GUIDELINES FOR IMPLEMENTATION OF ADIP SCHEME REVISED 1ST APRIL 2022

IMPLEMENTING AGENCY

Ministry of Social Justice and Empowerment will recognize an institute of national stature as the implementing agency for this scheme.

The head of the implementing agency will constitute the following for smooth implementation of the scheme:

- 1. <u>Internal Advisory Committee</u> consisting of five to six senior cochlear implant surgeons representing the different zones of the country. Any medical, surgical issues or any challenges faced by the implementing agency will be referred to the Internal Advisory Committee for advice.
- 2. <u>Internal ADIP Committee</u>, including, but not limited to
 - Two ENT Surgeons (Internal and External)
 - Head, Department of Audiology
 - Head, Department of SLP
 - Head, Department of Clinical Psychology/ Clinical Psychologist
 - All-India co-ordinator Pre-surgery team
 - All-india co-ordinator Post-surgical Rehabilitation team
- 3. <u>Pre-surgery team</u> at the institute, consisting of All-India Co-ordinator (AIC-CI) and zonal co-ordinators for each of the five geographic zones of the country.
- 4. <u>Post-operative Rehabilitation (POR) team</u> at the institute, consisting of All-India Co-ordinator (AIC-POR and zonal co-ordinators for each of the five geographic zones of the country.

GUIDELINES FOR CANDIDATE SELECTION

A. Eligibility of the Beneficiaries – General Criteria

A person with hearing disability fulfilling following conditions would be eligible for assistance under ADIP scheme.

- 1. Citizen of India.
- 2. Holding 40% Disability Certificate or Hearing Disability as defined in the RPWD Act 2016.
- 3. Monthly income from all sources not exceeding Rs. 30,000/- of parents/guardians/family.
- 4. Only unilateral cochlear implantation will be covered under this scheme.
- 5. Reservation for SC/ST/OBC beneficiaries will be implemented under the scheme as per the Government norms and at least 25% of the overall beneficiaries need to be girl child.

B. Audiological and Medical Criteria

There are a number of factors that determine the degree of success to be expected from cochlear implant. Eligibility of candidates will be determined by taking into account a person's hearing history, cause of hearing loss, amount of residual hearing, speech recognition ability, health status and family commitment to aural habilitation/rehabilitation, apart from mentioned eligibility criteria.

B-1) Children with pre-lingual hearing loss

- 1. Age of the beneficiary should be below 5 years on the date of receipt of application. Age shall be cross checked with the birth certificate issued by the competent authority for verification.
- 2. Bilateral severe-to-profound sensor ineural hearing loss.
- 3. All the children must be habituated to using behind the ear hearing aids for about 3 to 6 months to assess utility of usage of hearing aids. Proof of having used conventional hearing aids for sufficient time before advising cochlear implantation with details of process of speech therapy that they underwent from accredited rehabilitation personnel should be produced. Cases with meningitis to be considered as an exception and fast-tracked.
- 4. Little or no benefit from conventional hearing aids either in terms of better hearing, as evident from aided audiogram or acquisition of speech and language skills and comprehension of spoken language, as evident from therapy progress reports.
- 5. No medical contradictions to surgery and/or implantation.
- 6. No associated impairments such as Developmental Delay, Autistic Spectrum Disorder, Orofacial anomalies, sensory impairments, Attention Deficit Hyperactivity Disorder, Intellectual Deficits, Cerebral Palsy, neurodegenerative diseases, progressive medical conditions, short life expectancy.
- 7. No presence of cochlear malformations/anomalies.
- 8. No retro-cochlear pathology (no agenesis of auditory nerve)/central deafness.
- 9. Children with active middle ear infection may be considered for cochlear implantation only after middle ear pathology is resolved.
- 10. Parents/caregivers of the prospective beneficiary should be motivated to undergo pre- and post-surgery auditory verbal habilitation.

