



MEDICAL COVERAGE POLICY

SERVICE: Cochlear Implants and Auditory Brainstem Implants

Policy Number:	017
Effective Date:	09/01/2019
Last Review:	06/27/2019
Next Review Date:	06/27/2020

Important note:

Unless otherwise indicated, this policy will apply to all lines of business. Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

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PRIOR AUTHORIZATION: **Required.**

POLICY:

For Cochlear Implants and Auditory Brainstem Implant requests, InterQual® will be used to determine medical necessity when possible. If criteria are not available through InterQual®, this policy will be used to determine medical necessity.

For applicable members under the age of 18 years, please refer to the Texas mandated coverage for this service. See "Mandates" below.

For remaining members, please use this policy for determining medical necessity.

SWHP follows Medicare rules in considering cochlear implants and auditory brainstem implants as prosthetics. Medicare considers as prosthetics "cochlear implants and auditory brainstem implants, i.e., devices that replace the function of cochlear structures or auditory nerve and provide electrical energy to auditory nerve fibers and other neural tissue via implanted electrode arrays."

SWHP may consider a unilateral cochlear implant as medically necessary for a member with bilateral sensori-neural hearing loss when there is reasonable expectation that a significant benefit will be achieved from the device and when the following age-specific criteria are met:

For Medicare lines of business

- Cochlear implantation may be covered for treatment of bilateral pre- or-post-linguistic, sensori-neural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition. The following criteria must be met:
 - Diagnosis of bilateral moderate-to-profound sensori-neural hearing impairment with limited benefit from appropriate hearing (or vibro-tactile) aids;
 - Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
 - Freedom from middle ear infection, an accessible cochlear lumen that is



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structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;

- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

Cochlear implantation may be covered for individuals meeting the selection guidelines above and with hearing test scores of greater than 40% and less than or equal to 60% only when:

- The provider is participating in, and patients are enrolled in, either an FDA-approved category B investigational device exemption clinical trial as defined at 42 CFR 405.201, a trial under the Centers for Medicare & Medicaid (CMS) Clinical Trial Policy as defined at section 310.1 of the National Coverage Determinations Manual, or
- A prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for National Coverage Analyses and meeting specific quality standards.

For other lines of business:

Unilateral or bilateral cochlear implants may be considered medically necessary for members meeting ALL the following selection criteria:

- One year of age or older with severe to profound pre or post lingual (sensorineural) hearing loss (defined as a hearing threshold of 70 decibels [dB] or above); AND
- Limited benefit from hearing aids; AND
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation as age appropriate; AND
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system; AND
- No contraindications to surgery (i.e., infection, cranial nerve cannot be stimulated); AND
- The device is used in accordance with U.S. Food and Drug Administration (FDA) approved labeling.

For children under the age of one year, cochlear implantation may be considered medically necessary when they are diagnosed with profound deafness and meet the following criteria

- the diagnosis is confirmed by recognized audiology measures such as an auditory brainstem response or an auditory steady-state response, AND
- there is documentation that the child demonstrates lack of significant improvement in the frequencies used for hearing spoken language when using fitted hearing aids, in conjunction with aural habilitation, for a minimum of three months.

SWHP may covers a second cochlear implant in the contralateral (opposite) ear as medically necessary in an individual with an existing unilateral cochlear implant when the hearing aid in the contralateral ear produces limited or no benefit.

SWHP may consider the replacement of an existing cochlear implant as medically necessary when



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EITHER of the following criteria is met:

- currently used component is no longer functional and cannot be repaired
- currently used component renders the implant recipient unable to adequately and/or safely perform his/her age-appropriate activities of daily living

SWHP will replace hearing aids for children under the age of 18 years as often as every 3 years when required by Texas Mandate.

SWHP does not consider the upgrading of a cochlear implant system or component (e.g., upgrading processor from body-worn to behind-the-ear, upgrading from single- to multi-channel electrodes) of an existing, properly functioning cochlear implant as medically necessary.

