Initial Public Comment Cochlear Implantation
CAG-00107N July 8-August 8, 2004

Commenter: Anderson, John
Organization: Date: July 19, 2003 Comment:

I support upgrading the guidelines for cochlear implant qualification in medicare to match the FDA guidelines that are fully supported by a wide body of clinically approved data.

Commenter: Baltodano, Shelley, MS, CCC-A
Organization: Date: July 16, 2004 Comment:

I am in support of the NCD request recently submitted by Cochlear Americas. Medicare eligibility guidelines as they stand exclude individuals that will benefit from cochlear implantation and inhibits them from improving their quality of life. I work with several patients in our center that are examples of how life can improve with cochlear implantation. Patient ages range from 15 years through 95 years, and all report similar feelings regarding cochlear implantation and the benefits they receive. Our 80-year-old recipients score comparatively to our younger recipients and are still living a full life with the assistance of the cochlear implant. Many of my elderly patients live alone and come to appointments on their own. They are happier because they do not have to rely on others for assistance. I know they depend on their implants because they are devastated when the processor malfunctions and consider it a crisis. Furthermore, they are extremely grateful when hearing is restored. The cochlear implant changes their life. It gives them the opportunity to continue with their lives as if hearing loss was not a life altering disability. Besides these mentioned benefits, patients display an improved temperament and are much healthier overall. LetÆs face it hearing impairment makes a person irritable, depressed, and isolated from the world. How long could you go on like that? Would age change the way you feel? Be honest. Devastation from hearing impairment set aside, in many cases I must counsel the candidate the hearing impairment is not severe enough to qualify for cochlear implantation under Medicare guidelines and they are too old to qualify under FDA guidelines. You can imagine the disappointment.
Additionally, the current Medicare criteria regarding speech understanding is obsolete. Research proves that residual hearing influences cochlear implant rehabilitation and outcomes. Recipients that are implanted with residual hearing take less time to rehabilitate, are more likely to continue working and participating in social activities, and achieve higher performance from their implant. Many implant recipients are able to use the telephone, understand simple speech without the assistance of lipreading, and maintain their independence. If not rehabilitated, profoundly deaf individuals lose their desire, ambition, and hope. Why wait until the point of distress? We have the opportunity to facilitate rehabilitation before suffering takes place. Literature demonstrates the ability of aural rehabilitation to restore self-worth, wellness, and quality of life. Also, implantation has proved to be cost-effective.

Please revise the Medicare and Medicaid coverage language to reflect the current FDA eligibility standards. Many hearing impaired people will thank you. Your concern for their well being will not go unnoticed. This request is asking that Medicare assume the guidelines upheld by the FDA for criteria regarding speech perception and age. It should in no way influence the existing evaluation procedures for physical and mental health of the patient. Discrimination based on age and insurance carrier is inappropriate and should be resolved. I urge you to consider this carefully. Thank you for your time.

Commenter: Blevins, Nikolas
Organization: Stanford University Date: August 9, 2004
Comment:

As a cochlear implant surgeon at an academic institution, I strongly encourage the CMS to adopt new guidelines for the indications for cochlear implantation. The suggestions for revision have been submitted by Cochlear Americas Corp, and address the improved outcomes found in elderly as well as very young patients.

Consideration in bringing the CMS policies in line with evolving outcomes evidence is critical to provide patients with the benefits offered by cochlear implant technology.

Commenter: Brackmann, Derald
Organization: House Ear Clinic Date: July 19, 2004 Comment:

I am writing in support of the request for a national coverage determination (NCD) recently submitted by Cochlear Americas. Medicare eligibility guidelines for cochlear implantation must be revised. By revamping coverage language, CMS will improve outcomes among individuals 65 years and older; align Medicare guidelines with FDA approved indications; align more closely with audiological/medical standards generally accepted by the cochlear implant community; remove discrimination in coverage based upon payer or type of health insurance; promote enhanced quality of life, improved general health status, relief of depression and participation in health care decisions among a larger segment of the elderly with hearing loss.

Technological advances and observed, improved patient outcomes have expanded the clinical parameters of cochlear implantation. CMS last revised coverage guidelines in April of 1998. Since then, criteria for candidacy associated with post-implant outcomes have undergone considerable change. Foremost among those changes is the notion that higher pre-implant speech perception scores are associated with better post-implant outcomes in the adult population. Published literature strongly supports the validity of this assertion.

A related issue, and one relevant to CMS program objectives of promoting access and eliminating health disparities, is the issue of age. Published literature supports the notion that there is no difference in cochlear implantation outcomes for seniors versus a younger population, that is, age is not a predictor of outcome or benefit.

