

# Icon Medical Solutions, Inc.

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## Notice of Independent Review Decision

**DATE:** April 23, 2013

**IRO CASE #:**

**DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:**

Cochlear Implants/Cochlear Device System

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:**

The reviewer is certified by the American Board of Otolaryngology with 25 years of experience.

**REVIEW OUTCOME:**

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

Overturned (Disagree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

**INFORMATION PROVIDED TO THE IRO FOR REVIEW:**

01/14/13: Record of Initial Visit by FNP and MD with Ear Institute, PA  
01/14/13: DPOAE Test Report, Vestibular Evoked Potential Report, and Evoked Potential Report from the Ear Institute, PA  
01/28/13: MRI of the Brain and Internal Acoustic Canals with and without Intravenous Contrast report interpreted by Dr. with Hospital  
02/05/13: Return Visit by MD  
02/05/13: Testing by with The Ear Institute  
02/05/13, 02/25/13: Established Patient Visit from Ear Institute  
02/21/13: CT Temporal Bones without IV Contrast report interpreted by MD with Imaging  
02/21/13: Office Note  
02/21/13, 02/25/13: Evaluation by, AuD with Ear Institute  
02/25/13: Telecom Message Form by with Ear Institute  
03/05/13, 03/06/13, 03/07/13: Telecom Message Form from Ear Institute

03/07/13: UR performed by MD  
03/13/13: Consultation by MD  
03/14/13, 04/02/13: Correspondence from Coventry Health Care  
03/14/13: Telecom Message Form by with Ear Institute  
03/15/13: Email from with The Ear Institute, PA to  
04/02/13: UR performed by MD  
04/08/13: Progress Note by MD, PhD  
04//09/13: Request for Cochlear Implantation by MD, FACS and AuD with Ear Institute PA

**PATIENT CLINICAL HISTORY [SUMMARY]:**

The claimant is a male who sustained hearing loss when a pipe exploded near his head while working at a xx on xx/xx/xx.

01/14/13: The claimant was evaluated by FNP/ MD. It was noted that he had previously been evaluated by Dr. for bloody otorrhea and bilateral tinnitus. An audiogram on 09/16/12 after the incident revealed mild, bilateral high frequency sensory hearing loss. It was noted that within two days of the incident, the claimant reported complete bilateral hearing loss and cessation of his tinnitus. Record review demonstrated ABR on 11/06/12 reported as abnormal, "closely resembles auditory dyssynchrony," reflexes present, and ABR thresholds were suggested down to a level of 60 dBHL. Further review of office notes from other providers had revealed that he was able to communicate verbally with normal speech and tone but had limited ability to communicate with handwriting. On current visit (01/14/13), he was unable to communicate verbally; however, he was able to write complete sentences on paper and type complete sentences on his phone. It was noted that since the incidence, he had experienced dizziness, described as recurrent episodes of lightheadedness, imbalance, falling to the right and forward, delayed focusing of visual fields, and visual blurring with head motion. He had experienced falls, nausea, vomiting, and headaches with his dizziness episodes. His wife had noted that his verbal communication had declined since the incident. He denied photophobia and hyperacusis. He denied recurrence of his tinnitus, aural fullness, and further episodes of otorrhea. On physical exam, He was unable to communicate without difficulty with normal speech and voice. Gaze-evoked nystagmus was present in all directions of EOMs. External ear and pinna were normal in development and appearance. Binocular visualization of the ears performed due to inadequate otoscopy and/or need for manipulation. Right and Left: External canal was normal. Tympanic membrane was normal without retractions, perforations, or erythema. Middle ear was normal and clear of effusion. Tuning Forks: Per audiogram/OAE. Cerebellar testing revealed no drift, but positive for dysmetria and dysdiadochokinesia. Romberg exam revealed moderate sway. Tandem Romberg revealed severe sway. Gait was staggered. Tandem gait was severely unstable. Audiogram: Bilateral complete deafness. Pure-tone average, speech reception threshold, and word recognition score could not be calculated. Acoustic reflexes were present with ipsilateral and contralateral stimulation in the left ear and could not be measured in the right ear. Tympanograms were type A bilaterally. Distortion