SWHP considers a cochlear implant for the treatment of tinnitus in an individual who does not also have profound or severe sensori-neural deafness/hearing loss warranting the need for cochlear implantation as experimental, investigational or unproven.

SWHP may consider a unilateral auditory brainstem implant (ABI) medically necessary in members meeting the following criteria:

1. 12 years of age or older, AND
2. rendered deaf through the loss of both auditory nerves due to disease (e.g., neurofibromatosis or von Recklinghausen's disease) or bilateral surgical resection of auditory nerves.

OVERVIEW: The cochlear implant is an electronic prosthesis, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired. The device stimulates cells of the auditory spiral ganglion to provide a sense of sound to persons with hearing impairment. The patient selection criteria for cochlear implants were adapted from the FDA approved indications for cochlear implants.

An Auditory Brainstem Implant (ABI) is a modified cochlear implant intended to be used to stimulate the cochlear nucleus in the brainstem of patients who have had their eighth nerves severed during surgery for removal of bilateral neurofibromata, as in patients with Neurofibromatosis 2 (NF2).

MANDATES: Texas Mandate HB 490 enacted 2017

TIC Sec. 1367.253. **COVERAGE REQUIRED.** (a) A health benefit plan must provide coverage for the cost of a medically necessary hearing aid or cochlear implant and related services and supplies for a covered individual who is 18 years of age or younger.

(b) Coverage required under this section:

(1) must include:

- (A) fitting and dispensing services and the provision of ear molds as necessary to maintain optimal fit of hearing aids;



MEDICAL COVERAGE POLICY

SERVICE: Cochlear Implants and Auditory Brainstem Implants

Policy Number: 017

Effective Date: 09/01/2019

Last Review: 06/27/2019

Next Review Date: 06/27/2020

(B) any treatment related to hearing aids and cochlear implants, including coverage for habilitation and rehabilitation as necessary for educational gain; and

(C) for a cochlear implant, an external speech processor and controller with necessary components replacement every three years; and

(2) is limited to:

(A) one hearing aid in each ear every three years; and

(B) one cochlear implant in each ear with internal replacement as medically or audiological necessary.

(c) Except as provided by Subsections (b) and (d), coverage required under this section:

(1) may not be less favorable than coverage for physical illness generally under the plan; and

(2) must be subject to durational limits and coinsurance factors no less favorable than coverage provided for physical illness generally under the plan.

(d) Coverage required under this section is subject to any provision that applies generally to coverage provided for durable medical equipment benefits under the plan, including a provision relating to deductibles, coinsurance, or prior authorization.

(e) This section does not apply to a qualified health plan defined by 45 C.F.R. Section 155.20 if a determination is made under 45 C.F.R. Section 155.170 that:

(1) this subchapter requires the plan to offer benefits in addition to the essential health benefits required under 42 U.S.C. Section 18022(b); and

(2) this state must make payments to defray the cost of the additional benefits mandated by this subchapter.

Added by Acts 2017, 85th Leg., R.S., Ch. 979 (H.B. 490), Sec. 1, eff. September 1, 2017.

CMS: NCD 50.3 7/25/2005

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	69930 - Cochlear device implantation 92522 - Evaluation of speech sound production 92523 - Evaluation of speech sound production with evaluation of language comprehension and expression 92524 - Behavioral and qualitative analysis of voice and resonance 92601 - 92602 - Diagnostic analysis of cochlear implant, patient younger than 7 years of age 92603 - 92604 - Diagnostic analysis of cochlear implant, age 7 years or older 92626 - 92627 - Evaluation of auditory rehabilitation status 92630 - 92633 - Auditory rehabilitation 92640 - Diagnostic analysis with programming of auditory brainstem implant,
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ICD10 Codes:	Q85.00, Q85.02 - Neurofibromatosis H93.3X3 - D/O bilateral acoustic nerves H90.5 - Sensory/Neural hearing loss H90.3 - Sensoineural hearing loss, bilateral H90.6 - Mixed hearing loss, bilateral H80.23 - Cochlear otosclerosis, bilateral Q16.5 - Congenital malformation of inner ear
HCPCS Codes :	S2235 - Implantation of auditory brain stem implant 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, replacement L8619 - Cochlear implant external speech processor, replacement L8621 - Zinc air battery for use with cochlear implant device, replacement, each 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 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
Other Codes	V5273 - Assistive listening device, for use with cochlear implant