Additionally, there are other important factors related to this intervention. The impact of hearing loss on general health and quality of life particularly in older patients, and the cost effectiveness of implantation. Hearing loss in elderly patients is known to contribute to depression, a subjective decrease in well-being and quality of life, social isolation and a reduction in functional capacity. Aural rehabilitation, including cochlear implantation, has been shown to decrease depression and increase a sense of self-worth in hearing impaired persons. Implantation has been found to provide cost effective benefits to recipients.

Thank you for your attention to this matter.

Commenter: Bradham, Tamala
Organization: Vanderbilt Bill Wilkerson Center Date: July 21, 2004 Comment:

I am writing in support of the request for a national coverage determination (NCD) recently submitted by Cochlear Americas. Medicare eligibility guidelines for cochlear implantation must be revised. By revamping coverage language, CMS will:

ò Align Medicare guidelines with FDA approved indications; ò Remove discrimination in coverage based upon payer or type of health insurance; ò Improve outcomes among individuals 65 years and older; ò Promote enhanced quality of life, improved general health status, relief of depression and participation in health care decisions among a larger segment of the elderly with hearing loss.

CMS last revised coverage guidelines in April 1998. Due to technological advances, improved patient outcomes have expanded the clinical parameters of cochlear implantation. Since then, criteria for candidacy associated with post- implant outcomes have undergone considerable change as reflected in the changes in FDA guidelines for implantation. Foremost among those changes is the notion that higher pre-implant speech perception scores are associated with better post-implant outcomes in the adult population. Peer-reviewed published literature strongly supports the validity of this assertion.

A related issue, and one relevant to CMS program objectives of promoting access and eliminating health disparities, is the issue of age. Published literature supports the notion that there is no difference in cochlear implantation outcomes for seniors versus a younger population, that is, age is not a predictor of outcome or benefit. Duration of deafness, however, is a predictor of success. The greater the duration of deafness, the less benefit the person receives from the implant.

Additionally, there are other important factors related to this intervention: the impact of hearing loss on general health and quality of life particularly in older patients, and the cost effectiveness of implantation. Hearing loss in elderly patients is known to contribute to depression, a subjective decrease in well-being and quality of life, social isolation and a reduction in functional capacity. Aural rehabilitation, including cochlear implantation, has been shown to decrease depression and increase a sense of self-worth in hearing impaired persons. Implantation has been found to provide cost effective benefits to recipients.

In my former practice, many people could not receive the cochlear implant based on the current Medicare guidelines due to having some residual hearing in the low frequencies or speech scores slightly above 30%. This was very frustrating to my patients and in some cases, caused even further depression and withdrawal from their friends and family. For my patients who had some residual hearing, measurable sentence scores, and private insurance, they always performed better with their ônew hearingö provided by the cochlear implant than for those who had minimal, if any, measurable hearing sensitivity.

I strongly agree with the need to revise CMS coverage guidelines and support Cochlear AmericasÆ request for a concomitant national coverage decision. I ask that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Breneman, Alyce
Organization: Clinic Date: August 2, 2004 Comment:

I agree with the need to revise CMS coverage guidelines for cochlear implantation and support the request that has been submitted by Cochlear America. Criteria for candidacy have changed significantly in recent years. By changing coverage, CMS would align medicare quidelines to be in line with FDA approved guidelines. Research has shown that higher pre-implant scores are associated with better outcomes with an implant. This would improve outcomes for individuals age 65 and older, would remove discrimination based on insurance, and would enhance the quality of life for this population.

I ask you to revise Medicare coverage language to reflect current eligibility standards accepted by the cochlear implant providers.

Commenter: Staecker, Hinrich, MD Antonio, Stephanie Moody, MD Brightwell, Toni, M.S., CCC-A Erskine, Cara, CCC-SLP/A
Organization: University of Maryland Date: July 29, 2004 Comment:

We are writing this letter in support of Cochlear AmericaÆs submission to request for a national coverage determination. The current Medicare eligibility guidelines for cochlear implantation need to be changed. By changing the current CMS guidelines to meet FDA approved standards of <50% sentence scores pre-implant, CMS will ensure that those 65 and over will have improved outcomes, a better quality of life, and overall better mental and physical health. It is imperative to not discriminate coverage based on type of health insurance. All health coverages need to be united to meet the standards accepted in the cochlear implant community.

Over the years the advances in cochlear implant technology has warranted the expansion of inclusion criteria of cochlear implantation. Since 1998, when CMS last revised the candidacy criteria the outcomes have improved dramatically. One of the most important changes has been the correlation between higher pre-implant speech perception scores and the improved post implant outcomes in the adult population and this has been widely documented in the literature. Another issue is that age has no bearing on cochlear implant outcomes. The elderly do just as well as a younger adult population.

Furthermore, it is important to understand the impact hearing loss can have on individual, especially the elderly. Hearing loss is known to be a contributing factor in social isolation, depression, poor quality of life, overall general poorer health. The combination of cochlear implantation and aural rehabilitation have been shown to improve a hearing impaired individualÆs self esteem and also has been found to be cost effective.

