Sentara Health Plans

Commercial

Cochlear Implants, Bone Attached Hearing Aid Implants, Auditory Brain Stem Implants, Surgical 20

Table of Content

Effective Date	4/1992
Next Review Date	6/2025
Coverage Policy	Surgical 20
Version	6

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses the medical necessity for Cochlear Implants, Bone Attached Hearing Aid Implants, Auditory Brain Stem Implants.

Description & Definitions:

Auditory brainstem implants – (ABI) Osseointegrated Implants are surgically implanted electrodes connected directly to the brainstem with a decoding chip placed under the skin that transmits from a sound processer/ microphone placed behind the ear.

Bone-anchored hearing aid – (BAHAs) bone-anchored auditory implants, bone-conducted hearing device - The device is anchored to the mastoid bone, embedded behind the ear with a titanium bone implant to a removable external sound processor/ microphone that attaches to a small piece that sticks out of the skin.

- **Percutaneous bone conduction** - skin-penetrating implant, unilateral or bilateral attachment to external speech processor
- **Transcutaneous bone-conduction** - (tBAHAs) Partially implantable device, unilateral or bilateral magnetic attachment to external speech processor, outside of the mastoid which is removable

Cochlear implant – uniaural (monaural) or binaural (bilateral) - electronic device with electrodes implanted inside the cochlea to amplify sound to an external receiver implanted under the skin behind the ear.

Hybrid cochlear implant devices – internal cochlear implanted device with an external sound processor/microphone

Replacement batteries – disposable or rechargeable batteries

Unilateral Sensorineural Hearing Loss, a traditional cochlear implant – air conduction hearing aids (ACHA)

Criteria:

Hearing implants are considered medically necessary when request is for **1 or more** of the following:

- Cochlear implant may be indicated for **1 or more** of the following:

- Adult with **ALL** of the following:
  - Deafness (postlingual)
  - Intact cochlear nerves confirmed by CT or MRI, or acoustic neuroma excision planned and cochlear nerve preservation thought possible
  - Need for implant, as indicated by **1 or more** of the following:
    - Bilateral sensorineural hearing loss of greater than 70 dB
    - Less than 50% score on standardized open-set sentence recognition test in ear to be implanted and less than 60% in contralateral ear when using appropriately fitted hearing aids
  - Zero or marginal (eg, phoneme score of less than 50% on speech perception test presented at 70 dB) speech perception benefit from hearing aids
  - No lesions of acoustic nerve or central auditory pathway causing deafness
  - No organic brain syndrome
- Child with **ALL** of the following:
  - Age 9 months or older
  - Bilateral sensorineural hearing loss with unaided pure-tone average thresholds of 70 dB or greater
  - Family support and motivation to participate in postimplant rehabilitation
  - Minimal speech perception 30% or less or lack of developmentally appropriate auditory milestones measured using parent report scales
  - Three-month to six-month trial of binaural hearing aids documents lack of or minimal improvement (ie, less than appropriate based on age, developmental stage, or cognitive ability) in auditory development.
  - No evidence of central auditory dysfunction (eg, cortical deafness)
  - No evidence of cochleovestibular anomaly by CT or MRI that would preclude implant (eg, cochlear aplasia, complete labyrinthine aplasia, lack of cochlear nerve), or acoustic neuroma excision planned and cochlear nerve preservation thought possible

