Guidelines for Cochlear Implantation and Procurement of Cochlear Implant under ADIP Scheme (2014-2015), Department of Disability Affairs, Ministry of Social Justice and Empowerment, Govt. of India

As per the recommendations of the expert committee meeting held on 22-08-2014

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Objective

The objective of inclusion of cochlear implantation under ADIP scheme is to provide cochlear implantation to children and support for auditory verbal habilitation to operated children through empanelled rehabilitation centers.

Quantum of Assistance

Ministry of Social Justice and Empowerment will recognize an Institute of national stature from each zone to recommend children eligible under the Scheme for cochlear implant, with a ceiling of Rs. 6.00 lakh per unit to be borne by the Government. Ministry will also identify and recognize the Institutes in the zones wherein the surgery will be undertaken. Ministry will identify suitable agencies for providing cochlear implant (500 children per year) under the Scheme. Income ceiling for the beneficiaries will be same as for other aids/appliances.

   a) The cost of the surgery should not exceed the amount specified in the CGHS norms (Initial phase only CGHS approved/recognized and State Government nominated hospitals will be considered.

   b) Post-operative auditory habilitation services will be charged as per AYJNIHH norms or not exceeding the amount specified by CGHS norms.

   c) Travel/Boarding/lodging expenses of Rs 200/- per visit may be provided during post-operative rehabilitation under the scheme for a period of one year.

   d) If the cost of the implant including surgery and post-operative auditory habilitation exceeds ceiling amount covered under ADIP scheme, the remainder shall be contributed by the State Government/NGO/any other agencies/by the beneficiary concerned subject to prior approval of the committee.

I. Guidelines for Candidate Selection

A. Eligibility of the Beneficiaries-General

A person with disabilities fulfilling following conditions would be eligible for assistance under ADIP Scheme.

   1. An Indian citizen as per criteria specified below.
   2. Holds a 40% Disablement Certificate or as defined in the PWD act.
   3. Has monthly income from all sources not exceeding Rs. 20,000/- per month.
   4. In case of dependents, the income of parents/guardians should not exceed Rs. 20,000/- per month.
Note: Beneficiaries will be linked with Aadhar number or Ration Card or Voter I- card from.

B. Audiological and Medical Criteria

1. There are a number of factors that determine the degree of success to expect from cochlear implant. AYJNIHH and its regional centers will determine the candidates for cochlear implantation on an individual basis and take 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.

   B-1) Pre-lingual - before acquiring speech (1 to 5 years): Implantation in this age range will help the child to achieve maximum overall benefit as this age range is considered as critical period for overall development.

   B-2) Post-lingual - after acquiring speech (up to 12 years): Post lingual deafness can have detrimental effects on speech and language, and overall development. These children will get maximum benefit as they were already exposed to critical period.

B-1) Pre-lingual (1 to 5 years):

1. The child should be in the age group of 1-5 years as on 31st Dec of the financial year. Age of the beneficiary shall be cross checked with the birth certificate issued by the competent authority for verification (However the Screening Committee would be empowered to make exceptions beyond 3 years up to 6 years of age on a case to case basis, where the committee feels that a high possibility of success exists or if there are other compelling technical reasons warranting or making an exception).

2. Bilateral severe-to-profound sensorineural hearing loss.

3. All the children must be habituated to using behind the ear/body level hearing aids for about 3 to 6 months to assess utility of usage of hearing aids. Proof of having used conventional hearing aids along for sufficient time before advising cochlear implantation with details of process of speech therapy that they underwent from accredited rehabilitation personnel may be produced.

4. Little or no benefit from conventional hearing aids either in terms of better hearing or acquisition of speech and language skills and comprehension of spoken language.
5. There should not be any medical contradictions to surgery and or implantation. Children with abnormal cochlea/malformed cochlea are not considered for cochlear implantation.

6. These children should be free from any developmental delays and other sensory and oro-facial defects. These children should not have stubborn behavior and autistic tendencies.

7. No retro cochlear pathology (no agenesis of auditory nerve)/central deafness.

8. Children with active middle ear infection may be considered for cochlear implantation only after middle ear pathology is resolved.

9. Vaccination against H Influenza and Pneumococcus.

10. Motivated parents to attend auditory verbal habilitation. The parents of the child should be prepared to undergo a mandatory training on speech therapy and post operative care.