We believe that Cochlear AmericaÆs request exemplifies current cochlear implant literature and gives valid reason to change the current cochlear implant inclusion criteria. We agree with the need to revise CMS coverage guidelines and support Cochlear AmericaÆs request for national coverage determination. We ask that you consider amending Medicare coverage language to reflect current criteria.

Commenter: Buckler, Lisa
Organization: Midwest Ear Institute Date: July 21, 2004
Comment:

Imagine that you were only able to understand 50% of what was said to you, even with the most powerful hearing aids available. Now imagine that you can only understand 50% of what is said to you and you have Medicare. Your audiologist would have to tell you there is nothing that can be done to help you. In fact, to be eligible for any hearing help you have to be able to understand less than ONE THIRD of what is said to you.

This is the situation that many of my patients have faced. These patients are withdrawing from society, leaving jobs that they can no longer perform, claiming disability that has ongoing costs for CMS, rather than the more limited costs of the surgical procedure.

Also consider that our best performing patients are those with residual hearing. Patients who have residual, usable hearing have nerve endings that are still intact and are better able to assimilate the new information coming into the hearing nerve.

I whole-heartedly agree with the need to revise CMS coverage guidelines and support Cochlear Americas' request for a concomitant national coverage decision. I ask that you revise Medicare coverage to reflect current eligibility standards.

Commenter: Carter, Barbara
Organization: MED-EL Corporation Date: August 6, 2004
Comment:

On behalf of MED-EL Corporation, one of the three multi-channel cochlear implant manufacturers, I am writing in support of Cochlear CorporationsÆ request for national coverage determination to expand MedicareÆs current coverage guidelines for cochlear implantation (CIM 65-14). Last amended in 1998, candidacy guidelines must be revised to align with current FDA approved indications and generally accepted medical/surgical standards in the cochlear implant community.

As cochlear implant technology has improved, clinically we have seen expanded parameters for candidacy. Patients with moderately severe hearing loss and pre-operative speech perception scores between 30% and 50% are being successfully implanted. Likewise, patients with speech perception scores in the >50% range show significant improvement post-operatively and, in fact, they often reach scores equal to their normal hearing peers. This has been shown across all populations from young children to geriatrics, there does not seem to be a predictor with relation to age of patient.

Preservation of residual hearing with a cochlear implant has become a regular occurrence. In the past it was presumed that the introduction of a cochlear implant into the cochlea would destroy any remaining hearing a patient had, however, there may be substantial residual hearing capabilities with current atraumatic electrode arrays. By preserving the cochlear structures it is possible for individuals with better preoperative hearing to be implanted successfully. These patients are able to use a cochlear implant and incorporate their viable hearing in concert, which could significantly improve their post- operative scores as well as daily quality of life.

The most common predictors for cochlear implant benefit appear to be duration of deafness and speech perception ability with age of patient playing little to no role. To investigate the effects of pre-operative speech reception on post- operative speech recognition in cochlear implant patients, Rubinstein et al. (1999) compared postlingually deafened adults with and without residual speech reception and found that patients with higher levels of preoperative speech reception (40% CID, highest FDA approved indication at that time) perform significantly better than patients with less preoperative speech perception. More recent studies (Kelsall et al. and Shin et al.) compared implant performance in the elderly and younger adult patients analyzing the relationship between pre- operative and post-operative speech perception and found that elderly patients perform comparably to younger adult patients with matched years of deafness, despite the possible existence of age related auditory processing difficulties. When these predictors are comparable the elderly patient and the young patient will also likely need a similar amount of rehabilitation/habilitation to be a successful cochlear implant user. Thus, expanded coverage language under the Medicare program is necessary to provide Medicare beneficiaries the same access to the cochlear implant technology afforded to other non-Medicare young adult cochlear implant candidates.

The audiological benefits provided to cochlear implant patients significantly improves the quality of life for these patients, particularly in the senior population. Feelings of depression, isolation and loss of independence characterize the relationship between hearing loss and an individualÆs perception of quality of life. Studies comparing the quality of life of elderly cochlear implant patients to those below the age of 60 revealed comparable improvements in speech recognition and quality of life in both patient populations. Additionally, the cost- utility of cochlear implantation in elderly patients has been shown to provide cost-effective benefits (Wyatt et al).

As electrode design and implant technology are improved, surgical techniques refined, and increasingly positive results of implantation demonstrated, individuals with more residual hearing will be considered as implant candidates. Open-set speech understanding is now a realistic outcome for the majority of post- lingually deafened adults and some children. Aligning MedicareÆs candidacy criteria with current FDA indications and generally accepted medical standards in the cochlear implant community will ensure Medicare beneficiaries access to advances in cochlear technology and eradicate health disparities resulting from age.

