GUIDELINE STATEMENT

This guideline outlines the management of individuals with hearing loss whose treatment includes implanted bone conductive hearing aids (auditory osseointegrated device) or cochlear implants as required by the Children’s Rehabilitative Services Program, Arizona Health Care Cost Containment System, and State of Arizona.

PURPOSE

Clinical Practice Guidelines represent the multi-specialty interdisciplinary requirements for providing care for individuals with hearing loss and criteria for receiving implantable bone conductive hearing aids or cochlear implants. The purpose of this guideline is to promote a uniform level of care at CRS MSIC sites for members with hearing loss and to provide a general framework for treatment with non-air conductive hearing aids, specifically bone anchored hearing aids or cochlear implants. The relevance to specific situations will depend on individual variations in clinical course and professional judgment. In addition, this document should serve as a tool to assess programs, secure resources needed to enhance patient care and education, and guide the future development and treatment of Hearing Loss.

DEFINITIONS:

Children’s Rehabilitative Services (CRS): An AHCCCS program for children and adults with certain diagnoses which provide services using an integrated family-centered, culturally competent, multi-specialty, interdisciplinary approach.

Bone Anchored Hearing Aid (Baha): Also known as an auditory osseointegrated device, a bone conduction device for hearing. Baha is one brand name type for a bone anchored hearing aid. Implantable hearing devices used for hearing loss when individual is not a candidate for an air-conduction hearing aid usually due to a problem with the outer or middle ear.
Cochlear Implant: Is a type of hearing device that directly stimulates the nerve which allows hearing in the inner ear. Used for when usual hearing aids don’t provide improvement in hearing in individuals who have severe to profound hearing loss.

Community Based Services: means all local services including provider agencies, schools, private physician offices, hospitals, and/or any other local setting.

Air Conduction Hearing Aid: a device to amplify hearing based on an individual’s hearing loss, providing greatest amplification at frequencies where there is least hearing loss and least amplification for where there is less hearing loss.

Multi-Specialty Interdisciplinary Clinic (MSIC): The Specialty Medical Home for the members with diagnoses as designated by the Arizona Administrative Code (AAC) R9-7-202 (R9-22-1303, 10-1-2013).

Semi-Implantable Electromagnetic Hearing Aids (SEHA)
A semi-implantable electromagnetic hearing aid is proven and medically necessary for sensorineural hearing loss in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.

I. PROCEDURAL GUIDELINES for POLICY COMPLIANCE

A. CRS Enrollment:
Children diagnosed with hearing loss will benefit from evaluation and treatment by the CRS Multispecialty Interdisciplinary Team (MSIT).

B. Interdisciplinary Team Membership:
The following Team Members must participate during MSIC sites and team conferences to review the member information and determine the need to see the patient at a MSIC site. This may occur virtually through coordination of evaluations, team report. The CRS member and guardian/parent will be integral part of the team in discussing choices for treatment.

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<tr>
<th>Interdisciplinary Team Members</th>
<th>Available Personnel</th>
<th>Consultative Personnel</th>
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<td>The following personnel must be available to the member at the MSIC ENT Clinic</td>
<td>The MSIC site must have access for consultation to specialists including, but not limited to the following</td>
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<tr>
<td>• Otolaryngologist</td>
<td>• Child Life Specialist</td>
<td>• Primary Care Physician</td>
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<td>• LPN for ENT clinic</td>
<td>• Educator</td>
<td>• Speech Therapist</td>
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<td>• Audiologist</td>
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C. Team/Staff Meetings:

Team and staff meetings will be held based on the need for review for bone anchored, implanted or non-implanted and cochlear implant hearing aid alternative when air conduction hearing aid is not felt to be adequate for treatment and may potentially meet criteria.

D. Lead Physician Specialists:

Qualifications: The Lead Physician Specialist should be an otolaryngologist with expertise in hearing loss.

E. Facilities, Services and Staff requirements:

1. **Description:** Audiology is an AHCCCS covered service, within certain limitations, to evaluate hearing loss and rehabilitate persons with hearing loss through other than medical/surgical means.

2. **Amount Duration and Scope:** AHCCCS covers medically necessary audiology services to evaluate hearing loss for all members, on both an inpatient and outpatient basis. Hearing aids can be dispensed only by a dispensing audiologist with a valid hearing aid dispensing license. Hearing aids, provided as a part of audiology services, are covered only for members. Under the age of 21 receiving EPSDT services or are enrolled in KidsCare.

Audiology services must be provided by an audiologist who is licensed by the Arizona Department of Health Services (ADHS) and who meets the Federal requirements specified under Title 42 of the Code of Federal Regulations (42 C.F.R.) 440.110. Out-of-state audiologists must meet the Federal requirements.

