To CMD/MD/CEO of Network Hospital

**AST/1024/F88/2008-09, dated 03.03.2009**


Ref: Letter from Trust No. AST/326/ F88 / 2008-09, dated 29.01.2009

-00-

As intimated earlier in the reference letter cited above Trust is hereby communicating the detailed revised guidelines on Cochlear implant surgery and AV therapy to be followed by Network Hospitals under the scheme.

Hospitals are requested to go through these guidelines before sending the patients for evaluation by the Cochlear Committee. Hospitals shall particularly note the following points under revised Guidelines.

- Extension of coverage up to 12 years of age group from present 6 years. (With specific indications-Note selection Criteria)

- Physical evaluation of the child and parents by the Committee before the pre-authorization is approved online by Trust.

- To leave the choice to the beneficiary whether to have BTE processor or Body-worn processor subject to basic criteria of instrument being adhered to after duly obtaining informed consent from the parents in prescribed form.

- Online approval of AV therapy progress by the Technical Committee at the end of every quarter through WebEx recording, thus not requiring appearance of child and parents before the committee.

- Online workflow starting from pre-authorization, committee recommendation (Not Evaluation), Trust approval and claim settlement

Hospital shall also refer to web portal [www.aarogyasri.org](http://www.aarogyasri.org). Hospital may refer the following for guidance on online work flow.

<table>
<thead>
<tr>
<th>Online pre-authorization process</th>
<th>Module-VIII E Preauthorization</th>
<th>Rajiv Aarogyasri Manual on Surgical and Medical Treatment (3rd revised edition) Page no 243 to 288</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Mapping and AV therapy</td>
<td>Module-XIII – Cochlear implantation – Initial Mapping and Switch on and Audio Verbal Therapy</td>
<td>Rajiv Aarogyasri Manual on Surgical and Medical Treatment (3rd revised edition) Page no 355 to 372</td>
</tr>
</tbody>
</table>

Enclosed-Detailed Revised Guidelines (8 Pages) with Parents Consent Proforma.

For Aarogyasri Health Care Trust

Chief Executive Officer

Copy to:
The Principal Secretary to C.M., A.P. Secretariat, Hyderabad.
The Principal Secretary to Govt. HM&FW Dept., A.P. Secretariat, Hyderabad.

Ph : (0) 91-040-24652540,24652478, Mobile : 9963153399, Fax : +91-040-24657715
e-mail : babuahamed@yahoo.com, babuahamedias@gmail.com website: www.aarogyasri.org
Behind Ear Processor (భాగం తూర్త సంఖ్య మానం) పేరు‌వాడు

Body Processor (ఏరా సంఖ్య మానం) పూర్తి సంప౰్కం

…………………………………………………………

మామలు……………….. దాని తిను ఆస్తు సంచాలనం నేషనల్ మొత్తం సంఖ్యలు కేంద్రంలో ప్రాంతానికి విలువించిన ప్రత్యేకించడానికి ప్రతి రెండు సంఖ్య మానం (Behind Ear Processor మానం

నించాది పరిస్థితిలోగా మాండి వివిధ కారణాలతో ప్రతి రెండు సంఖ్య మానం (Behind Ear Processor మానం)/ Body Processor మానం), అయితే కుమారులు కంపెనీ కొనసాగించడమే లభించిన రెండు సంఖ్య మానం లేదా వివిధ తరువాతి ప్రతి రెండు సంఖ్య మానం

…………………………………………………………

అనువు

ప్రతి ఆస్తు సంచాలనం నేషనల్ మొత్తం సంఖ్యలు కెన్ద్రంలో ప్రతి రెండు సంఖ్య మానం

ఆస్తు సంచాలనం నేషనల్ మొత్తం సంఖ్యలు కెన్ద్రంలో ప్రతి రెండు సంఖ్య మానం అయితే కొనసాగించడమే లభించిన రెండు సంఖ్య మానం లేదా వివిధ తరువాతి ప్రతి రెండు సంఖ్య మానం

మామలు మామలు మామలు మామలు

& లోపిడి & లోపిడి & లోపిడి
GUIDELINES FOR COCHLEAR IMPLANTATION

Under the scheme financial assistance to the tune of Rs.6.5 lakhs is being provided to the BPL patients undergoing cochlear implantation surgery and auditory verbal therapy for the totally deaf children below 12 years of age in the identified Network Hospitals. Since these children are likely to have multiple congenital malformations in association with deafness and both parents and child need to be counseled and evaluated (Pre-Implant Counselling and Evaluation) by the Network Hospital, it is imperative to confirm their fitness to undergo surgery and get benefited from the therapy. Hence Trust resolved to screen these patients by a team of specialists in the field before pre-authorization approval is given to the Network Hospital to perform surgery.