Based on the peer reviewed medical literature, advances in cochlear technology and accepted medical standards in the cochlear implant community, it is imperative that the candidacy criteria for cochlear implantation under the Medicare program be revised to include patients with pre-operative sentence scores up to 50% to allow equal access to all cochlear implant candidates, regardless of age, and promote continued health care improvements.

Commenter: Clarke, Christine K., M.S., CCC-A
Organization: Brigham & Women's Hospital Date: July 17, 2004 Comment:
If the FDA deems that cochlear implantation is beneficial with poorer than 60% sentence recognition, Medicare should align their guidelines to match the FDA and pay for implantation on adults with poorer than 60$ sentence recognition. It is unacceptable that patients with poor speech discrimination have to struggle to communicate with others when there is help available. Too many of my patients could benefit greatly with a cochlear implant. Please change the standard to include payment for cochlear implant candidates with sentence recognition scores poorer than a %60.

Commenter: **Dahlstrom, Lisa** Organization: University of
Utah ENT Date: July 15, 2004 Comment:

I am writing in support of the request for a national coverage dtermination (NCD) recently submitted by Cochlear Americas. Medicare eligibility guidelines for cochlear implantation must be revised. By revamping coverage language, CMS will:

-Improve outcomes amoung individuals 65 years and older; -Align Medicare guidelines with FDA approved indications;

-Align more closely with audiolgical/medical standards generally accepted by the cochlear implant community;

-Remove discrimination in coverage based upon payer or type of health insurance;

-Promote enhanced quality of life, improved general health status, relief of depression and participation in health care decisions among a larger segment of the elderly with hearing loss.

As advances have been made in cochlear implants, convidence has also been established in the usefulness of this device in improving the quality of life for all hearing impaired individuals. As an audiologist I have seen significant improvements for many of our patients who have been getting only limited benefit from hearing aids. By expanding the criteria for implant recipents we are better able to meet the needs of all patients.

I believe that Cochlear Americas' submission accurately represents current cochlear implant literature and provides a platform for change. I agree wiht the need to revise CMS coverage gudelines and support Cochlear Americas' request for a concomitant national coverage decision. I ask that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Dierkes, Audra
Organization: Date: August 9, 2004 Comment:

I am writing in support of the request for a national coverage determination (NCD) recently submitted by Cochlear Americas. Medicare eligibility guidelines for cochlear implantation must be revised! Revising the coverage language for cochlear implantation will allow CMS to: ¶ Improve outcomes among individuals 65 years and older; ¶ Align Medicare guidelines with FDA approved indications; ¶ Align more closely with audiological/medical standards generally accepted by the cochlear implant community; ¶ Remove discrimination in coverage based upon payer or type of health insurance; ¶ Promote enhanced quality of life, improved general health status, relief of depression and participation in health care decisions among a larger segment of the elderly with hearing loss.

Technological advances and observed, improved patient outcomes have expanded the clinical parameters of cochlear implantation. CMS last revised coverage guidelines in April 1998. Since then, criteria for candidacy associated with post-implant outcomes have undergone considerable change. Foremost among those changes is the idea that higher pre-implant speech perception scores are associated with better post-implant outcomes in the adult population.

Published literature strongly supports the validity of this assertion. A related issue, and one relevant to CMS program objectives of promoting access and eliminating health disparities, is the issue of age. Published literature supports the notion that there is no difference in cochlear implantation outcomes for seniors versus a younger population, that is, age is not a predictor of outcome or benefit.
Additionally, there are other important factors related to this intervention: the impact of hearing loss on general health and quality of life particularly in older patients, and the cost effectiveness of implantation. Hearing loss in elderly patients is known to contribute to depression, a subjective decrease in well-being and quality of life, social isolation and a reduction in functional capacity. Aural rehabilitation, including cochlear implantation, has been shown to decrease depression and increase a sense of self-worth in hearing impaired persons. Implantation has been found to provide cost effective benefits to recipients.

I believe that Cochlear AmericasÆ submission accurately represents current cochlear implant literature and provides a platform for change. I agree with the need to revise CMS coverage guidelines and support Cochlear AmericasÆ request for a concomitant national coverage decision. I ask that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Dosch, Curtis

Organization: Memorial Medical Center Date: August 6, 2004
Comment:

I am writing this comment to support a national determination (NCD) for cochlear implantation. Cochlear Americas has recently submitted this request for revision of Medicare eligibility guidelines for patients receiving cochlear implants. By revising these guidelines, the following will be accomplished: Outcomes for individuals over 65 will be improved, Medicare guidelines will follow approved FDA criteria, there will be more consistency with generally accepted audiological/medical standards, discrimination in coverage based upon type of health insurance or payer will be eliminated and the general health status and quality of life for individuals with hearing loss will be enhanced.