B-2) Children with acquired hearing loss between >5 to 18 years of age

- 1. Age of the beneficiary should be between >5 and 18 years on the date of receipt of application. Age shall be cross checked with the birth certificate issued by the competent authority for verification.
- 2. Bilateral severe-to-profound sensor ineural hearing loss.
- 3. All the children must be habituated to using behind the ear hearing aids for about 3 to 6 months to assess utility of usage of hearing aids. Proof of having used conventional hearing aids for sufficient time before advising cochlear implantation with details of process of speech therapy that they underwent from accredited rehabilitation personnel should be produced. Cases with meningitis to be considered as an exception and fast-tracked.
- 4. Little or no benefit from conventional hearing aids for better hearing or use of speech and language skills and comprehension of spoken language. Word Recognition Score with hearing aids in both ears separately should be 30% or less in quiet with pediatric word list.
- 5. Other conditions from 5 to 9 above as applicable for pre-lingual hearing loss (1-5 years) are also applicable here.
- 6. The child and family members should have realistic expectations from cochlear implantation.

C. Pre-implant Candidacy evaluation

1. Audiological Investigation Protocol:

The applicants must undergo following essential diagnostic tests at the centre with qualified and RCI registered Audiologist/Speech Language Pathologist with Minimum BASLP qualification:

Children with pre-lingual hearing loss:

- 1. Pure-tone audiometry (PTA)
- 2. Behavioral Observation Audiometry or Visual reinforcement audiometry (if not cooperative for PTA)
- 3. Impedance audiometry (tympanometry and Reflexometry)
- 4. Oto-acoustic Emission
- 5. ABR and/or ASSR
- 6. Aided Audiogram with appropriate/ optimized hearing aids separately for both ears

Children with acquired hearing loss:

- 1. Pure-tone audiometry (PTA)
- 2. Speech Audiometry
- 3. Impedance audiometry (tympanometry and Reflexometry)
- 4. Oto-acoustic Emission
- 5. ABR and/or ASSR if indicated
- 6. Aided Audiogram (aided WRS in quiet and noise whenever possible)

2. Other assessments:

- 1. Assessment of speech and language development in children and speech-language skills in older children, including articulation, voice, language assessment.
- 2. Psychological assessment.
- 3. ENT evaluation.
- 4. Pediatric evaluation for pre-lingual hearing loss.
- 5. Other medical evaluations as deemed necessary (neurology, ophthalmology).

Reports of pre-operative evaluations conducted by a qualified and recognized professional should be submitted in the prescribed format along with the application form.

3. Radiological Investigation Protocol:

Format of reporting should be uniform and as prescribed by the implementing agency.

- a. HRCT temporal bone for bony cochlea and middle ear cleft
- b. 3D MRI for membranous cochlea/neural bundle and MRI brain

4. Pre-implant Family Counseling:

- a) Candidates for cochlear implantation need to be informed of the potential risks and benefits of cochlear-implantation and the impact it may have on their life.
- b) The surgical procedure and its risks should be described along with a physical description and, preferable demonstration, of the internal and external portions of the device.

- c) The post-surgical programming and rehabilitation procedures should be charted out and informed to the parents.
- d) The most important aspect here is to give realistic expectation regarding performance outcome with the implant.
- e) Pre-CI counseling of family/beneficiary is mandatory and should be conducted by the ASLP in detail at the empanelled hospital/center prior to submission of application or before the surgery.
- f) Pre-CI counseling kit developed by AYJNISHD(D) should be used. Expectation questionnaire should be administered before pre-CI counseling and Recall questionnaire should be administered after pre-CI counseling. The administered questionnaires duly signed by the ASLP and family/beneficiary should be attached with the application form during submission of application form or submitted with parent/beneficiary declaration form prior to surgery.

5. Declaration from Parent/Caregiver or beneficiary:

- a. The parents/legal guardians of the beneficiary/beneficiary will give an undertaking that they will undergo post-implant rehabilitation program as recommended in the scheme for a minimum period of 36 months for pre-lingual children and 24 months for acquired hearing loss.
- b. The parents /legal guardians of the beneficiary/beneficiary will also give an undertaking that DEPwDs and implementing agency will not be held responsible for any surgical and/or post-surgical complications, or post-implant outcomes.