INFORMATION:

Typical life of related cochlear implant parts:

<u>Part</u>	<u>Frequency</u>
Battery charger kit	1 per 3 years
Cochlear auxiliary cable adapter	1 per 3 years
Cochlear belt clip	1 per 3 years
Cochlear harness extension adapter	1 per 3 years
Cochlear signal checker	1 per 3 years
Disposable batteries for ear-level processors	72 per 6 months
Headset (3-piece component)	1 per 3 years
Headset cochlear coil (individual component)	1 per year
Headset cochlear magnet (individual component)	1 per year
Headset microphone (individual component)	1 per year
Headset cable or cord	4 per 6 months
Microphone cover	1 per year
Pouch	1 per year
Rechargeable batteries (per set of 2)	1 per year
Transmitter cable or cord	4 per 6 months

POLICY HISTORY:

Status	Date	Action
New	8/1/2010	New policy
Reviewed	12/6/2011	Reviewed.



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Last Review: 06/27/2019

Next Review Date: 06/27/2020

Reviewed	3/29/2012	Reviewed.
Reviewed	2/28/2013	Reviewed. CMS section added.
Reviewed	3/06/2014	Criteria made consistent with CMS. ICD10 codes added
Reviewed	3/05/2015	No changes
Reviewed	3/17/2016	Updated codes. Added ref to NCD 50.3
Reviewed	3/28/2017	No changes
Reviewed	2/20/2018	Made changes to criteria. Added brainstem implants
Reviewed	2/25/2019	Retired policy. IQ to be used going forward
Updated	6/26/2019	Policy returned to service. IQ and Mandate language added.

REFERENCES: The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

- Schleich P, Nopp P, D'Haese P. Head shadow, squelch, and summation effects in bilateral users of the MED-EL COMBI 40/40+ cochlear implant. *Ear Hear.* 2004;25:197-204.
- Schön F, Müller J, Helms J, Nopp P. Sound localization and sensitivity to interaural cues in bilateral users of the Med-El Combi 40/40+ cochlear implant system. *Otol Neurotol.* 2005;26:429-437.
- Schön F, Müller J, Helms J. Speech reception thresholds obtained in a symmetrical four-loudspeaker arrangement from bilateral users of MED-EL cochlear implants. *Otol Neurotol.* 2002; 23:710-714.
- Seeber BU, Baumann U, Fastl H. Localization ability with bimodal hearing aids and bilateral cochlear implants. *J Acoust Soc Am.* 2004;116(3):1698-1709.
- Senn P, Kompis M, Vischer M, Haeusler R. Minimum audible angle, just noticeable interaural differences and speech intelligibility with bilateral cochlear implants using clinical speech processors. *Audiol Neurotol.* 2005;10:342-352.
- Quentin Summerfield A, Barton GR, Toner J, et al. Self-reported benefits from bilateral cochlear implantation in post-lingually deafened adults: Randomised controlled trial. *Int J Audiol.* 2006;45:1-9.
- Verschuur CA, Lutman M, Ramsden R, et al. Auditory localization abilities in bilateral cochlear implant recipients. *Otol Neurotol.* 2005;26:965-971.
- van Hoesel RJ, Tyler RS. Speech perception, localization, and lateralization with bilateral cochlear implants. *J Acoust Soc Am.* 2003;113:1617-1630.
- Neuman AC, Haravon A, Sislian N, Waltzman SB. Sound-direction identification with bilateral cochlear implants. *Ear Hear.* 2007;28(1):73-82.
- Schafer EC, Thibodeau LM. Speech recognition in noise in children with cochlear implants while listening in bilateral, bimodal, and FM-system arrangements. *Am J Audiol.* 2006;15(2):114-126.
- Ricketts TA, Grantham DW, Ashmead DH, et al. Speech recognition for unilateral and bilateral cochlear implant modes in the presence of uncorrelated noise sources. *Ear Hear.* 2006;27(6):763-773.
- Litovsky R, Parkinson A, Arcaroli J, Sammeth C. Simultaneous bilateral cochlear implantation in adults: A multicenter clinical study. *Ear Hear.* 2006;27(6):714-731.
- Bauer PW, Sharma A, Martin K, Dorman M. Central auditory development in children with bilateral cochlear implants. *Arch Otolaryngol Head Neck Surg.* 2006;132(10):1133-1136.
- Long CJ, Carlyon RP, Litovsky RY, Downs DH. Binaural unmasking with bilateral cochlear implants. *J Assoc Res Otolaryngol.* 2006;7(4):352-360.
- Tyler RS, Noble W, Dunn C, Witt S. Some benefits and limitations of binaural cochlear implants and our ability to measure them. *Int J Audiol.* 2006;45 Suppl 1:S113-S119.
- National Health Service (NHS), Bassetlaw Primary Care Trust. Policy on the Commissioning of Cochlear Implants. Reference: PCT CM 35. Barnsley, UK: NHS Bassetlaw Primary Care Trust; revised March 2006.
- Australian Association of the Deaf Inc. Policy on cochlear implants. Policies. Brisbane, Australia: Australian Association of Cochlear Implants and Auditory Brainstem Implants