The Federal requirements mandate that the audiologist must have a Master’s or Doctoral degree in audiology and meet one of the following conditions:

a. Have a certificate of clinical competence in audiology granted by the American Speech-Language-Hearing Association (ASHA), or

b. Have successfully completed a minimum of 350 clock-hours of supervised clinical practicum (or be in the process of accumulating such supervised clinical experience under the supervision of a qualified Master’s or Doctoral-level audiologist), performed not less than nine months of supervised full-time audiology services after obtaining a Master’s or Doctoral degree in audiology or a related field, and successfully completed a national examination in audiology approved by the Secretary of the U.S. Department of Health and Human Services.

c. AHCCCS has eliminated coverage of Bone-Anchored Hearing Aid (BAHA) and Cochlear Implants for ages 21 and older but will cover supplies, equipment maintenance and repair of component parts if not operating effectively at time authorization is sought. (AHCCCS Medical Policy Manual) AMPM Chapter 300 Exhibit 300-3)

3. **Audiology Assessments and Equipment.**

Audiologic assessments must be consistent with accepted standards of audologic practice.
F. Community Based Services not provided by CRS:

Community based services provided under the AHCCCS program may be provided for any of the multispecialty, interdisciplinary team if not available at the MSIC to provide timely and appropriate services for the member’s needs.

II. Guidelines for Management and Treatment of Hearing Loss with Implantable Hearing Aids (Auditory Osseointegrated Device) and Cochlear Implants

A. Goals:

1. To maintain maximum individual functioning for members who would be candidates for bone anchored hearing aids or cochlear implants.
2. To improve quality of life for members with hearing loss.

B. Objectives:

1. To maintain a network with specialists able to anticipate and treat hearing loss related physical and psychosocial problems for effective management and outcomes. This implies easy accessibility to all team members experienced with the comorbidities and educational needs of members with conductive, mixed hearing loss, or sensorineural hearing loss. Specialists must be able to provide accurate and timely diagnosis as well as be knowledgeable of appropriate treatments for these conditions. This will allow appropriate community/social integration including transition to adulthood. Nurses at the MSIC must also be experienced or have additional training to be competent in supporting the member’s treatment and educational needs.
2. Services will be provided in multispecialty, interdisciplinary clinic in a member centric, family friendly, culturally sensitive manner.

III. Pre Implant Team Evaluation for both auditory osseous integrated or cochlear implant: Member must undergo a pre implant evaluation as follows within 6 months of the potential implant date, noting that MRI/CT scan would not have to be repeated if does not occur within 6 months unless there is a suspected reason clinically that findings affecting need for implant might have changed.

A. Exam and Diagnostic Imaging. Otologic examination and imaging study for cochlear nerve and temporal bone anatomy if cochlear implant being considered.

B. Comprehensive audiologic evaluation. The test battery may include behavioral, Auditory Brainstem Response (ABR) threshold assessments and/or Oto-Acoustic Emissions (OAE) as needed, as well as speech perception tests appropriate to child's age, and assessment of middle ear function.

C. Hearing Aid Testing. Real ear aided testing with child's conventional amplification, including age appropriate speech and sound perception tests, as well as hearing aid function checks.

D. Communication Assessment. Communication assessment, which may consist of comprehensive speech-language evaluation and/or assessment of augmentative/alternative or sign language skills.

E. Psychological Evaluation: Assessment of developmental, emotional, social, and behavioral functioning, as well as overall adjustment to the medical condition. Assessment of patient readiness and family expectations, as well as motivation for adherence to treatment regimen.
F. **Academic Performance.** If school age, review of preschool or school records for academic performance, special education service and any communication therapy progress.

G. **Assessment by audiologist and social worker or psychologist.** Assessment of family understanding of implant process and outcome expectations, as well as their previous record of compliance with child's medical, audiologic, and therapy plans.

H. **Team conference or review of summation of evaluations.** Findings are reviewed and documented regarding implantation. For Multi-Specialty Interdisciplinary Clinics (MSICs) opting for Team Conference, participants should include, minimally, the Otologist, audiologist, speech language pathologist, and psychologist. Educational professionals, early interventionists, social worker and parents will participate, being an integral part of the team in expressing treatment preferences and goals. Team input may be by virtual conference and also with coordination of evaluator’s records and recommendations.