D. Procedure for selection of Candidates

Applications in the prescribed format along with necessary documents will be submitted by prospective beneficiaries/families of beneficiaries or through the empanelled hospitals and habilitation centers online through the website www.adipcochlearimplant.in Required documents include:

- Birth certificate
- Income certificate from government authority
- Disability certificate
- Caste certificate, if applicable.
- Photograph of the applicant
- Copy of Aadhar card of the applicant
- Hearing evaluation report
- Speech and language evaluation report
- Psychology evaluation report
- Report on use of hearing aid Aided audiogram and/or benefit trial
- HRCT temporal bone and MRI temporal bone report
- Filled Recall questionnaire after pre-CI counseling
- Filled pre-CI Expectation questionnaire

Implementing agency will prescribe formats for the above documents/reports and share on the website so that all the reports can be in uniform format.

- 1. Preliminary Scrutiny of applications should be done by zonal co-ordinators and AIC of pre-surgery committee. The applications should be categorized as Eligible and complete, incomplete, not eligible.
- 2. Eligible and complete applications should be added to a state-wise waitlist for provisional approval by ADIP committee when implants are in stock. Incomplete applicants should be informed to submit the pending documents and reports. Communication should be sent to not eligible candidates citing the appropriate reason.
- 3. In cases where there is no agreement between various reports, reports are ambiguous, or in cases with borderline/questionable eligibility, the ADIP committee should take the final decision.
- 4. The eligible/suitable candidates should be provided provisional approval on first come first serve basis, after which the empanelled hospital once again should confirm the eligibility according to ADIP guidelines and should submit declaration from the parent/beneficiary.
- 5. If the number of eligible candidates exceeds the limit of the number of beneficiaries to be covered under the ADIP scheme during particular year, final approval of candidates should be based on waiting list on first come first serve basis.
- 6. Parent/beneficiary declaration form mentioning the empanelled center for post-operative rehabilitation duly signed by parent/prospective beneficiary should be submitted by the surgeon/surgery center.
- 7. The surgeon should re-verify and certify eligibility under ADIP scheme. The eligibility certificate should be submitted to implementing agency.
- 8. Implant should be dispatched to the surgery center after receiving declaration and eligibility certificate.
- 9. Reimbursement of the charges should be done after bills are raised by the surgery center and verified by the AIC and Zonal coordinators.

EMPANELMENT OF HOSPITALS AND SURGEONS

- 1. Implementing agency will invite applications from potential hospitals for empanelment. Attempts should be made to empanel hospitals and habilitation centers across all parts of the country to make services accessible to all prospective beneficiaries.
- 2. Internal ADIP committee/ Internal Advisory Committee will scrutinize the applications in view of the prescribed criteria.
- 3. Application forms will be forwarded to DEPwDs for consideration in meeting of Core Group of Hearing Impaired.
- 4. Evaluation team will conduct inspection of the hospital to review the available facilities.
- 5. Empanelment of hospitals will be done by the Core Group.
- 6. Selected hospitals will sign MOU with implementing agency for the empanelment

A. Guidelines for empanelment of Hospitals and Surgeons

- 1. New hospitals, both Government and private, will be encouraged to apply and supported with the help of mentorship.
- 2. Government as well as private hospitals who have active CI program on date of application and a CI surgeon working at the hospital doing implants under some other schemes or with private funding should be considered.