Patient outcomes and technological advances have improved sine the last CMS revised coverage guidelines were published in April 1998. Since this time published literature has shown that higher speech perception test scores, pre- operatively are associated with better post- operative outcomes in the adult population.

A related issue that should be considered with CMS program objectives of eliminating discrepancies in providing health services and promoting access, is the issue of age. Published literature supports the fact that age is not a predictor of outcome or benefit.

The impact of hearing loss on general health and quality of life should be considered.The loss of the ability to communicate can contribute to social isolation and a decrease in functional capacity. Hearing loss in the elderly population has been known to contribute to depression. Cochlear implantation with aural rehabilitation has been shown to enhance communication abilities and increase a sense of self-worth in the hearing impaired population.

Cost effectiveness is another factor related to this intervention. Cochlear implantation has been found to provide cost effective benefits to recipents.

Our hospital has performed over 200 cochlear implant surgeries. Many of the individuals receiving these implants have been Medicare recipents. The majority of these patients have demonstrated improvements in speech, language and auditory abilities as well as enhancements regarding the general quality of life issues.

The submission from Cochlear America accurately represents published criteria in current literature and indicates the need for a change in the CMS coverage guidelines. I agree with the need for revision and support this request for a concomitant national coverage decision. I ash that you revise Medicare coverage language to reflect current eligibility standards.

Thank you for your consideration.

Commenter: Driscoll, Colin
Organization: Mayo Clinic Date: August 6, 2004
Comment:

I am writing in support of Cochlear America's submission requesting a change in eligibility guidelines for cochlear implantation.

The cochlear implant has a tremendously positive impact on the lives of patients with hearing loss. As an Otolaryngologist and cochlear implant surgeon I have been priviliged to care for hundreds of patients with severe to profound hearing loss. The effects of severe to profound hearing loss on general health and quality of life is significant and should not be underestimated. The cochlear implant alleviates many of these problems and has been shown in a number of studies to be a cost effective intervention in adults and children. I have participated in a study looking specifically at outcomes in adults over age 70 (Cochlear Implant Outcomes in the Elderly, Otology Neurotolgy, 2004 May:25(3):298-301). This study demonstrated that this population performs almost as well as younger groups and clearly gains significant benefit. It has been clear in the literature and day-to day clinical practice that the eligibility guidelines for medicare need to be revised. Patients with more residual hearing should be candidates and discrimination based on age or payor should no longer be accepted.

I strongly support the submission from Cochlear America's and it accurately reflects what is currently reported in the scientific literature. Urgent updating is needed to allow these hearing impaired patients the opportunity to benefit from this incredible technology.

Commenter: Ford, Megan
Organization: Date: July 21, 2004 Comment:

I support the request for a national coverage determination (NCD) (recently submitted by Cochlear Americas). We need to revise CMS coverage guidlines!!!PLease revise Medicare coverage language to reflect current eligibilty standards. Thank you

Commenter: Gans, Richard, Ph.D.
Organization: American Academy of Audiology Date: August 6, 2004 Comment:

Support for Request to Revise Current Guidelines

The American Academy of Audiology, representing over 9,000 audiologists, supports the request for a national coverage determination (NCD) to revise the current Medicare eligibility guidelines for cochlear implantation. In doing so, a number of important outcomes will be realized that include: 1) greater hearing and communication outcomes for individuals 65 years and older, 2) Medicare guidelines that are comparable to FDA-approved guidelines and to those currently utilized by cochlear implant centers, 3) similar candidacy criteria to all patients with significant hearing loss regardless of health insurance type, therefore eliminating possible discrimination, and 4) improved quality of life and well being to the elderly who struggle to communicate due to severe or profound hearing loss.

Current Candidacy Criteria

The criteria for adult cochlear implant candidates have changed over time due to advancements in speech recognition associated with technological improvements. Presently, the majority of adults who have received cochlear implants show substantial pre-to-post operative improvements on tests of speech recognition as early as 1-3 months post-implant, and most understand speech without lipreading cues. Additionally, FDA-approved guidelines for cochlear implantation of all devices available in the United States have been broadened to include individuals with greater amounts of residual hearing. Even though these candidates may also achieve relatively higher speech perception scores when wearing optimal hearing aids, their performance with a cochlear implant may be significantly greater compared to their aided performance. Published research indicates that pre-implant hearing experience is a significant predictor of post-implant performance.

Effects of Age on Cochlear Implant Performance

Age is not a contraindication for cochlear implant candidacy. In the elderly population, significant improvements have been shown for speech perception scores following cochlear implantation compared to pre-implant scores obtained with powerful well-fit hearing aids. Published studies have also demonstrated that outcomes for those over the age of 65 years are similar to those individuals implanted at ages younger than 65. , Elderly patients, therefore, receive the same benefits of cochlear implantation as younger patients, which includes the ability to understand sentences without lipreading and thus converse on the telephone, to detect soft speech and environmental sounds, and even to enjoy music.