The Trust constituted a committee and the Committee after detailed discussion formulated following guidelines to be followed by Network Hospitals.

1.0 HOSPITAL INFRASTRUCTURE

1.1 Hospital shall have services of well trained ENT Surgeon in Cochlear Implant Surgery and well equipped theatre facility with following equipment:

i. Operating microscope --- Two numbers
ii. Skeeter drill for Cochleostomy ---- Two numbers
iii. Benair micro motor ---- Two numbers
iv. Facial nerve monitor ---- One number
v. Two sets of microear surgery instruments - Two sets
vi. Laser Co2 Lumens surti touch --- One number

1.2 Audiology and Audio-Verbal Rehabilitation set-up

There should be a well-established Audiology Department along with Audio-Verbal Rehabilitation Unit set-up with following qualified, regular personnel and equipment.

1.2.1 Personnel

a) An Audiologist and / Speech Pathologist (one post) with masters degree in Audiology and / or Speech, Language Pathology from any recognized institution.

b) An Audio-Verbal Rehabilitation specialist- one post-- well versed in audio verbaltherapy techniques and software used in such methods. He/She should have undergone training from recognized institutions or persons accredited with imparting AVT for very young hearing handicapped children. The mother tongue of the specialist should be Telugu and should know how to write and read the Telugu language. He / She must be proficient in teaching Telugu Grammar.
1.2.2 Equipment

a) Audiology Equipment:

The following equipment is absolutely necessary and should be available in the network hospital in order to conduct various types of audiological assessments to decide the candidacy for cochlear implantation and thereafter for audio verbal rehabilitation therapy work.

i) Pure tone audiometer ………………… one

ii) Free field equipment ………………… one set

iii) Impedance audiometer ………………… one

iv) Oto-Acoustic Emission audiometer…… one

v) ABR with Auditory Steady State Response Audiometer… one

vi) Dedicated Computer system with internet facility (minimum 2mbps)

vii) Connection), Digital Camera, Printer, Scanner etc.

viii) Personnel programming systems for mapping and programming approved types of cochlear implants.

ix) Visible Speech Instrument with latest software for imparting the audio verbal therapy (One unit)

x) Various teaching aids used for teaching language……One set

xi) There should be two sound treated rooms to accommodate the above audiological equipment and for carrying out the periodic cochlear implant mapping work. The size of the each room should be 14’x12’. The sound treated rooms should be two-room set-up with negligible electrical static activity with ambient noise levels below 25 dB.

xii) There should be a separate well ventilated 10’x10’ room exclusively for imparting the audio-verbal therapy along with teaching aids in which the child, therapist and the mother of the child should participate.

2.0 PRE-DIAGNOSTIC PROTOCOL

2.1 Guidelines for Candidate selection

2.1.1 Audiological and Medical Criteria.

a) This scheme is applicable to children suffering from total deafness either,

   a. Pre-lingual- before acquiring speech
   b. Post lingual: - after acquiring speech

b) The age group covered is 0 to 12 years.

c) Younger the age group, better would be the benefits from Cochlear Implantation. Further the age mentioned in the ration card/health card is the age of the child at the time of issue of ration card. Hospitals shall cross check the actual age as on date and can use the birth certificate for verification if required.

d) Cochlear implant may not be the first choice when considering deaf children above 2 years of age. Proof of having used conventional hearing aids along with details of process of speech therapy that they underwent from accredited rehabilitation personnel may be produced. If not, the hospital shall take
necessary steps to give hearing aid under the existing Government schemes and speech therapy for sufficient time before advising cochlear implantation.

e) These deaf children must have used hearing aids. If no benefit is derived from the use of Conventional hearing aids either in terms of better hearing or acquisition of adequate language or communication skills then they should be considered for CI. Here the motivation on part of the child to express through speech by imitation is an important factor to be considered.

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

g) The deaf children at least should have had developed some language and attempting to communicate through speech for basic needs. Children who are used to alternate mode of communication like gestures and signs and poorly motivated to use speech communication are poor candidates for cochlear implantation.

h) The deaf Children with abnormal Cochlear/ malformed Cochlear are not considered for Cochlear Implantation. The decision of the Technical committee is final in this matter.

i) Children with active middle - ear infection should be considered for Cochlear implantation only after middle - ear pathology is resolved.

j) In addition the following other criteria to be followed for selection of children between 6-12 years of age group

1. Children having profound hearing loss due to infections and other pathology in post-lingual group, who are not benefited even after usage of conventional hearing aid.