11. Child should not suffer from Mental Retardation/ Development delay.

12. Child may need to be assessed by clinical psychologist in case of suspected abnormal psychological behaviour.

B-2) Post-Lingual (below 12 years)


2. 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 along for sufficient time before advising cochlear implantation with details of process of speech therapy that they underwent from accredited rehabilitation personnel may be produced.

3. Little or no benefit from conventional hearing aids either in terms of better hearing or acquisition of speech and language skills and comprehension of spoken language.

4. Other conditions applicable for pre-lingual (1-5 years) are also included.
II. Pre-implant Candidacy evaluation

A. Audiological Investigation Protocol:

The children must undergo following essential diagnostic tests at the centre with qualified Audiologist/Speech Language Pathologist with Minimum MASLP qualification:

1. Pure-tone audiometry (PTA)
2. Behaviour Observation Audiometry (if not cooperative for PTA)
3. Impedance audiometry
4. Oto-acoustic Emission
5. ABR and/or ASSR
6. Aided Audiogram
7. Assessment of speech and language development.

AYJNIHH, Mumbai and its regional centers will carry out pre-operative audiological evaluation for selection of suitable candidates for cochlear implantation. The charges for evaluation are as per AYJNIHH norms.

B. Radiological Investigation Protocol:

The following radiological investigations should be done to these children before sending for pre-authorization.

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

The cost of radiological evaluation has to be borne by the parents.

C. Pre-implant Family Counseling

1. 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.

2. 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.

3. The post surgical programming and rehabilitation procedures should be charted out and informed to the parents.

4. The most important aspect here is to give a realistic expectation regarding performance outcome with the implant.
D. Parent Declaration

1. The parents or legal guardians of the implantee will give an undertaking saying that they will undergo post-implant rehabilitation program as recommended by AYJNIHH for a minimum period of 12 months.

2. The parents or legal guardians of the implantee will also give an undertaking saying that AYJNIHH and its regional centre(s) will not be held responsible for any surgical and/or post-surgical complications.

E. Procedure for selection of Candidates:

1. Notifications will be issued by AYJNIHH inviting applications from the eligible/perspective cochlear implantee in leading newspapers and also will be in the official website of AYJNIHH with a clause that AYJNIHH reserves the right to accept or reject any application without any reason thereof.

2. A preliminary screening committee consisting of Director-ADIP, Director-AYJNIHH, Director-CRC, HOD-Audiology, Assistant Directors, one internal expert and one external expert will scrutinize the received applications and prospective candidates will be referred to the nearest centers of AYJNIHH for detailed candidacy evaluations.

3. The respective centers after carrying out detailed candidacy evaluation, the list of eligible/suitable candidates for cochlear implantation will be forwarded to AYJNIHH, Mumbai for necessary approval.

4. If the number of eligible candidates exceeds the limit of the number of beneficiaries to be covered under the ADIP scheme during particular ear, a lottery system will be drawn for final selection of candidates.

5. Only unilateral cochlear implantation will be covered under this scheme.

6. Reservation for SC/ST/OBC beneficiaries under the Scheme as per the Government norms and at least 25% of the overall beneficiaries need to be girl child.

III. Empanelment of Hospitals and Surgeons:

AYJNIHH, Mumbai will empanel hospitals and doctors considering their facilities for cochlear implantation surgery. Initially it is proposed that the surgeries will only taken up in government hospitals where ENT departments are only running successful cochlear implant programmes and have done a minimum of 25+ C.I. Surgeries. These hospitals will
have to sign MOU with AYJNIHH. If it is required to enlist the private hospitals in absence of the govt. hospitals not having the program, the following guidelines shall be applicable:

A. Guidelines for empanelment of Hospitals and Surgeons:

1. Initial phase of implementation only CGHS approved and State Government nominated hospitals will be considered.

2. Hospital should have services of experienced ENT Surgeon in cochlear implant surgery. Any ENT surgeon who had 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), will be considered as surgeon with adequate experiences.

3. Hospital should have services of well trained Audiologist and Speech Language Pathologist. Audiologist and Speech Language Pathologist should have minimum qualification of M. Sc (speech & hearing) or equivalent.