- 3. Hospital should have services of experienced ENT Surgeon in cochlear implant surgery. Any ENT surgeon who has performed a minimum of 25 cochlear implant surgeries independently, with CE Marked (European Certification) or FDA (Food and drug administration) of USA approved implants or Drug Control General of India (DCGI) which controls the quality regulation through organization for Central Drugs Standard Control Organization (CDSCO), should be considered as surgeon with adequate experiences. The hospital should provide detailed data of all patients operated by particular surgeon along with the application form.
- 4. New hospitals without established CI center will have to choose a mentor from the list of approved mentors provided by the implementing agency while applying for empanelment.
- 5. Hospital should have services of well-trained Audiologist and Speech Language Pathologist. Audiologist and Speech Language Pathologist should have minimum qualification of B. Sc (speech & hearing) or equivalent.
- 6. Hospital should have well equipped theatre facility with following equipment:
 - Operating microscope with bright illumination, up to 20X magnification and focus
 adjustment with tilt able eyepiece and variable focus, LED or Xenon illumination. Please
 specify the make and model. Facility for recording of surgical video in a reproducible
 format and viewing of surgery in large screen monitor. Back up microscope in case of
 intraoperative failure of main microscope
 - Instrument set:
 - b. Blade handle for 15 and 11 number blades
 - c. Toothed and non-toothed thumb and Adson forceps
 - d. Dissecting Mayo scissors
 - e. Broad periosteal elevator
 - f. Freer perichondrial /periosteal elevator
 - g. Micro forceps fine tip
 - h. Micro forceps cup
 - i. Micro forceps- upturned cup
 - j. Micro scissors
 - k. Micro pick straight
 - 1. Micro pick –curved
 - m. Needle holder 8cm
 - n. Micro pick- right angled
 - o. Micro pick- angled Shuckenecht type
 - p. Suction tips large 2 numbers
 - q. Suction tip micro numbers 12-26
 - r. Suction tip adapters
 - s. All instruments to complete the set of mastoidectomy surgery
 - t. Company specific instruments as per the company of the implant supplied from ADIP (This can be procured a few days prior to planned surgery)
 - Cautery good quality with cutting and bipolar forceps, patient plate and standard safety settings
 - Micro drill system with operating speed at least 40000 RPM with brushless motor, self-irrigation system and torque control
 - Drill set:

- 1. Cutting burrs sizes 7mm, 6mm, 5mm, 4.5 mm, 4 mm, 3.5 mm, 3 mm, 2.5 mm, 2mm, 1 mm, .8mm, .6mm
- 2. Diamond burrs same as above
- 3. Taper diamond long burrs for cochleostomy 0.8mm and 0.6mm
- Micro drill system equivalent to Skeeter with .8mm, .7mm and .5mm tips
- Anesthesia equipment with gas control, pressure monitoring, ventilation and gas scavenging facilities, a good Boyle's machine and ventilator suitable for use in children below 5 years of age
- Multipara meter monitoring with SpO2, ETCO2, blood pressure, pulse rate
- Efficient suction apparatus with variable suction control (Number 2 one as standby)
- Cautery systems with bipolar cutting and coagulation systems
- Standardised Patient warmer system Thermal blanket specified for Operation theatre use in children
- Operation theatre tables with lift, tilt and elevation functions- hydro electronic Hydraulic surgeon chair /
- Overhead lighting system of at least 60000 lux
- Operation theatre table with lift, tilt and elevation functions, manual, and with provision for intra operative X-ray
- Cardiac defibrillator and an emergency cart
- Intra operative Imaging C arm Preferred
- Portable X-ray machine Ok
- Facility and audiologist for intra operative NRT

Optional facilities

- Intra operative CT
- Titanium instruments for surgery
- Facial nerve monitor with facility of live monitoring of cranial nerves and recording of
- 7. Evaluation team comprising of one senior cochlear implant surgeon and one senior speech and hearing professional from the respective zone will verify facilities and records through online or face-to-face interaction. They will recommend empanelment considering all the three basic requirements for cochlear implant surgery, i.e. a) cochlear implant surgeon with adequate experience, b) adequate infrastructure, instruments, equipment and c) facilities for implantation surgery.
- 8. Implementing agency will prepare a format for Memorandum of Understanding (MOU) with the empanelled hospitals with other terms and conditions essential for smooth and successful implementation of the scheme. Empanelled hospitals should sign MOU with the head of the implementing agency. Those hospitals who have not signed the MOU will not be empanelled.
- 9. Empanelment should be reviewed every two years.
- 10. By default, empanelment will be discontinued for the centers who have not operated a single case in a period of two years from the time of empanelment, so that newer applications from the same /nearby area can be considered.
- 11. The centers who have operated 1 to 5 cases in a period of two years from the time of empanelment should be guided to identify and register more children in next one year and empanelment will be reviewed after 1 year.