Product OAEs present from 1-6 kHz in the right ear and from 1.25-3 kHz and 4 kHz in the left ear. Vestibular Evoked Myogenic Potentials: Asymmetry ratio was 40%, weaker on the right. No repeatable waveforms at 70 dB bilaterally. IMPRESSION: Abnormal auditory perception. Auditory dyssynchrony, based on both subjective and objective tests. Headaches. Dizziness. Imbalance. Left vestibular weakness as seen on VEMP testing. His symptoms and conditions listed above are at least, if not all, related to his past concussion sustained at work on 09/16/12, as he had reported normal hearing prior to the incident which declined shortly (although not immediately) after the incident. PLAN/RECOMMENDATIONS: MRI of the brain and IACs with and without contrast. Discussed fall precautions. Electrocochleography. Videonystagmography. VOR testing. CI evaluation. Follow up after completion of the above testing.

01/28/13: MRI of the Brain and IACs W/WO IV Contrast report interpreted by Dr.. CONCLUSION: Normal examination of the brain and posterior fossa. There is mild paranasal pansinusitis, with no air-fluid levels.

02/05/13: The claimant was evaluated by, MD. On physical exam, he exhibited poorly modulated voice and remained resistant to speaking, but verbal speaking could be elicited with encouragement. His ear canals and tympanic membranes were normal in appearance under binocular microscopy with absence of signs of erythema perforations, or middle ear effusions. Testing: Videonystagmography: Oculomotor testing demonstrated abnormal latencies of the saccadic eye movements and low gain of both the pursuit and optokinetic eye movements. With positional testing, downbeating nystagmus was seen with head positioning to the left and center and left beating nystagmus was seen with head and body positioning to the left side. With bithermal caloric stimulation, he demonstrated a non-clinically significant 13% right reduced vestibular response. Vestibular Autorotation Testing: Gain and phase abnormalities present for head motion in both the horizontal and vertical planes. IMPRESSION: Bilateral sensorineural hearing loss, which appears to be severe-to-profound, although he may have a component of auditory dyssynchrony. Vestibular/oculomotor dysfunction. Left vestibular weakness on VEMP testing. Imbalance. RECOMMENDATIONS: Considering that he is postlingually deaf, I would expect him to be able to communicate orally. Although, he has remained resistant due to his self confidence issues regarding inability to modulate his voice. Considering that I was able to encourage him to speak verbally, my concern for a central neurological disorder was lessened. Although, I still suggested he proceed with neurological consultation. I believe he is likely a good candidate for cochlear implantation and would likely respond to this well, likely bringing him back into the hearing world and improve his ability to communicate. If we were to perform cochlear implantation on one side and he responded well, then we could consider cochlear implantation on the contralateral side. He will proceed with cochlear implant evaluation in my office. He will undergo ABR with thresholds at that time. CT of the temporal bones. If surgery is selected, he will need cardiac clearance prior to surgery. Vestibular/balance rehabilitation therapy with my specially

trained physical therapist to address his dizziness issues. Follow up in my office after completion of the above testing. I encouraged them to proceed with the tests quickly since he is severely distraught by his hearing loss, and I hope to address this as quickly as possible.

02/05/13: Testing by with The Ear Institute. INTERPRETATION: The patient demonstrated a caloric Reduced Vestibular Response (RVR) of 13% in the right ear. This RVR value is within normal limits. From the four irrigations, left beating nystagmus was 4% stronger than the right beating nystagmus. This value for Directional Preponderance is within normal limits. External ocular photography was completed to visually assess eye movements, including torsion. Torsion was not seen during testing.

02/21/13: CT Temporal Bones W/O IV Contrast report interpreted by MD. IMPRESSION: Normal CT of the temporal bones.

02/21/13: The claimant was seen for ABR testing by, AuD. Click stimuli were presented at 90 dB nHL in both ears with two runs of condensation and two runs of rarefaction each side. The tracings did not match exactly, but did not show an inversion either, which would be a confirming finding of auditory dyssynchrony. Waves I, III, and V were within normal limits and interpeak latencies were also within normal limits in the right ear. Waves I and V were within normal limits, but wave III was delayed with interpeak latencies I-III and I-V being delayed but III-V within normal limits in the left ear. Repeatable waveforms were present in both ears with alternating clicks down to 60 dB nHL. These findings are not consistent with typical auditory dyssynchrony, but they also indicate a significantly worse hearing loss than would be expected with present OAEs and Acoustic Reflexes.