Impact of Substantial Hearing Loss on Quality of Life

Cochlear implantation has been shown to provide cost-effective benefits to patients. Significant hearing loss results in social isolation, depression, increased fatigue and a reduction in quality of life. The consequences of either severe or profound hearing loss can have an even greater impact for the elderly person who is facing the effects of age. Aural rehabilitation to maximize hearing benefit, including cochlear implants, has been shown to reduce the negative effects of significant hearing loss and improve quality of life.

Support of the American Academy of Audiology

The American Academy of Audiology supports: 1)efforts to revise CMS coverage guidelines, 2)the request for a national coverage decision, and 3)uniformity in guidance provided by the FDA and CMS.

We ask that you revise Medicare coverage language to reflect current eligibility standards expanded in 2000 by the FDA.

The American Academy of Audiology is the largest professional audiology organization in the country, representing over 9,000 audiologists. Audiologists have received MasterÆs or Doctoral degrees from accredited university graduate programs to diagnose, treat, and manage hearing loss and balance problems.

Commenter: Gary, Lucinda B., MA
Organization: Atlanta Cochlear Implant Group Date: July 19, 2004 Comment:

Thank you for accepting public input on the Medicare coverage guidelines for cochlear implantation. I am a clinical audiologist working in cochlear implants in a major metropolitan area. Our office sees a wide range of patients from babies recently identified with hearing loss to adults over the age of 80. I have participated in several Food and Drug Adminstration clinical trails addressing the safety and effectiveness of cochlear implants in children and adults. In every clinical trail I have found the testing both pre-surgically and post-surgically to be extensive and comprehensive. The clinial trials have attempted identify the factors leading to success with cochlear implant use, and provide patients with access to a technology that is safe for long term use and effective in providing a significant improvement is speech understanding ability. The cochlear implant manufacturers have provided numerous studies on the safety and efficacy of implants and the medical community has done

independent research on the questions of candidacy, aural habilitation and speeech coding strategies. The Food and Drug Administration has reviewed the studies, held public hearings on the information and determined that cochlear implants are a safe and effective treatment for patients with severe to profound hearing loss and less than 50% speech discrimination on sentence material. However, Medicare uses the guideline of less than 30% speech discrimination for approval to have cochlear implant surgery. The FDA is charged with the task of reviewing scientific studies and determining what treatments are safe and effective. The Ear, Nose and Throat Advisory Panel of the FDA is well versed in cochlear implantation and the panel is comprised of professionals with extensive training in medicine and clinical study analysis. The ENT Advisory panel recognized the benefits of implanting patients with higher speech discrimination ability in 1998 when they recommended raising the guideline to 40% correct speech discrimination and again in 2000 when the guideline was raised to its current score of 50% correct speech discrimination. This disparity in guidelines leaves Medicare patients with decreased access to cochlear implantation and causes patients to wonder why the current medical research has satisfied the concerns of the FDA but has not been made a part of Medicare policy. I urge you to review the medical literature supporting cochlear implantation in patients with severe to profound hearing loss and up to 50% correct word discrimination ability and change the Medicare guidlines to reflect the current FDA recommendations. Thank you very much.

Commenter: Geier, Lisa, PhD, CCC-A
Organization: St. John's Cochlear Implant Program Date: Thu, Jul 15, 2004 7:24 PM Comment:

I wanted to make a comment about the Medicare Coverage Guidelines for cochlear implantation. I support the request by Cochlear Americas to revise the current Medicare coverage language for cochlear implantation. Those of us who see patients benefit from cochlear implants know that the more speech recognition they have pre-implant, the better they do post-operative despite age at implantation. Please help a subset of people that could obtain significant improvement in hearing, speech understanding, quality of life, improved communication with medical care givers and family. I see this miracle every day, but we are missing some people because their hearing just isn't quite "bad enough", even though we know they would benefit from a cochlear implant even more than the profoundly deaf individual!

Commenter: Gilden, Jan
Organization: Houston Ear Research Foundation Date: July 16, 2004 Comment:

I am writing in support of the request for a national coverage determination (NCD) recently submitted by Cochlear Americas. I am involved as the Director and an audiologist with Houston Ear Research Foundation, a cochlear implant center, which has been providing cochlear implants for over 21 years. We have implanted and worked with over 750 cochlear implant recipients, both pediatric and geriatric. We have seen the technological advances in cochlear implantation during the past 20 years and have observed candidacy criteria change during this time as a result of technological advances. As a result, we have also observed more individuals benefit from the cochlear implant technology and enrich the quality of their lives. Medicare eligibility guidelines for cochlear implantation must be revised. By revamping coverage language, CMS will:

1)improve outcomes among individuals 65 years and older. At our center, we routinely evaluate cochlear implant candidates over 65 years of age, many over 70, and even over 80. After receiving the cochlear implant, these individuals once again have been able to participate in family activities. We hear from their families that we have enriched their lives and returned their family members to them.

