MSA MEDICAL SERVICES ADMINISTRATION

Bulletin

Michigan Department of Community Health

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Distribution: Hearing Centers, Hospitals, Practitioners

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Subject: Coverage of Cochlear Implants and Auditory Osseointegrated Implants

Effective: April 1, 2012

Programs Affected: Medicaid, Children's Special Health Care Services (CSHCS)

The Michigan Department of Community Health is updating the Hearing Services Chapter of the Medicaid Provider Manual to clarify and expand on the standards of coverage and prior authorization requirements for cochlear implants and auditory osseointegrated implants. Bilateral cochlear implants are being added as a covered service for beneficiaries ages 12 months through 20 years.

Cochlear Implants

Cochlear implants are devices that replace the function of the cochlear structures and provide electrical energy to auditory nerve fibers. It requires a surgically placed internal device and external hardware. The surgery must be performed by a licensed medical doctor (M.D.) or doctor of osteopathy (D.O.) who specializes in otolaryngology and has training and expertise in this surgical procedure.

Cochlear implantation may be an option to improve communication skills for persons with severe to profound hearing loss who receive limited or no benefit from hearing aids.

1. Standards of Coverage

   Unilateral cochlear implantation and associated mapping/calibration are covered and reimbursable under the Medicaid and Children Special Health Care Services (CSHCS) programs with prior authorization for eligible beneficiaries using Food and Drug Administration (FDA) approved implants. Cochlear implants are covered for pre or post lingual deafness.

   Bilateral cochlear implantation and associated mapping/calibration are covered and reimbursable under the Medicaid and CSHCS programs with prior authorization for beneficiaries ages 12 months through 20 years using FDA approved implants.

   Hearing aids, hearing aid services, and accessories may be covered after the beneficiary has received a unilateral cochlear implant with prior authorization. Documentation must be submitted to support improvement in speech perception abilities using a hearing aid in the opposite ear. Documentation of hearing aid audibility measures (i.e. speech mapping) on prescriptive hearing aid measurements may be submitted for beneficiaries that are unable to participate in speech perception testing.

   Implantation criteria for all beneficiaries regardless of age are as follows:

   - Diagnosis of bilateral severe to profound sensorineural hearing loss with limited benefit from appropriate hearing aids for ages 24 months and older. Beneficiaries 12 through 23 months old must experience a profound hearing loss.
   - Submission of a letter from the treating otolaryngologist establishing medical necessity and recommending implantation.

- Limited benefit demonstrated from appropriately fitted hearing aids with consistent use over a 3-6 month period. The trial period may be waived or shortened with appropriately submitted documentation of medical necessity.
- Evidence of a functioning auditory nerve.
- Freedom from middle ear infection or any other active disease.
- An accessible cochlear lumen structurally suited to implantation. No evidence of lesions in the auditory nerve and acoustic areas of the central nervous system. This may be demonstrated by CT scan or other appropriate radiological evaluation.
- No contraindication to anesthesia/surgery (medically, surgically and psychologically).
- Cognitive ability to use auditory cues and demonstrate a conditioned response.
- Psychological development, motivation of the candidate, and/or commitment of the beneficiary and family caregivers to undergo a program of prosthetic fitting, training and long term rehabilitation.
- Realistic expectations of candidate, and/or family caregiver(s), for post implant educational/vocational rehabilitation, as appropriate.
- Reasonable anticipation by treating providers that the cochlear implant(s) will confer awareness of speech at conversational levels.
- Documented intervention and/or school placement as appropriate, supporting a concentrated Oral/Auditory or Total Communication approach to learning/communication. The educational plan should include professionals with specialization in education of the deaf and hard of hearing.

2. Prior Authorization

The following documentation must be submitted with the request for prior authorization:

Note: All audiological evaluations must have been performed within one year of the date of the request for prior authorization, unless otherwise specified.

Beneficiaries of All Ages	• A letter from the managing otolaryngologist with evaluation supporting medical necessity and treatment recommendations. • Documentation of appropriately fit hearing aids verified through prescriptive measurements. Aided audiograms as supplemental documentation to prescriptive measurements. • Aided speech perception test battery. • An accessible cochlear lumen structurally suited to implantation. No evidence of lesions in the auditory nerve and acoustic areas of the central nervous system. This may be demonstrated by CT scan or other appropriate radiological evaluation. • Identification of the cochlear manufacturer of the internal device with the model of the external processor. • Identification of the anticipated side to be implanted (unilateral only).
Ages 12 through 23 Months	In addition to the documentation for beneficiaries of all ages, the following must also be submitted: • Confirmation of bilateral profound sensorineural hearing loss (PTA equal to or greater than 90 dB HL, ANSI 1989). Electrophysiological assessment must corroborate behavioral testing. • Lack of auditory skills development and minimal hearing aid benefit documented by parent questionnaire (such as the IT-MAIS). • Speech and language evaluation. • Minimal or no benefit from appropriate amplification following an adequate period of auditory training, minimally 3-6 months of amplification, using the best ear responses. The trial period may be waived or shortened with appropriately submitted medical documentation. • Documented intervention or school placement as appropriate. The Individualized Family Service Plan (IFSP) should include individuals with specialization in the education of children who are deaf or hard of hearing.