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**SERVICE: Cochlear Implants and
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- the Deaf; November 3, 2006. Available at: <http://www.aad.org.au/info/policycochlear.php>. Accessed June 19, 2007.
18. Wackym PA, Runge-Samuels CL, Firszt JB, et al. More challenging speech-perception tasks demonstrate binaural benefit in bilateral cochlear implant users. *Ear Hear.* 2007;28(2 Suppl):80S-85S.
 19. Peters BR, Litovcisky R, Parkinson A, Lake J. Importance of age and postimplantation experience on speech perception measures in children with sequential bilateral cochlear implants. *Otol Neurotol.* 2007;28(5):649-657.
 20. Beijen JW, Snik AF, Mylanus EA. Sound localization ability of young children with bilateral cochlear implants. *Otol Neurotol.* 2007;28(4):479-485.
 21. Tyler RS, Dunn CC, Witt SA, Noble WG. Speech perception and localization with adults with bilateral sequential cochlear implants. *Ear Hear.* 2007;28(2 Suppl):86S-90S.
 22. Wolfe J, Baker S, Caraway T, et al. 1-year postactivation results for sequentially implanted bilateral cochlear implant users. *Otol Neurotol.* 2007;28(5):589-596.
 23. Portmann D, Felix F, Negrevergne M, et al. Bilateral cochlear implantation in a patient with long-term deafness. *Rev Laryngol Otol Rhinol (Bord).* 2007;128(1-2):65-68.
 24. Galvin KL, Mok M, Dowell RC. Perceptual benefit and functional outcomes for children using sequential bilateral cochlear implants. *Ear Hear.* 2007;28(4):470-482.
 25. Grantham DW, Ashmead DH, Ricketts TA, et al. Horizontal-plane localization of noise and speech signals by postlingually deafened adults fitted with bilateral cochlear implants. *Ear Hear.* 2007;28(4):524-541.
 26. Smith ZM, Delgutte B. Sensitivity to interaural time differences in the inferior colliculus with bilateral cochlear implants. *J Neurosci.* 2007;27(25):6740-6750.
 27. Gordon KA, Valero J, Papsin BC. Binaural processing in children using bilateral cochlear implants. *Neuroreport.* 2007;18(6):613-617.
 28. Murphy J, O'Donoghue G. Bilateral cochlear implantation: An evidence-based medicine evaluation. *Laryngoscope.* 2007;117:1412-1418.
 29. Ching TY, van Wanrooy E, Dillon H. Binaural-bimodal fitting or bilateral implantation for managing severe to profound deafness: A review. *Trends Amplif.* 2007;11(3):161-192.
 30. National Institute for Health and Clinical Excellence (NICE). Cochlear implants for children and adults with severe to profound deafness. Appraisal Consultation Document. London, UK: NICE; December 2007.
 31. U.S. Food and Drug Administration (FDA). FDA public health notification: Importance of vaccination in cochlear implant recipients. Rockville, MD: FDA; October 10, 2007. Available at: <http://www.fda.gov/cdrh/safety/101007-cochlear.html>. Accessed January 5, 2008.