2) Align Medicare guidelines with FDA approved indication. It is well documented that the younger we implant babies, the better is the long-term results with cochlear implants. We have seen over and over again how implanting at 12 months of age reduces the deficiency of hearing loss so by the time that child is school age, they are able to be mainstreamed without missing a beat.

3) Align more closely with audiological/medical standars generally accepted by the cochlear implant community.

4) Remove discrimination in coverage based upon payer or type of health insurance.

5) Promote enhanced quality of life, improved general health status, relief of depression and participation in health care decisions among a larger segment of the elderly with hearing loss.

Technological advances and observed, improved patient outcomes have expanded the clinical parameters of cochlear implantation. CMS last revised coverage guidelines in April 1998. Since then, criteria for candidacy associated with post-implant outcomes have undergone considerable change. Foremost among those changes is the notion that higher pre-implant speech perception scores are associated with better post-implant outcomes in the adult population. Published literature strongly supports the validity of this assertion. A related issue, and one relevant to CMS program objectives of promoting access and eliminating health disparities, is the issue of age. Published literature supports the notion that there is no difference in cochlear implantation outcomes for seniors vs a younger population, that is, age is not a predictor of outcome or benefit. Additionally, there are other important factors related to this intervention: the impact of hearing loss on general health and quality of life particularly in older patients, and the cost effectiveness of implantation. Hearing loss in elderly patients is known to contribute to depression, a subjective decrease in well-being and quality of life, social isolation and a reduction in functional capacity. Aural rehabilitation, including cochlear implantation, has been shown to decrease depression and increase a sense of self-worth in hearing impaired persons. Implantation has been found to provide cost effective benefits to recipients. I believe that Cochlear Americas' submission accurately represents current cochlear implant literature and provides a platform for change. I agree with the need to revise CMS coverage guidelines and support Cochlear Americas' request for a concomitant national coverage decision. I ask

that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Johnson, Megan, MA, CCC-A
Organization: The Speech and Hearing Center Date: July 30, 2004 Comment:

This is a letter to document my immense support for prompt revision of the existing Medicare coverage policy for cochlear implantation and mapping procedures. As a Cochlear Implant Audiologist, I have witnessed the improved quality of life and participation among the elderly cochlear implant recipients. Hearing loss is detrimental to a personÆs ability to communicate and converse with the hearing world. Elderly persons withdraw from family members and society when they have difficulty hearing and understanding conversation. Cochlear implants have rescued the patients that no longer benefit from powerful hearing aids. Elderly patients that lose their hearing in adulthood usually continue to verbally communicate with descent speech and can easily learn to hear through the cochlear implant.

From a research perspective, elderly patients can provide feedback about the processors, mapping procedures, and overall speech perception with their cochlear implant. Children can have a difficult time expressing their hearing capabilities that help the audiologist fine-tune the processor. Elderly cochlear implant recipients are critical to training audiologists and promoting the on-going advances in cochlear implant technology.

Audiologists serve as an influential part of the cochlear implant team for assessing and evaluating cochlear implant candidates. Audiologists are specially trained to map the cochlear implant processors, from the initial stimulation to unlimited follow-ups. In addition, training includes testing procedures to document improvement over time (pre- and post- implantation) and trouble-shooting.

Medicare should not separate the cochlear implant candidate based on the type of healthcare coverage or age of the candidate. It is the surgeonsÆ responsibility to consider the patientÆs medical contraindications, as well as, short-term and long-term benefit from the implant. Surgeons and audiologists are legally obligated to abide by the FDA guidelines and Medicare should administer their guidelines with FDA, as well.

I am certain that Medicare wants to promote the improved quality of life for their patients, and to reasonably compensate their providers. I appreciate all consideration given to this issue.

Commenter: Larky, Jan

Organization: University of California, San Francisco Date: July 23, 2004 Comment:

I am writing to request that CMS revise Medicare eligibility guidelines for cochlear implantation. By altering (updating) the coverage language, CMS will

1. Align Medicare guidelines with the FDA approved indications
2. Improve outcomes for individuals 65 years and older
3. Align more closely with audiological/medical standards generally accepted by those of us who work with cochlear implant candidates and recipients on a daily basis
4. Remove discrimination in coverage based upon payer or type of health insurance
5. Promote enhanced quality of life, improved general health status, relief from depression and participation in health care decisions among a larger segment of the elderly with hearing loss

Candidacy criteria have expanded over the past 20 years. Certainly technological advances have contributed tremendously, as have clinical expertise in candidacy selection. CMS last revised coverage guidelines in April 1998 and these are woefully out of date with current standards. Predominant in candidacy selection is the notion that higher pre-implant speech perception scores are associated with better post- implant outcomes in the adult population. This assertion is supported in the literature.