- Hybrid cochlear implant devices (i.e. Nucleus® Hybrid™ L24 Cochlear Implant System etc.) may be indicated for **ALL** of the following:
  - Individual is at least 18 years of age with bilateral severe-to-profound high-frequency sensorineural hearing loss but with residual low-frequency hearing sensitivity allowing hearing of low-frequency sounds when **ALL** of the following preimplantation criteria are met:
    - Individual has limited benefit from appropriately fit bilateral hearing aids
    - Moderate hearing loss in the low-frequencies (that is, hearing thresholds no poorer than 60 decibels hearing level up to and including 500 hertz [averaged over 125, 250, and 500 hertz]) in the effected ear selected for implantation
    - Severe to profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 hertz greater than or equal to 75 decibels hearing level) in the effected ear
    - Moderately severe-to-profound mid- to high-frequency hearing loss (threshold average of 2000, 3000, and 4000 hertz greater than or equal to 60 decibels hearing level) in the contralateral ear
    - Abnormal speech perception scores as evidenced by **ALL** of the following:
      - Consonant-Nucleus-Consonant word recognition score from 10% to 60% in the ear to be implanted
      - Consonant-Nucleus-Consonant word recognition score in the contralateral ear equal to or better than in the ear to be implanted, but not more than 80% in the best-aided condition
    - Individual does not have lesions in the auditory nerve and acoustic areas of the central auditory pathway (nervous system)
    - Individual is does not have active middle ear infections
    - Individual is able to participate in a post-hybrid cochlear implant rehabilitation program so they can achieve benefit from the hybrid cochlear implant device
- Bone-anchored hearing aid (ie Percutaneous, Transcutaneous) is indicated for **ALL** of the following:
  - Age 5 years or older
  - Bilateral or unilateral conductive or mixed (both conductive and sensorineural) earing loss of greater than 20 dB
  - Cortical bone thickness of 3 mm or more
  - Middle or external ear pathology not amenable to surgical reconstruction
  - Pure-tone average bone conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) less than or equal to level appropriate for model to be implanted
  - Speech discrimination score greater than or equal to 60% in affected ear
  - Trial of air conduction hearing aid failed or not appropriate, as indicated by **1 or more of** the following:

        - Anatomy will not allow for proper fitting.
        - Lack of substantial audiologic improvement with air conduction hearing aid
        - Individual develops significant otitis externa, suppurative otitis media, or recurrent ear canal infections, which preclude long-term use.
- Partially implantable bone-anchored hearing aids (BAHAs) with **ALL** of the following:
    - Age 5 years or older
    - moderate to severe sensorineural hearing loss
    - evidence of a medical condition precluding use of an air conduction aid by **1 or more** of the following:
        - Congenital or surgically induced ear malformations of the external or middle ear canal (for example, atresia); or
        - Severe chronic external otitis or otitis media; or
        - Tumors of the external ear canal or tympanic cavity; or
        - Dermatitis of the external ear canal, including reactions from ear molds used in air conduction hearing aids; or
        - Other anatomic or medical conditions that contraindicate the use of an air conduction hearing aid
    - absence of middle ear disease
- For individual with unilateral sensorineural hearing loss, a traditional cochlear implant (e.g., MED-EL Cochlear Implant System) is considered medically necessary for the treatment of profound sensorineural hearing loss (PTA of 70 dB HL or greater at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) when an individual meets **ALL** of the following:
    - Age 5 years or older
    - Individual was only able to obtain limited benefit from an appropriately fitted unilateral hearing aid
    - Individual experienced little or no benefit from wearing a contralateral routing of signal (CROS) hearing aid or other relevant device (e.g., bone-anchored hearing aid [BAHA]) for at least one month
    - Individual meets **1 or more** of the following:
        - Individual has single sided deafness (SSD) with normal hearing or mild sensorineural hearing loss in the other ear
        - Individual has asymmetric hearing loss (AHL) defined by mild to moderately severe sensorineural hearing loss in the one ear with profound sensorineural hearing loss in the other, with a difference of at least 15 dB in pure tone averages (PTAs) between
- Auditory brainstem implants may be indicated when ALL of the following are present:
    - Auditory implant needed, as indicated by **1 or more** of the following:
        - Adult with **ALL** of the following:
            - Bilateral sensorineural hearing loss of greater than 70 dB
            - Postlingually deafened
            - Zero or marginal speech perception benefit from hearing aid
            - No organic brain syndrome
        - Child with **ALL** of the following:
            - Age 12 Years or older
            - Bilateral sensorineural hearing loss of greater than 70 dB, with minimal speech perception or severe delay in verbal language acquisition
            - Failure of all appropriate amplification and auditory training attempts
            - Family support and motivation to participate in rehabilitation
    - Brainstem implant needed instead of cochlear implant, as indicated by **1 or more** of the following:
        - Agenesis of middle ear confirmed by MRI
        - Aplasia or hypoplasia of cochlear nerve confirmed by MRI
        - Cochlear nerve avulsion
        - Cochlear ossification confirmed by CT or MRI
        - Failure of cochlear implant in patient with intact cochlear nerve
        - Neurofibromatosis type 2, and acoustic neuroma resection planned in the setting of **1 or more** of the following:
            - Contralateral acoustic neuroma present and **1 or more** of the following:
                - Cochlear nerve able to be preserved in ipsilateral ear, but poor intraoperative electrically evoked auditory brainstem response and electrically evoked compound action potential
                - Cochlear nerve not able to be preserved in ipsilateral ear
            - Contralateral acoustic neuroma previously excised and **1 or more** of the following:

        - Contralateral cochlear implant or auditory brain implant providing poor hearing rehabilitation
        - Contralateral hearing absent
    - Otosclerosis with gross cochlear destruction confirmed by CT or MRI
    - Schwannoma
    - Severe acoustic neuropathy
    - Significant malformation of labyrinth or cochlea confirmed by CT or MRI (eg, common cavity or rudimentary otocyst)
    - Unmanageable facial nerve stimulation caused by cochlear implant
- Replacement batteries for cochlear implants are considered medically necessary with **1 or more** of the following:
    - Individual may receive disposable replacement batteries per the brand's usual medically necessary frequency
    - Individual using rechargeable batteries may receive two batteries per device one a year
    - Individual using rechargeable batteries may receive a replacement charger every 3 years

Cochlear Implants, Bone Attached Hearing Aid Implants and Auditory Brain Stem Implants are considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- Cochlear Implant for tinnitus
- Cochlear implants which have not been approved by the FDA
- Upgrades to an existing, functional external system to achieve aesthetic improvement, such as smaller profile components, or a switch from a body-worn, external sound processor to a behind-the-ear (BTE) model
- Fully implantable middle ear hearing aid (e.g., Esteem)
- Tinnitus Masking Devices including the Neuromonics Oasis Tinnitus TX System for all indications

Coding:

Medically necessary with criteria:

Coding	Description
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69715	Implantation, osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; with mastoidectomy
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
69717	Replacement (including removal of existing device), osseointegrated implant, temporal bone, with percutaneous attachment to external speech processor/cochlear stimulator; without mastoidectomy
69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex

69930	Cochlear device implantation, with or without mastoidectomy
69799	Unlisted procedure, middle ear [when specified as implantation of semi-implantable or fully implantable hearing aid]
69949	Unlisted procedure, inner ear [when specified as implantation of hybrid cochlear device]
92630	Auditory rehabilitation; prelingual hearing loss
92633	Auditory rehabilitation; postlingual hearing loss
92640	Diagnostic analysis with programming of auditory brainstem implant, per hour
L8621	Zinc air battery for use with cochlear implant device and auditory osseointegrated sound processors, replacement, each
L8614	Cochlear device, includes all internal and external components
L8615	Headset/headpiece for use with cochlear implant device, replacement
L8616	Microphone for use with cochlear implant device, replacement
L8617	Transmitting coil for use with cochlear implant device, replacement
L8618	Transmitter cable for use with cochlear implant device or auditory osseointegrated device, replacement
L8619	Cochlear implant, external speech processor and controller, integrated system, replacement
L8622	Alkaline battery for use with cochlear implant device, any size, replacement, each
L8623	Lithium-ion battery for use with cochlear implant device speech processor, other than ear level, replacement, each
L8624	Lithium-ion battery for use with cochlear implant or auditory osseointegrated device speech processor, ear level, replacement, each
L8627	Cochlear implant, external speech processor, component, replacement

L8628	Cochlear implant, external controller component, replacement
L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8692	Auditory osseointegrated device, external sound processor, used without osseointegration, body worn, includes headband or other means of external attachment
L8693	Auditory osseointegrated device abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each
L8699	Prosthetic implant, not otherwise specified [when specified as hybrid cochlear device, including all internal and external components]
S2235	Implantation of auditory brain stem implant

Considered Not Medically Necessary:

Coding	Description
S2230	Implantation of magnetic component of semi-implantable hearing device on ossicles in middle ear

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2024: June – expanded criteria references updated
- 2023: May
- 2022: February, May
- 2021: May, December
- 2020: April (unarchived), June
- 2019: November (archived)
- 2016: February, April
- 2015: July
- 2014: April, October
- 2013: March, November
- 2012: March, August
- 2011: March, July
- 2010: April
- 2009: March