- 12. If the operating surgeon leaves/ retires from the empanelled hospital then the responsibility of the beneficiaries for any post-operative medical issues/ complications rest on the empaneled hospital. Empanelled hospital is responsible for empanelment of another surgeon meeting the eligibility criteria and appointed at the same hospital for continuing the empanelment under the ADIP CI scheme.
- 13. The cochlear implant team at the hospital will be responsible for ensuring uninterrupted post-operative habilitation for the prescribed duration and also for monitoring post-operative habilitation i.e. therapy and mapping at the empanelled center for the prescribed duration.
- 14. Feedback should be obtained from the family/beneficiary at least twice a year regarding the post-implant outcomes in the various areas.

B. Cochlear Implant Surgery

- 1. The empanelled hospital should perform the surgery only with approval from the implementing agency.
- 2. Procured implants will be dispatched to the concerned hospitals by the implementing agency. Hospital should provide acknowledgement of receipt of implant immediately.
- 3. After completion of surgery, the concerned hospitals should submit bills along with the requisite documents as per the guidelines provided by the implementing agency within one week of surgery.
- 4. No other charges should be collected from parents/beneficiaries for surgery and post-operative care
- 5. As and when required, empanelled hospitals should permit personnel from the implementing agency, empanelled rehabilitation centers or concerned cochlear implant companies as observers during surgery
- 6. The choice of hospital for surgery and habilitation center for post-operative services including therapy and mapping will be made by the family/beneficiary from the list of empanelled hospitals and centers available on website. The choice will be made by the family before the surgery through parent declaration form.
- 7. Decision about requests for transfer of hospital or habilitation center will be made by the implementing agency.

POST-OPERATIVE REHABILITATION

A. Empanelment of habilitation centers

- 1. Implementing agency will empanel habilitation professionals and centers across the country who will be responsible for the post-operative therapy and mapping.
- 2. The empanelled professionals should have minimum experience of one year of providing rehabilitation services to CI children.
- 3. The center should have at least one of the following RCI registered professional:
 - a) Audiologist & speech language pathologist with a minimum of BASLP
 - b) Special educator with minimum of B.Ed (HI),
 - c) Auditory Verbal Therapist.
- 4. Mapping centers should have minimum one Audiologist with BASLP along with the

- required mapping facilities.
- 5. The implementing agency should scrutinize the applications of habilitation professionals and their centers as per the prescribed criteria for empanelment.
- 6. The implementing agency has the right to cancel the empanelment of any habilitation professional/center if the services are not found to be satisfactory.
- 7. The empanelled professionals should undergo training for auditory verbal habilitation and mapping at regular intervals through workshops conducted by implementing agency

B. Cost of post-operative services

- a) For children with pre-lingual hearing loss, the cost of post-operative therapy services at empanelled habilitation centers should not exceed Rs. 50,000/- per year (3 sessions per week for a period of three years/156 sessions per year for three years).
- b) For children with acquired hearing loss, the cost of post-operative therapy services at empanelled habilitation centers should not exceed Rs. 32000/- per year (2 sessions per week for a period of two years/104 sessions per year for two years).
- c) For all beneficiaries, cost of mapping at empanelled center should not exceed Rs. 10,000/- for the first year and Rs. 5000/- each for the second and third year.
- d) None of the empaneled professionals/centers, under any circumstances should collect any charges from the beneficiaries.

C. Schedule for post-operative aural rehabilitation

Mapping Schedule

- 1) Switch on (Three weeks after surgery. Also involves kit counselling i.e. showing caregivers/beneficiaries how to handle device-basics)
- 2) 4th Day (includes showing caregivers/beneficiaries the basic troubleshooting)
- 3) 1 week post switch on
- 4) 2 weeks post switch on
- 5) 4 weeks post switch on
- 6) 6 weeks post switch on
- 7) 10 weeks post switch on
- 8) 4 weeks post switch on
- 9) 18 weeks post switch on
- 10) Follow-up once in two months or three months depending on an individual recipient
- 11) At the end of 1year post switch on, bi-annual follow up normally suffices for older children but follow up needs to be more frequent for young children and toddlers (quarterly)
- 12) Each mapping session involves checking electrodes, fine tuning T and C levels, confirming care and maintenance practices from the caregivers and troubleshooting as needed.