2. Children having congenital profound hearing loss and not benefited even after usage of any other hearing aid.

3. Children who are used to oral-aural method of communications and pursuing inclusive education.

2.1.2 Audiological Investigation Protocol.

The children must undergo following essential diagnostic tests at hospital own centre with qualified personnel handling and reporting.

a) Behavior Observation Audiometry (BOA)
b) Puretone Audiometry
c) Impedance audiometry
d) Oto-acoustic Emission Audiometry
e) ABR and ASSR test report
f) Aided Audiogram
g) Assessment of language and speech development.
2.1.3 Radiological Investigation Protocol

The following radiological investigations should be done to these children before sending for pre-authorization.
   a. MRI Cochlea
   b. CT Scan of Temporal Bone

2.1.4 Psychological Criteria

   a) Patient should not suffer from Mental Retardation/development delay
   b) The deaf children should have developed adequate social and adjustable behavior. Stubborn behavior is one of the main contraindication for cochlear implantation.
   c) Child may need to be assessed by clinical psychologist in case of suspected abnormal psychological behavior.

2.2 Pre Implant Counseling By Audiologist

2.2.1 Pre-implant counseling

Extensive Pre-implant counseling by the audiologist is very important with regard to the following factors to derive maximum benefit from cochlear implantation.

   a) Who would benefit from Cochlear Implantation?
   b) What exactly the Cochlear Implant does?
   c) Familiarization with Cochlear implant hardware
      a. Internal implant (Explanation through posters and video)
      b. External Speech processor
   d) Choice of External Speech Processor
   e) Weather to use Behind The Ear or Body Worn speech processor?
   f) The patient and parents must be counseled adequately about the advantages and disadvantages in using Behind The Ear or Body Worn speech processor.
   g) Particularly the following points must be made clear to them in addition to other points.
   h) Who would benefit from Cochlear Implantation?
   i) Maintenance and running costs. Parents should be made aware of follow-up expenditure once the mandatory maintenance coverage from the Trust ceases after one year
   j) Parents and family should be made aware of how to maintain the delicate apparatus and precautions to be taken in handling the equipment.
   k) They should also know cost of spares which are covered under warranty and which are not covered. They should be provided with service numbers and contact person of service center. The company should do the repairs and replacements, if any, without any difficulty to the patient.
l) Do's and Don'ts: Child and parents must be taught the Do's and Don'ts such as:
   i. Delicate handling of equipment,
   ii. Proper upkeep of external apparatus,
   iii. Continuous wearing.
   iv. Avoiding rough handling and violent jerks to equipment,
   v. Avoid nudging or acute bending of cables,
   vi. Keeping the area and apparatus clean,
   vii. Avoiding oily surface to equipment
   viii. Avoid exposure of the processor to moisture and water etc.,

j) Parents / family should be made aware of running costs such as battery replacements etc., and how frequently they are supposed to do it.

k) Realistic expectations to be explained to the patient and parents considering the age at which Cochlear Implantation is done and subsequent long drawn out audio-verbal rehabilitation process.

l) The importance of Audio-Verbal Therapy/ rehabilitation after the implantation should be emphasized with following points
   • What is Audio Verbal Therapy?
   • The role of the mother in Audio Verbal Therapy
   • How basic communication skills to be developed on the basis of need based activity and reinforcement process?
   • Parents should be made aware that mere Cochlear Implantation would not develop speech. Speech has to be learnt as done like in any other normal individual.
   • Cochlear Implantation act as means to hear all the sounds including speech spoken by others and language and speech have to be learnt. The family should be realistic in expecting the outcome of the Cochlear Implantation considering the age at which it has been done and other Constraints and factors involved.

m) Commitments from the parents, hospital and the patient. The mother should be adequately trained as to how to use the implant and its maintenance.

n) After Cochlear Implantation is done, the whole family should adopt to communicate through speech and no other means.

o) After the cochlear implantation is done there would be online periodical assessment of the implanted child by the committee with regard to the progress after cochlear implantation.

3.0 IMPLANT SPECIFICATIONS

- Hospital shall procure standard original implant (and not refurbished) for use under the scheme.
- **Selection of type of instrument (weather to use Behind The Ear or Body Worn speech processor?)**.
- Hospital shall leave the choice to the beneficiary whether to have BTE processor or Body Worn processor after informed consent, the Network Hospitals shall obtain informed consent from either of the parent duly counter signed by the Surgeon, Audiologist and Aarogyamithra in the given proforma while sending them for screening by the Technical Committee.
The implant should further meet the following minimum basic requirements.

1) Company should provide minimum 5 years warranty
2) Hospital audiologist shall provide regular mapping services to the patients.
3) Servicing of the implant shall be available in Andhra Pradesh.
4) Minimum of 16 Electrode contacts with 8 channels must be available.
5) Implant thickness should not be more than 4.2 mm.
6) In the rare event of defective and non-performing implant, it should be replaced with new piece and hospital shall undertake redo surgery free of cost.