- 2008: March
- 2007: October
- 2002: March
- 2000: November
- 1998: December
- 1996: July

Reviewed Dates:

- 2018: July
- 2017: November
- 2015: June
- 2010: March
- 2005: September
- 2004: September, October
- 2003: March, October
- 2001: November
- 1999: December
- 1994: February

Effective Date:

April 1992

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2023, Sep 21). Retrieved Apr 19, 2024, from MCG: https://careweb.careguidelines.com/ed27/index.html

CLINICAL PRACTICE GUIDELINE: COCHLEAR IMPLANTS. (2019, Jul). Retrieved Apr 19, 2024, from American Academy of Audiology Task Force: https://www.audiology.org/wp-content/uploads/2021/05/CochlearImplantPracticeGuidelines.pdf

Cochlear Implantation for Adults With Single-Sided Deafness. (2023, Jun 12). Retrieved Apr 19, 2024, from Hayes - a symplr company: https://evidence.hayesinc.com/report/hta.cochlear5513

Cochlear Implants. (2022, Feb 03). Retrieved Apr 19, 2024, from U.S. Food and Drug Administration: https://www.fda.gov/medical-devices/implants-and-prosthetics/cochlear-implants

EPSDT Supplement B - Chapter Subject: Audiology and Hearing Program. (2019, May 02). Retrieved Apr 19, 2024, from Department of Medical Assistance Services - MES Public Portal: https://vamedicaid.dmas.virginia.gov/sites/default/files/2023-07/EPSDT%20Audiology%20and%20Hearing%20Manual%20-%20%28updated%205.2.19%29_FINAL.pdf

Hearing amplification in adults. (2024, Apr 17). Retrieved Apr 19, 2024, from UpToDate: https://www.uptodate.com/contents/hearing-amplification-in-adults?search=cochlear%20implant&source=search_result&selectedTitle=2%7E99&usage_type=default&display_rank=2#H3029744140

LCA: Billing and Coding: External Components for Cochlear Implants (A53708). (2019, Oct 01). Retrieved Apr 19, 2024, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53708&ver=16&keyword=Cochlear&keywordType=starts&areaId=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

NCD: Cochlear Implantation (50.3). (2022, Sep 26). Retrieved Apr 19, 2024, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=245&ncdver=3&keyword=Cochlear&keywordType=starts&areaId=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

Nucleus 24 Cochlear Implant System - P970051/S172. (2020, Apr 07). Retrieved May 10, 2024, from US Food and Drug Administration: https://public4.pagefreezer.com/content/FDA/01-06-2023T13:38/https://www.fda.gov/medical-devices/recently-approved-devices/nucleus-24-cochlear-implant-system-p970051s172

Part 874 Ear, Nose, and Throat Devices: Subpart D—Prosthetic Devices. (2024, Apr 15). Retrieved Apr 19, 2024, from Code of Federal Regulations: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-874/subpart-D

Transcutaneous Bone–Anchored Hearing Aids. (2022, Dec 29). Retrieved Apr 19, 2024, from Hayes - a symplr company: https://evidence.hayesinc.com/report/dir.transbaha4740

Title 38.2 - Chapter 34 - § 38.2-3418.21. Coverage for hearing aids and related services. (2023). Retrieved May 13, 2024, from Code of Virginia: https://law.lis.virginia.gov/vacodeupdates/title38.2/section38.2-3418.21/

Percutaneous Bone-Anchored Hearing Aids. (2022, Dec 07). Retrieved May 10, 2024, from Hayes - a symplr company: https://evidence.hayesinc.com/report/dir.bone0002

Special Notes: *

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

Cochlear Implants, Bone Attached Hearing Aid Implants, Auditory Brain Stem Implants, SHP Surgical 20, Cochlear Implant, Deafness, sensorineural hearing loss, hearing loss, Hearing Aids, Bone Anchored, Bone Conduction, Auditory Brainstem Implants, Auditory implant, Brainstem implant, cochlear nerve, Otosclerosis, acoustic neuropathy, Schwannoma, Middle Ear Implantable, Semi-Implantable Electromagnetic Hearing Aids, SEHA, Hybrid cochlear implant devices, Bone-anchored hearing aid, BAHA, BAHS, MED-EL