 32. Ali W, O'Connell R. The effectiveness of early cochlear implantation for infants and young children with hearing loss. NZHTA Technical Brief Series. Christchurch, New Zealand: New Zealand Health Technology Assessment (NZHTA); 2007.
 33. Wisconsin Department of Health and Family Services. Replacement parts for cochlear implants and bone-anchored hearing devices. Attachment 3. Wisconsin Medicaid and BadgerCare Update. No. 2005-20. Madison, WI; Wisconsin Department of Health and Family Services; March 2005. Available at: <http://dhs.wisconsin.gov/medicaid/updates/2005/2005pdfs/2005-20.pdf>. Accessed August 25, 2008.
 34. Schwartz MS, Otto SR, Shannon RV, et al. Auditory brainstem implants. *Neurotherapeutics.* 2008;5(1):128-136.
 35. Papsin BC, Gordon KA. Bilateral cochlear implants should be the standard for children with bilateral sensorineural deafness. *Curr Opin Otolaryngol Head Neck Surg.* 2008;16(1):69-74.
 36. Bichey BG, Miyamoto RT. Outcomes in bilateral cochlear implantation. *Otolaryngol Head Neck Surg.* 2008;138(5):655-661.
 37. Centers for Medicare & Medicaid Services (CMS). Hearing aids and auditory implants. Medicare Benefit Policy Manual, Ch. 16 - General Exclusions from Coverage, Sec. 100 (Rev. 39; Issued: 11-10-05; Effective: 11-10-05; Implementation: 12-12-05). Baltimore, MD: CMS; 2005. Available at: <http://www.cms.hhs.gov/manuals/downloads/bp102c16.pdf>. Accessed January 6, 2008.
 38. National Institute for Health and Clinical Excellence (NICE). Cochlear implants for children and adults with severe to profound deafness. NICE Technology Appraisal Guidance 166. London, UK: NICE; January 2009.
 39. Elvsåshagen T, Solyga V, Bakke SJ, et al. Neurofibromatosis type 2 and auditory brainstem implantation. *Tidsskr Nor Laegeforen.* 2009;129(15):1469-1473.
 40. Bond M, Elston J, Mealing S, et al. Effectiveness of multi-channel unilateral cochlear implants for profoundly deaf children: A systematic review. *Clin Otolaryngol.* 2009;34(3):199-211.
 41. Bond M, Mealing S, Anderson R, et al. The effectiveness and cost-effectiveness of cochlear implants for severe to



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**SERVICE: Cochlear Implants and
Auditory Brainstem Implants**

Policy Number: 017

Effective Date: 09/01/2019

Last Review: 06/27/2019

Next Review Date: 06/27/2020

profound deafness in children and adults: A systematic review and economic model. Health Technol Assess. 2009;13(44):1-330.

42. Kaplan AB, Kozin ED, Puram SV, et al. Auditory brainstem implant candidacy in the United States in children 0-17 years old. Int J Pediatr Otorhinolaryngol. 2015;79(3):310-315.
43. Peters JP, Ramakers GG, Smit AL, Grolman W. Cochlear implantation in children with unilateral hearing loss: A systematic review. Laryngoscope. 2016;126(3):713-721.