4. Hospital should have well equipped theatre facility with following equipment:
   a) Operating microscopes with adequate illumination— two numbers
   b) High Speed drill for drilling/cochleostomy together with micro motor— two numbers (with straight and contra hand pieces)
   c) Irrigation facility
   d) Micro-ear surgery instruments including mastoid surgery set—two sets
      Micro Instruments – cutting and diamond burrs and cochleostomy burrs, suction tips, crocodile and cup forceps, sickle knife, micro scissors, straight and curve picks, electrode guide (Skeeter – Optional)
   e) Facial nerve monitor – one number
   f) Telemetric equipment, dummy implant etc. to be provided by the manufacturer at time of surgery

5. Inspection team will visit the hospital for physical verification of facilities and records. They will recommend empanelment considering all the three basic requirements for cochlear implant surgery, i.e. cochlear implant surgeon with adequate experiences, adequate infrastructure, instruments, equipments and facilities for implantation surgery.

6. AYJNIHH, Mumbai 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 project. Empanelled hospitals should sign MOU with the Director, AYJNIHH, Mumbai.
7. Empanelment should be reviewed every two years or in the event of empanelled Doctor leaving the Hospital. However, the responsibility of already operated children for any post operative medical issues/complications rest with the empanelled Doctor performed surgery. He should arrange further follow up of children either in same hospitals or another empanelled hospital.

8. AYJNIHH, Mumbai and its regional centers will be responsible for post-operative auditory verbal habilitation for one year which includes mapping.

B. Cochlear Implant Surgery:

1. The empanelled hospital will do the surgery according to the selection list prepared by AYJNIHH, Mumbai.

2. Implants will be supplied to concerned hospitals by selected cochlear implant companies according to the supply orders issued by AYJNIHH, Mumbai.

3. After completion of surgery, the concerned hospitals should submit Delivery chalan, operative note and a copy of implant registration form.

4. AYJNIHH, Mumbai will release the payment to concerned cochlear implant companies after obtaining above documents and invoice from concerned companies.

5. Empanelled private hospitals will be permitted to charge an amount fixed by AYJNIHH for surgery from time to time. No other charges should be collected from parents for surgery and post-operative care.

6. As and when required, empanelled private hospitals should permit two Audiologists from AYJNIHH and its empanelled rehabilitation centers as observers during each intra-operative monitoring.

The choice of Hospitals for surgery and Rehabilitation centers for post-operative auditory habilitation services will be done by AYJNIHH, Mumbai.

IV. Procedure for empanelment of Hospitals and Surgeons:

1. Initially it is proposed that the surgeries will only be taken up in CGHS approved/recognized and State Government nominated hospitals will be considered.

2. Preference will be given in the location where the Institute headquarters and its regional centers are located for wider coverage.
3. A committee constituted by AYJNIHH will scrutinize the expression of interest received as per the guidelines formulated and recommend suitably for entering into an MOU.

V. Post-operative rehabilitation

1. AYJNIHH, Mumbai and its regional centers will be responsible for post-operative auditory verbal habilitation for one year which includes mapping.

2. The post-operative rehabilitation services will be charged as per the AYJNIHH norms or not exceeding the amount specified by CGHS norms.

3. In case of expansion of activities, the services will be outsourced through open advertisement with leading dailies through DEAP for inviting expression of interest.

4. The centers should have experience of minimum 2 years in providing post-operative rehabilitation services to such children nearly to 50.

5. The centre should have the expertise manpower in the area of post-operative auditory habilitation services.

6. The center should have one audiologist/speech therapist with MASLP and two special educators with AVT specialization and mapping facilities.

7. The committee constituted by AYJNIHH will scrutinize the responses received and recommend the centers fitting into criteria prescribed by the Institute.

VI. Schedule for post-operative aural rehabilitation:

A. Mapping Schedule

1. Switch on (Three weeks after surgery. Also involves kit counselling i.e. showing caregivers how to handle device-basics)
2. 4th Day (includes showing caregivers 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. 14 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 1 year 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.

B. AVT Schedule:

1. A minimum of one hour sessions for at least twice or thrice a week for a span of one year.

VII. Procedure for Procurement of Cochlear Implant:

1. The cochlear implant should be duly approved by CE Marked (European) US-FDA or Drug Control General of India (DCGI) which controls the quality regulation through organization for Central Drugs Standard Control Organization (CDSCO). The procurement of cochlear implant will be done by ALIMCO as per the specifications recommended by the core committee.

The cochlear implant program requires a complete monitoring of the progress of each patient very closely through various audiological, technical support and habilitation issues and thus it is recommended that AYJNIHH act as Nodal Agency.