IV. **Clinical Indications for implanted Auditory Osseointegrated Device (Bone Conductive Hearing Aid)**

A. **Unilateral or bilateral implantable bone conductive aids** may be considered medically necessary as an alternative to an air conduction hearing aid in patients with hearing loss AND another medical condition that renders an air conductive hearing aid unusable such as malformation of the external ear canal or middle ear including, AND when used according to FDA approved indications but not limited to:

1. Microtia which makes wearing an external aid impossible,
2. Stenosis or atresia of the external auditory canal, chronic middle ear infection and drainage,
3. Severe otitis external and allergic reactions to external hearing aids.

B. **Semi-Implantable Electromagnetic Hearing Aids (SEHA)**
A semi-implantable electromagnetic hearing aid is proven and medically necessary for sensorineural hearing loss in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications

C. **Implantable Bone-Anchored Hearing Aid (BAHA) for Conductive or Mixed Hearing Loss:**

1. A unilateral implantable bone-anchored hearing aid is proven and medically necessary for conductive or mixed hearing loss in one or both ears in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.
2. Bilateral implantable bone-anchored hearing aids are proven and medically necessary for conductive or mixed hearing loss in both ears in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.

D. **Implantable Bone Conductive Hearing Aid for Sensorineural Hearing Loss**

1. An unilateral implantable bone-anchored hearing aid is proven and medically necessary for sensorineural hearing loss in one ear in a patient who is not a candidate for an air-conduction hearing aid and when used according to FDA approved indications.
2. An unilateral or bilateral implantable bone-anchored hearing aids are proven and medically necessary for sensorineural hearing loss in both ears when both of the following criteria are present:
   a. The poorer ear is not a candidate for an air-conduction hearing aid due to a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60%; and
b. The better hearing ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more.

3. An implantable bone-conduction (bone-anchored) hearing aid may be considered as an alternative to an air conduction CROS (contralateral routing of signal) hearing aid in patients with single-sided sensorineural deafness and normal contralateral hearing, and when used according to FDA approved indications OR

4. An implantable bone-conduction (bone-anchored) hearing aid may be considered as an alternative to an air conduction CROS (contralateral routing of signal) hearing aid in patients with single-sided sensorineural deafness and normal contralateral hearing, and when used according to FDA approved indications.

E. **Audiological criteria:**

1. The poorer ear is not a candidate for an air-conduction hearing aid due to a speech reception threshold of 70 dB or more OR a word discrimination score of less than 60%; and
2. The better hearing ear has a speech reception threshold of 35 dB or less and a speech discrimination score of 60% or more.

F. **Age:** 5 years or older. An exception to the 5 year old age would include patients with bilateral atresia or bilateral conductive hearing loss.

G. **Cortical bone thickness of 3 mm or more.** Exceptions to this rule need clinical justification by otologist performing procedure prior to CRS review of request and it is noted that it may require a longer period of osseointegration.

H. **Trial of air conduction hearing aid failed or not appropriate,** as indicated by 1 or more of the following:

1. Anatomy will not allow for proper fitting.
2. Lack of substantial audiologic improvement with air conduction hearing aid
3. Patient develops significant otitis external, supportive otitis media, or recurrent ear canal infections, which preclude long-term use

I. **Psychosocial Evaluation:**
All of the following:

1. Patient's cognitive function must be sufficient to allow him/her to understand and participate in the decision-making process and in the care/maintenance of the implant unit. AND
2. Patient/family must have been compliant with previous medical and audiological management at CRS. AND
3. Patient/family must commit to necessary otological, audiological, educational and therapeutic follow-up outlined in the treatment plan.

V. **Clinical Indications for a Cochlear Implant**

Cochlear implantation provides an awareness and identification of sounds and facilitates communication for persons who have profound sensorineural hearing loss (nerve deafness). Deafness may be prelingual/perilingual or postlingual. AHCCCS covers medically necessary services for cochlear implantation solely for EPSDT members. Reference AMPM 430 Early and Periodic
Screening, Diagnostic and Treatment (EPSDT) Services. When used according to U.S. Food and Drug Administration (FDA) labeled indications, bilateral or unilateral cochlear implantation is proven and medically necessary for patients who meet all of the following criteria:

A. Diagnosis of bilateral prelingual or postlingual moderate-to-profound-sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;

B. Ability to follow or participate in a program of aural rehabilitation; Bilateral sensorineural hearing loss with unaided pure tone average thresholds of 70 dB or greater

C. Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation (examples cochlear aplasia, complete labyrinthine aplasia, lack of cochlear nerve), and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;

D. No contraindications to surgery

See the U.S. Food and Drug Administration (FDA) section for FDA indications for each cochlear implant device. Specific criteria vary with the device

Refer to UnitedHealthcare. Cochlear Implants. Policy Number 2013T0070K, Effective Date: August 1, 2014


Bibliography:


