cochlear implant service	For more complex maintenance needs, the cochlear implant service	7.2 Device Maintenance	Fax is no longer used.	Specification Working Group	December 2022

will provide advice via telephone, fax, email, text etc	will provide information on how to contact the service.				
Any device failures must be reported to the MHRA Adverse Incidents section	Any device failures must be reported to the MHRA Adverse Incidents section and the company that supplied the implant.	7.2 Device failure	Added requirement to notify the manufacturer.	Specification Working Group	December 2022
Records of measurement of all programmes installed in the software, and of all tests performed by the multi-disciplinary team, must be kept. Progress with the cochlear implant will be monitored through at least three assessments in the first year and then again at routine reviews which should be offered at a minimum annually after the switch on. These tests will include the patient's ability to hear sounds and speech, as well as assessment of quality of life.	Records of measurement of all programmes installed in the software, and of all tests performed by the multi-disciplinary team, must be kept. Progress with the cochlear implant will be monitored through at least three assessments in the first year and then again at routine contacts which should be offered in line with patient need. This may be offered through the use of patient-initiated follow-up. These tests will include the patient's ability to hear sounds and speech, as well as assessment of quality of life.	7.2 Monitoring	Revised wording to reflect follow-up frequency based on individual patient need and the use of patient-initiated follow-up.	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	November 2022 March 2023
These to include: • Cochlear Implant Co-ordinator/ Head of Service Role • Clinical Scientists (Audiology/Clinical Physics) • Clinical physiologists	The multidisciplinary team should comprise a core team including: • Cochlear Implant Co-ordinator/ Head of Service • Clinical Scientist (Audiology/Clinical	7.4 Essential Staff Groups	This expands the clinical team described as rehabilitation therapists. The following professionals may also form part of this	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing with commissioned	December 2022 March 2023

(Audiology) • Rehabilationists / Hearing Therapists • Speech & Language Therapists • Consultant Otologists	Physics) and/or Clinical Physiology (Audiology) • Rehabilitation Therapists (this may include, Speech and Language Therapist, Teacher of the Deaf, Hearing Therapist, Auditory Verbal Therapist) • Minimum of two experienced Otologists who should have received Fellowship training, or equivalent, in cochlear implantation. Access should also be available to other appropriate health professionals • Neuroradiologists • Audiovestibular Physicians • Geneticists • Paediatricians • Specialists in Older People's Medicine.		team - speech and language therapists, teachers of the deaf and auditory verbal therapists Also includes a minimum of two Otologists in the team. This is standard practice and is met by all commissioned services. Also includes reference to wider members of the MDT which the service should have access to.	Cochlear Implant Centres.	
	Facilities • Audiological testing will comply with British Society of Audiology Practice Guidance for The Acoustics of Sound Fields Audiometry in	7.5 Essential equipment and/or facilities	New section, detail not previously included. The text is in line with existing British Society of Audiology and BCIG guidelines	Specification Working Group Reflects current practice as confirmed through informal stakeholder testing	December 2022 March 2023

	Clinical Audiology Applications (2019) • Facilities for patients should be accessible, safe, suitable, and family friendly for a deaf population (including for patients with additional comorbidities). This should include the provision of visual or other devices to alert the patient that the clinician is ready to see them. • Electro-medical equipment necessary to deliver a safe and effective service. Equipment should be serviced on a regular basis and annual electromedical safety checks should be carried out. All equipment must be appropriately calibrated to current British and ISO standards, with calibration and service records appropriately retained.		and is met by existing commissioned services.	with commissioned Cochlear Implant Centres.	
-	• Mental Health Services for the Deaf (Adults and Children)	7.6 Interdependent Services	Additional service added.	Specification Working Group	December 2022 March 2023

			This is an existing commissioned service omitted from the previous specification interdependencies.	Reflects current practice as confirmed through informal stakeholder testing with commissioned Cochlear Implant Centres.	
Appendix 1: Quality Standards	Removed	Appendix 1	This section is not required in the new template. Quality metrics for services will be held in separate quality dashboard.	Specification Working Group	March 2023

Note: Informal stakeholder testing was completed with the commissioned providers of the service between 23/2/23 and 10/3/23. Respondents agreed that the document reflected the current patient pathway and would not result in financial implications for the delivery of care. Respondents noted a couple of other minor edits to the documentation which have been incorporated.