Texas Children's	Implantable Hearing Device Guideline	
Guideline # 6186	***Categories*** Clinical →Care Management CM, TCHP Guidelines, Utilization Management UM	***This Guideline Applies To:*** Texas Children's Health Plan ***Document Owner*** Andrea Canady

GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization of all Implantable Hearing devices, including cochlear implants, auditory brainstem implants (ABI), and bone anchored hearing aids (BAHA) and any associated surgeries or accessories**.**

PRIOR AUTHORIZATION GUIDELINE

1. Non-implantable hearing devices and services do not require authorization. Medical Policy in the current Texas Medicaid Provider Procedures Manual applies.
2. Replacement batteries for implantable hearing devices do not require prior authorization.

3. All requests for prior authorization for implantable hearing devices are received via fax, phone, online submission or mail by the Utilization Management Department and processed during normal business hours.

4. To request prior authorization for an implantable hearing device, the following documentation must be provided:
   2.1. Complete Texas Standard Prior Authorization Request Form for Health Care Services
   2.2. Support for the medical necessity for the selected implantable hearing device or service
   2.3. Documentation of who will be providing the device or service (i.e. facility, DME or medical supplier)

5. Establishing Medical Necessity for Implantable Hearing Devices:
   3.1. Cochlear Implants:
      3.1.1. Implantation of a U.S. Food and Drug Administration (FDA) approved single or multi-channel cochlear implant is considered medically necessary , when all of the following criteria are met:
         3.1.1.1. The member is 12 months of age or older
         3.1.1.2. The member has bilateral severe-to-profound pre- or post lingual hearing loss (sensorineural deafness), defined as a hearing threshold of pure tone average (PTA) of 70 decibels (dB) or greater
         3.1.1.3. The member has demonstrated inability to derive benefit from appropriately fitted hearing aid devices ; and
         3.1.1.4. The member has a cochlear lumen that is structurally suited

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

3.1.1.5. The member is free from lesions in the auditory nerve and acoustic areas of the central nervous system; and
3.1.1.6. The member is free from otitis media or other active middle ear infections; and
3.1.1.7. The member is able to participate in a post-cochlear implant rehabilitation program in order to achieve benefit from the cochlear implant device as demonstrated by the Cognitive ability to use auditory cues and written documentation of agreement by the member or the member's parent or guardian that the member will participate.

3.1.2. Unilateral implantation of an FDA approved single or multi-channel cochlear implant is considered medically necessary for subsequent bilateral implantation (that is, sequential implantation) without retesting of hearing when the above criteria are met at the time of the initial (first) cochlear implantation.

3.1.3. Upgrade to or replacement of an existing external speech processor, controller or speech processor and controller (integrated system) is considered medically necessary for a member whose response to existing components is inadequate to the point of interfering with the activities of daily living or when components are no longer functional.

3.2. Auditory Brainstem Implants

3.2.1. An FDA-approved auditory brainstem implant (ABI) is considered medically necessary in an individual when all of the following criteria are met:
3.2.1.1. Is 12 years of age or older; and
3.2.1.2. Diagnosed with neurofibromatosis type 2 or schwannomatosis; and
3.2.1.3. Is completely deaf as a result of bilateral neurofibromas of the auditory nerve.

3.2.2. Upgrade to or replacement of an existing external sound processor, remote assistant or both components is considered **medically necessary** for an individual whose response to existing components is inadequate to the point of interfering with the activities of daily living or when components are no longer functional.

3.2.3.

3.3. Bone Anchored Hearing Aids

3.3.1. An implantable bone-anchored hearing aid is considered medically necessary for individuals who meet the criteria specified in either situation below.
3.3.1.1. An implantable bone-anchored hearing aid is considered medically necessary as an alternative to an air conduction hearing aid for individuals 5 years of age or older who meet both audiologic and medical condition criteria as follows:
3.3.1.1.1. Audiologic criteria (must meet one):
3.3.1.1.1.1. Bilateral implant: Moderate to severe bilateral symmetric bone conductive or mixed (conductive and sensorineural) hearing loss. Unilateral implant: Conductive or mixed (conductive and sensorineural) hearing loss Medical condition criteria (must meet at least one):
3.3.1.1.2.1. Congenital or surgically induced ear malformations of the external or middle ear canal (for example, atresia); or
3.3.1.1.2.2. Severe chronic external otitis or otitis media; or

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

3.3.1.1.2.3. Tumors of the external ear canal or tympanic cavity; or
3.3.1.1.2.4. Dermatitis of the external ear canal, including reactions from ear molds used in air conduction hearing aids; or
3.3.1.1.2.5. Other anatomic or medical conditions that contraindicate the use of an air conduction hearing aid.