Ages 24 Months through 17 years	In addition to the documentation for beneficiaries of all ages, the following must also be submitted: • Confirmation of bilateral severe to profound hearing loss (PTA equal to or greater than 70 dB HL, ANSI 1989). • Lack of auditory skills development and minimal hearing aid benefit (word recognition scores less than or equal to 30% on open set tests such as the Multisyllabic Lexical Neighborhood Test, Lexical Neighborhood Test, or other appropriate developmental tests). • Speech and language evaluation. • Minimal or no benefit from appropriate amplification following an adequate period of auditory training, minimally 3-6 months of amplification, using the best ear responses. • Documented intervention or school placement as appropriate. The Individualized Family Service Plan (IFSP) or Individualized Education Plan (IEP) should include individuals with specialization in the education of children who are deaf or hard of hearing.
Ages 17 Years and Older	In addition to the documentation for beneficiaries of all ages, the following must also be submitted: • Confirmation of bilateral severe to profound hearing loss (PTA equal to or greater than 70 dB HL, ANSI 1989). • Minimal or no benefit from appropriate amplification following an adequate period of auditory training, minimally 3-6 months of hearing aid use. Audiologically, the beneficiary will score less than or equal to 40% under best aided conditions on an open-set sentence recognition testing (such as the HINT Sentences).

Replacement of the internal cochlear implant device on a previously approved procedure will be covered in cases when the cochlear implant team indicates function of the internal device has failed and is no longer under warranty. A letter from the manufacturer corroborating the internal device failure is required.

3. Mapping/Calibration

Cochlear implant mapping/calibration is the programming of the speech processor used to analyze sound and convert the speech information into electrical impulses to the implanted electrodes. Mapping and calibration of the cochlear device must be provided by a licensed audiologist, who has training and expertise in these procedures. Other team members should include a speech and language pathologist, psychologist, and deaf educator, as determined by the beneficiary's need.

A maximum of ten mapping sessions are allowed for one year from the date of implantation of the cochlear implant.

4. Non-Covered Items

Repair or replacement of spare equipment (e.g., old parts and accessories in working condition for back-up use in emergencies).

Auditory Osseointegrated Implants

The auditory osseointegrated system has both implanted and external components. The implanted component is a small post that is surgically attached to the skull bone behind the ear. The external component is a speech processor which converts sound into vibrations; it connects to the implanted post and transmits sound vibrations directly to the inner ear through the skull, bypassing the middle ear.

1. Standards of Coverage

Medicaid and CSHCS cover the least costly alternative that meets the beneficiary's medical need for medical supplies, durable medical equipment or orthotics/prosthetics.

The surgically implanted components and external speech processor are covered as a bundled procedure at the hospital benefit level. All repairs and replacements, including the processor and batteries, are covered at the Prosthetic and Orthotics benefit level.

The implantation of the auditory osseointegrated device is covered without prior authorization. One (unilateral) auditory osseointegrated device will be covered per beneficiary. A second (bilateral) auditory osseointegrated device is not a covered benefit.

Medicaid and CSHCS will cover auditory osseointegrated devices with a unilateral or bilateral conductive or mixed conductive and sensorineural hearing loss, where the condition prevents restoration of hearing using a conventional air-conductive hearing aid and when the following criteria are met:

A. Use of an FDA approved device in accordance with its recommended use.

B. Beneficiary must be 5 years of age or older to qualify for surgically implanted components.

C. Beneficiary must have one of the following conditions:

1) Congenital malformations of the middle/external ear or microtia.
2) Severe chronic otitis externa and/or chronic suppurative otitis media with chronic drainage preventing use of conventional air-conduction hearing aids.
3) Conductive loss due to ossicular disease and not appropriate for surgical correction.
4) Tumors of the external ear canal and or tympanic cavity.
5) Unilateral sensorineural hearing loss (single sided deafness).

Conditions not meeting these criteria are considered investigational/experimental and are not covered.

2. Audiological Criteria

A. Unilateral or Bilateral conductive or mixed hearing loss:

1) Puretone average bone conduction thresholds better or equal to 65 dB HL in ear to be implanted.
2) A speech recognition score better than 60% using appropriate speech recognition testing.

B. Unilateral profound sensorineural hearing loss:

1) Confirmed profound hearing loss (greater than 90 dB HL) in one ear with the confirmed bone conduction thresholds in the opposite ear of 40 dB HL or better.

3. Osseointegrated device, external sound processor, used without osseointegration (Soft band device without surgically implanted components).

This device will be covered for beneficiaries who meet the above criteria but have either not reached the age of 5 years or are not appropriate surgical candidates. Prior authorization is required. The soft band device is not covered for unilateral sensorineural hearing loss (single sided deafness).

Required documentation for soft band without surgical components:

A. Complete audiology studies that define the type and degree of hearing loss in each ear.

B. Audiology report with history of hearing aid use and documentation of inability to use an air conduction hearing aid.

C. Letter from otolaryngologist stating medical need.

D. A copy of the manufacturer's actual invoice showing the processor make and model, serial number, invoice price, applicable discounts, and shipping and handling charges. If the manufacturer's actual invoice is not included, medical review staff will assign a penny screen to the code until the invoice is received.

4. Replacement of Auditory Osseointegrated Devices

   Replacement of external processors for surgically placed auditory osseointegrated devices require prior authorization and will not be covered more frequently than once every four years. Replacements are not covered during the warranty period. Processor repairs exceeding the published maximums will require prior authorization.

5. Non-Covered Items

   Repair or replacement of spare equipment (e.g., old parts and accessories in working condition for back-up use in emergencies).

Manual Maintenance

Retain this bulletin until it has been incorporated into the Medicaid Provider Manual.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Community Health, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mail at ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, and phone number so you may be contacted if necessary. Providers may phone toll-free 1-800-292-2550.

Approved

Stephen Fitton, Director
Medical Services Administration