4.0 PRE-AUTHORIZATION FORMS AND REPORTS

Network hospital should follow the regular procedure of admission, evaluation and pre-authorization procedures (through the website of the Trust –www.aarogyasri.org) before sending the patient for committee evaluation.

5.0 FREQUENCY OF COMMITTEE MEETING

Committee will meet in the office of the Trust on fixed scheduled dates based on the requirement.

6.0 APPOINTMENT FOR SCREENING

Based on the number of cases evaluated as per norms and sent for preauthorization by the Network Hospital, an appointment schedule will be given to the hospitals. The Hospital should bring these patients along with both the parents on the scheduled dates without fail. The cost of transportation, food and accommodation (if required) to the patient and parents for evaluation by the committee shall be borne by the Network Hospital.

7.0 CERTIFICATION OF APPROVAL

Based on the assessment, the Committee will give online approval, after which the Trust will approve pre-authorization for hospital to undertake surgery

8.0 HOSPITAL RESPONSIBILITIES

- Must have requisite infrastructure in the form of both qualified manpower and proper equipment.
- Shall give adequate pre-implant counseling to both child and parent
- Shall arrange for interaction between parents of the patients drafted for surgery with patients and their parents who underwent similar surgery in the same hospital to help proper understanding of the procedure and its benefits
Shall facilitate parents to understand about the availability of different implants and their differences particularly with regards to speech processor.

Shall obtain informed consent from the parent with regards to type of external speech processor (Behind the ear or Body worn) in prescribed proforma

Provide standard implant based on selection of implant by the parent and shall ensure proper follow-up services by the company such as mapping, up gradation, servicing, maintenance and replacement under warranty.

Should cooperate with the inspection team to inspect facilities and medical records and arrange interaction with the beneficiaries admitted in the hospital and during the audio-verbal rehabilitation process as and when required.

Should properly evaluate the patient as per the guidelines given above, before sending the patient for assessment by the committee

Make available all the relevant documents in original along with pre-authorization forms to the committee.

Shall undertake redo surgery in the rare event of implant failure.

Arrange for the appearance of the fully evaluated patients along with both the parents to appear before the committee as per the schedules.

Shall arrange for re-counseling to the parents and patient during intervening period of reevaluation as and when suggested by the Technical Committee in their evaluation certificate.

Hospital shall ensure to provide quality audio verbal rehabilitation services – free of cost, on alternate - day basis to the Cochlear implantees even after the mandatory one year period is over, since most of the children require 3-4 years or more time for the rehabilitation till the child acquires fairly adequate communication skills.

Shall undertake to maintain on service the speech processor in terms of disposables (accept batteries) for two years after prescribed time limit under the scheme

9.0 ONLINE SUBMISSION OF BILLS

The above installments will be released through online transaction on submission of bills after successful completion of each phase of the treatment duly certified by the committee after periodical online evaluation for postoperative events and subject to submission of the following documents

- Certification by the Technical Committee
- Pre-authorization forms with photograph
- Copy of the Health Card/Ration Card.
- Copy of Implant brochure, registration details, warranty card and Maintenance Commitment document from the company.
- Reports with films
- Case sheet
- Copy of discharge summary
- Post-operative X-Ray
- Detailed Bill duly signed by the parents with the registration number of the implant and cost mentioned separately
- Patient feedback form
- Acknowledgement of transport charges.
10.0 SWITCHON AND INITIAL MAPPING

Hospital shall upload the following documents while raising claim for Switch on and initial mapping in the follow-up claim module (please see the Trust Portal).

- Webex Video Recording of the switch-on process
- Photograph Showing child along with external speech processor with label showing the registration number of the instrument
- Shall submit the proposed plan of AV Therapy and goals

11.0 AV THERAPY

Hospital shall upload the following documents while raising claim for AV Therapy for each quarter in the follow-up claim module (please see the Trust Portal).

- Webex recording of AV Therapy Session clearly showing the face of the child, parent and AV Rehabilitationist.
- Progress report of the child AV Rehabilitationist certifying the progress vis-à-vis goals achieved and reasons for failure if child not achieved goals.
- Parents assessment of progress in online proforma.

12.0 ONLINE WORKFLOW

All the documentation required for the workflow shall be done online at the appropriate time schedules. Hospital may refer the following for guidelines on online workflow.

<table>
<thead>
<tr>
<th>Online pre-authorization process</th>
<th>Module VIII – E Preauthorisation</th>
<th>Page 243 to 285</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Mapping and AV therapy</td>
<td>Module XIII – Cochlear implantation – Initial Mapping and Switch on and Audio Verbal Therapy</td>
<td>Page 355 to 372</td>
</tr>
</tbody>
</table>

Hospitals may also visit www.aarogyasri.org to view and download the manual.