Post implant therapy schedule

All therapy sessions should be individual and one-on-one.

- 1. Children with pre-lingual hearing loss 3 sessions of 45 minutes to 1 hour duration per week for a period of three years/156 sessions per year for three years.
- 2. Children with acquired hearing loss 2 sessions of 45 minutes to 1 hour duration per week for a period of two years/104 sessions per year for two years.
- 3. All efforts should be taken by the empaneled professionals/centers to ensure regular attendance in therapy and improved outcomes of all the beneficiaries.
- 4. The empaneled professionals should prepare and execute therapy plans/IEPs according to the available early childhood curriculum.
- 5. Progress reports should be submitted by the professional/center to the implementing agency every quarter with details of attendance and bills for reimbursement.
- 6. Every empaneled professional/center should conduct parent meetings at regular intervals.
- 7. Professionals/centers should be proactive in conducting research and outcome studies for the beneficiaries attending post-implant habilitation at their center.

PROCEDURE FOR PROCUREMENT OF COCHLEAR IMPLANT

- 1. The procurement of cochlear implant will be done by ALIMCO on tender basis as per the technical specifications recommended by the Technical Committee.
- 2. Tender process should also focus on comparing post-implant service, repair and accessory costs before finalizing the company.

PROVISIONS AS PER THE REVISED SCHEME

	Revised
Income criteria	Upto Rs. 22500/- pm full cost
	Rs. 22501 to 30000/- pm 50% cost
Children with pre-	A maximum of Rs. 7.0 lakhs will be borne by the Government
lingual hearing loss -	per beneficiary in case of children with pre-lingual hearing loss.
1 to 5 years of age	This will include the cost of the implant, the surgery, therapy,
	mapping, travel, and pre-implant assessments.
Children with	Age limit extended to 18 years (EARLIER LIMIT WAS 12
acquired/ post-	YEARS)
lingual hearing loss	
Children with	A maximum of Rs. 6.0 lakhs will be borne by the Government
acquired/ post-	per beneficiary in case of children with pre-lingual hearing loss.
lingual hearing loss	This will include the cost of the implant, the surgery, therapy,
	mapping, travel, and pre-implant assessments.
Cost of the surgery	The cost of the surgery in empanelled hospital should not exceed
	Rs. 75000/- including mentor fee of 25,000/ Charges will be paid
	to the hospitals after completion of surgery of each beneficiary.
Post-operative	a) Mapping for 3 years not to exceed Rs 10000 , 5000 and 5000 /-
rehabilitation for	per year

pre-lingual hearing	
loss – 1 to 5 years	b) Therapy for 3 years not to exceed Rs 50000/- per year (3
	sessions per week for a period of three years/156 sessions per
	year for three years)
Post-operative	a) Mapping for 3 years not to exceed Rs 10000, 5000 and 5000/-
rehabilitation for	per year
post-lingual hearing	
loss - 5 to 18 years	b) Therapy for 2 years not to exceed Rs 32000/- per year (2
	sessions per week for a period of two years/104 sessions per year
	for two years)
Travel, lodging,	Travel, lodging/boarding expenses of Rs 200/- per visit will be paid
boarding expenses –	directly to the family. This payment will be made on a quarterly
pre-lingual hearing	basis after the therapy center certifies the attendance for the
loss 1 to 5 years	stipulated number of therapy sessions.
	Rs. 200/ per visit for 468 therapy sessions over a period of three
	years i.e., a total amount of Rs. 93,600/-
Travel, lodging,	Travel, lodging/boarding expenses of Rs 200/- per visit will be paid
boarding expenses –	directly to the family. This payment will be made on a quarterly
ACQUIRED/post-	basis after the therapy center certifies the attendance for the
lingual hearing loss	stipulated number of therapy sessions.
upto 18 years	Rs. 200/- per visit for 208 therapy sessions over a period of two
	years i.e., a total amount of Rs. 41,600/-
Cost of pre-implant	For all beneficiaries, a fixed amount of Rs. 10,000/- will be
evaluations	reimbursed towards cost of pre-surgical evaluations and work-
	up after the surgery is done.