02/21/13: The claimant was seen by, AuD for cochlear implant evaluation. Audiometric testing revealed the following: PTA: RT: NR, LT: NR (tested 01/14/13). AZBio: 0% in left-only and right-only aided condition (clinic Phonak Maxx311 Forte BTE). The claimant and his wife were counseled regarding cochlear implant candidacy. He was very interested in the option of simultaneous bilateral cochlear implantation. He was counseled that it would take time to adjust to the new sound and for speech to become easier to understand. He was provided with an adult CI candidacy packet.

02/25/13: The claimant was evaluated by MD. TREATMENT/PLAN: Discussed the option of left cochlear implantation. Explained that considering the atypical ABR results and the possibility of auditory dyssynchrony, I am not positive how he will respond to cochlear implantation. Although, I think there was a reasonable likelihood that he will get a good response. Will start with cochlear implant on the left side, and if a good result is obtained, can perform cochlear implantation on the contralateral ear. He will need cardiac clearance prior to surgery. He will also be undergoing neurological evaluation with Dr.. Continue VBRT.

02/25/13: The claimant was seen by, AuD for additional cochlear implant counseling. He wanted to go with the Advanced Bionics device and order both a Neptune and an ear-level processor. He opted to choose the next generation sound processor in lieu of immediate delivery of a Harmony processor. An order form was filled out for a Neptune processor.

03/07/13: UR performed by, MD. RATIONALE: "1. While the patient appears to be a candidate for cochlear implantation, it is unclear whether the recommended Advanced Bionics device, Neptune and ear-level processor is the most appropriate level models and it would be reasonable to first obtain additional information including product description, cost and possible options. Further assessment of the requested devices is needed. 2. The patient will see Dr. Truitt for a neurologic evaluation. It would be reasonable to review the findings and recommendations as they may have a bearing on the appropriateness of cochlear implantation."

03/13/13: The claimant was evaluated by MD. On physical exam, Dr. could not get him to speak more than a single syllable. He expressed himself in writing. Extraocular movements were intact. He had fast eye blinks when Dr. attempted to shine a light in his eyes, so the discs were not seen. Pupils were 6 down to 3.5 mm bilaterally. "He certainly has hearing loss but appears to have at least grossly intact visual fields." On neurological exam, he was markedly depressed and anxious, but very cooperative. He did not appear to have hearing at any normal volume. He did not attempt to speak. Sensory exam was somewhat difficult, especially trying out pinprick testing, but his vibratory sense and proprioception were intact. He had a fairly stable gait but did tend to step out to the right on heel and toe walk. He bumped into the wall on the right when walking. Romberg was not tested due to the instability. IMPRESSION: "This gentleman has a very significant postconcussion syndrome. In addition, he has a degree of PTSD in my opinion, chiefly due to the fact that he cannot hear and cannot interact with his family. This makes his depression more significant than one typically sees with postconcussion syndrome. In addition, he has profound hearing loss. I do think that the difficulty with speech is psychological in this gentleman who cannot hear himself speak. He is suffering from very significant depression as a result of this injury." Dr. recommended that previous recommendations by Dr. be pursued. She recommended Lexapro and seeing a psychiatrist for depression. She started him on Elavil for postconcussion symptoms and Norco for headache. She planned to recheck him in one month.

03/14/13: Correspondence from Coventry Health Care indicated that the claimant had shown suicidal tendencies back in November 2012 when he wandered into a highway under the influence of drugs/medication.

04/02/13: Correspondence from states: "I talked to UR nurse and she told me the Peer Review doctor agrees that you need the cochlear implant; however, he talked to at Dr office yesterday as the Peer Dr. needs to know if they have checked to see if another brand of the cochlear implant would be just as good as

there is a big cost difference between the brand Dr. is proposing and others available. The UR nurse is hopeful this will be resolved quickly and we can proceed. Sorry about the delay. ”