3.3.1.2. An implantable bone-anchored hearing aid is considered medically necessary to improve speech recognition in individuals 5 years of age and older with unilateral sensorineural hearing loss (that is, single sided deafness) and normal hearing in the other ear. Normal hearing in the non-affected ear is defined as PTA air conduction threshold less than or equal to 20 dBs at 0.5, 1, 2, and 3 kHz.

3.3.2. A transcutaneously worn, non-surgical application of an implantable bone-anchored hearing aid (bone conduction-type hearing aid) utilizing a headband or Softband is considered medically necessary as an alternative to an implantable bone-anchored hearing aid or air conduction hearing aid in individuals who meet the criteria specified in either (A) or (B), above, except for the age limitation of 5 years of age or older which does not apply for a transcutaneously worn bone-anchored hearing aid.

3.3.3. Replacement parts or upgrades to existing bone-anchored hearing aid components (for exampleprocessor, headband or Softband) are considered medically necessary for individuals whose response to existing components is inadequate to the point of interfering with activities of daily living or when components are no longer functional.

6. Requests that do not meet the criteria established by this guideline will be referred to a TCHP Medical Director/Physician Reviewer for review and the Denial Policy will be followed.

7. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

REFERENCES:

Government Agency, Medical Society, and Other Authoritative Publications:

- American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS). Available at:http://www.entnet.org/content/position-statements. Accessed on 10/12/18.
    1. Cochlear Implants Revised 3/2/14
    2. Bone Conduction Hearing Devices Revised 9/17/16
- American Speech-Language-Hearing Association (ASHA). ASHA Practice Policy. Available at:http://www.asha.org/policy. Accesed on 10/12/18

Printed copies are for reference only. Please refer to the electronic copy for the latest version.

- Joint Audiology Committee Clinical Practice Statements and Algorithms Available at: https://www.asha.org/policy/GL1999-00013/U.S. Food and Drug Administration (FDA) 510(k) Premarket Notification Database. Summary of Safety and Effectiveness. Rockville, MD: FDA. Bone-anchored and bone conduction hearing systems. Available at:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
- Agency for Healthcare Research and Quality (AHRQ). Effectiveness of cochlear implants in adults with sensorineural hearing loss [Internet]. Technology Assessment Report. 2011 June. Project ID: AUDT0501. Available at:http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id80TA.pdf.
- Centers for Medicare and Medicaid Services (CMS). National Coverage Determination: Cochlear Implantation. NCD #50.3. Effective April 4, 2005. Available at:http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed on 10/12/18.
- Rubin LG, Papsin B. Committee on Infectious Diseases and Section on Otolaryngology-Head and Neck Surgery. Cochlear implants in children: surgical site infections and prevention and treatment of acute otitis media and meningitis. Pediatrics. 2010; 126(2):381-391.
- U.S. Food and Drug Administration (FDA). Medical Devices Databases. Cochlear implants. Rockville, MD: FDA. Available at: http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm. Accessed on June 12, 2015.
- U.S. Food and Drug Administration (FDA). Premarket Approval Database. Summary of Safety and Effectiveness. Rockville, MD: FDA. Nucleus Hybrid L24 Cochlear Implant System. Available at:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P130016.
- Texas Medicaid Provider Procedures Manual Accessed October 2018 http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx

Original Document Creation Date: 10/21/2016	This Version Creation Date: 10/12/2018	Effective/Publication Date: 11/29/2018

Printed copies are for reference only. Please refer to the electronic copy for the latest version.