04/02/13: UR performed by, MD. RATIONALE: “Based on the records submitted, the requested service, cochlear implantation, has not been documented to be medically necessary. There were no audiograms submitted for review, but instead written summaries of patient testing results. The test results indicate a difference between patient voluntary responses to pure tones (none), and involuntary responses. The latter indicates the patient might have some residual hearing, and that question requires further testing. A summary of medical records was provided wherein it was noted that the patient experienced a blast injury on xx/xx/xx and was diagnosed with complete bilateral hearing loss. However, ABR testing showed click response at 90 dB down to 60 dB. Voluntary responses to pure tones indicated total absent of sound perception in both ears at the loudness capacity of the audiometer, which seems factitious in light of the involuntary ABR results. AZbio was 0% in both ears aided (Phonak Maxx 311 Forte BTE). According to audiologists, “These test results were indicative of a significantly worse hearing loss than would be expected with present OAE and acoustic reflexes.” Said another way, an experienced audiologist would expect some voluntary response to sound stimulation given the presence of involuntary responses to OAE and acoustic reflex testing. The patient also has dizziness with no mention of tinnitus. In this case, the exact amount of residual hearing in both ears is uncertain at this point as well as the amount of possible spontaneous return of hearing after the sudden hearing loss, if any, remains to be defined. Prior to cochlear implantation of any ear, which is a surgical procedure that often destroys residual functional inner ear structures, and precludes the use of that ear in the future for any type of hearing other than electrical stimulation, it is incumbent on the treatment team to establish unequivocally that the patient’s hearing is, in fact, permanently gone and/or functionally absent. Such proof of loss of usable hearing requires non-voluntary audiological testing such as acoustic reflexes, evoked response emissions, or similar, and in this case that testing did not establish the presence of a profound hearing loss, or complete anacusis. Test/retest error and consistency must be established, and there must be writing evidence of the patient’s motivation, ability and willingness to undergo necessary rehabilitation services to insure success of the cochlear implant. Neurological and psychological assessment would be important in that respect, and has not occurred to date. The audiological data in this particular case does not establish unequivocally the medical necessity of a cochlear implant at this particular time.”

04/08/13: The claimant was reevaluated by, MD. He stated that he was doing about the same. He did not have side effects from either the Elavil or Lexapro. He did not feel that his depression had changed in any way. Dr. recommended that he continue with vestibular exercises. She planned to increase the Elavil and recheck him in one month. She recommended psychiatric evaluation and treatment.

04/09/13: Letter of Medical Necessity by, MD/, AuD. **MEDICAL NECESSITY:** “meets the FDA qualifications for a cochlear implant, and it is medically necessary for him to receive one. Alan presents with bilateral complete non-functional hearing loss (no response to pure tones at the limits of the equipment bilaterally). The cochlear implant is an auditory prosthesis that is the only accepted medical treatment for Alan’s condition. In addition, testing reveals that Alan receives no benefit from conventional hearing aids. Specifically, while wearing amplification, he scored 0% on AzBio sentence testing in quiet. Moreover, even with conventional amplification, Alan cannot understand speech.” **ADDITIONAL ASSESSMENT:** “Alan was evaluated by Neurologist Dr. on 03/13/13, who agreed that regaining hearing is crucial for him. She observed no reaction to loud noises, and no ability to understand oral speech. It is Dr. opinion that the fact that he cannot hear and cannot interact well with his family is significantly contributing to his PTSD and depression. She supports the recommendation for cochlear implantation.” **Billing/Coding Information:** The ICD-9-CM diagnosis code for condition is 389.18. The billing codes for this procedure and prosthetic equipment are: 69930, L8614, 92584, 95940, 95867, and 69990. We have requested placement of an Advanced Bionics device, with Neptune and ear-level processor. The total cost for all internal and external equipment is \$33,500. This is comparable to the other leading manufacturer of cochlear implants (Cochlear Americas), whose internal and external equipment costs \$35,700.”

**ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:**

The previous adverse decisions are overturned. It is my opinion that the claimant has met criteria for cochlear implant. He does not have any response to conventional hearing aids. He has bilateral profound hearing loss. There is inconsistency between his voluntary thresholds and the ABR; however, the ABR is not a criteria for cochlear implant. Since there is the clinical disparity between the ABR and voluntary thresholds, I recommend only a single implant to determine if he has benefit prior to considering implantation of the opposite ear. Therefore, the request for Cochlear Implants/Cochlear Device System is medically necessary.

ODG is silent regarding cochlear implants.

**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- INTERQUAL CRITERIA**
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- MILLIMAN CARE GUIDELINES**
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- TEXAS TACADA GUIDELINES**
- TMF SCREENING CRITERIA MANUAL**
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**