Additionally, is the issue of age and elimination health disparities related to age is central to this request. Published literature (ours included) supports the notion that there is no difference in cochlear implantation outcomes for seniors versus a younger population. In other words, age is not a predictor of outcome. [Chatelin, V, Kim, EJ, Driscoll, C, Larky, J, Polite, C, Price, L, Lalwani, AK. Cochlear implant outcomes in the elderly. Otology & Neurotology 2004, 25(3): 298-301.]

As a clinician I am forced to explain to Medicare recipients that though they meet FDA criteria for implantation they do not meet MedicareÆs criteria for implantation. In other words, if s/he had private coverage an implant would be available. This leaves the candidate with the following two options: (1) continue to monitor hearing on an annual basis and return for evaluation if/when any decrease in hearing sensitivity and/or speech comprehension is noted, and (2) self-pay for the procedure and follow-up care.

Other important factors related to this intervention, which must be considered include: the impact of hearing loss on general health and quality of life particularly in older patients and the cost-effectiveness of implantation overall. Hearing loss contributes towards depression, social isolation, and affects all interpersonal interactions. Most of my patients feel rejuvenated following implantation and feel socially connected once again. ItÆs as though they come out of their shell. Many of the elderly are no longer afraid to be alone, or ride in an elevator alone. (After all, what if the elevator gets stuck and you cannot hear rescue instructions!)

The benefit of implantation is so tremendous and reaches into every aspect of a personÆs life, and the cost-benefit data supports implantation for all segments of the population, including the elderly. It is time for CMS to align coverage with the current standard of care.

Commenter: Lormore, Kelly
Organization: Indiana University Cochlear Implant Team Date: August 9, 2004 Comment:

I am writing in support of the request for a national coverage determination (NCD) recently submitted by Cochlear Americas. Medicare eligibility guidelines for cochlear implantation must be revised! Revising the coverage language for cochlear implantation will allow CMS to: ¶ Improve outcomes among individuals 65 years and older; ¶ Align Medicare guidelines with FDA approved indications; ¶ Align more closely with audiological/medical standards generally accepted by the cochlear implant community; ¶ Remove discrimination in coverage based upon payer or type of health insurance; ¶ Promote enhanced quality of life, improved general health status, relief of depression and participation in health care decisions among a larger segment of the elderly with hearing loss.

Technological advances and observed, improved patient outcomes have expanded the clinical parameters of cochlear implantation several times in the past 5 years. CMS last revised coverage guidelines in April 1998. The criteria for candidacy associated with post-implant outcomes changed considerably! Foremost among those changes is the idea that higher pre-implant speech perception scores ARE associated with better post-implant outcomes in the adult population.
There are several publications that strongly supports and validate this assertion. A related issue, and one relevant to CMS program objectives of promoting access and eliminating health disparities, is the issue of age. Published literature supports the concept that there is no difference in cochlear implantation outcomes for the senior population versus a younger population. AGE is NOT a predictor of outcome or benefit.

Among the other important factors related to this intervention: the impact of hearing loss on general health and quality of life particularly in older patients, and the cost effectiveness of implantation. Hearing loss in elderly

patients is known contributor to depression, a subjective decrease in well-being and quality of life, social isolation and a reduction in functional capacity. Aural rehabilitation, including cochlear implantation, has been shown to decrease depression and increase a sense of self-worth in hearing impaired persons. Implantation has been found to provide cost effective benefits to recipients.

I believe that Cochlear AmericasÆ submission accurately represents current cochlear implant literature and provides a platform for change. I agree with the need to revise CMS coverage guidelines and support Cochlear AmericasÆ request for a concomitant national coverage decision. I ask that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Lusis, Ingrida

Organization: American Speech Language Hearing Association Date: August 9, 2004 Comment:

ASHA RECOMMENDATION THAT CMS ADOPT FDA LABELING TO EXPAND
RANGE OF PATIENTS THAT QUALIFY FOR MEDICARE COVERAGE

The American Speech-Language-Hearing Association (ASHA) is the professional and scientific association of more than 114,000 speech-language- pathologists, audiologists, and speech, language, and hearing scientists. We appreciate the opportunity to submit comments regarding the expanded use of cochlear implants.

The indications for this product, as expanded by the Food and Drug Administration (FDA) in November 2000, are reasonable and appropriate for adoption by the Medicare program. We reference the Mayo ClinicÆs cochlear implant program which was established over 20 years ago. The Mayo program commonly performs cochlear implantation of children under two years old because of the high success rate. Former director (1986 û 1994) of the Mayo ClinicÆs implant program, Martin S. Robinette, Ph.D., stated that there are remarkably increased benefits to patients with higher pre-implant speech perception scores (i.e., greater than 30 percent).

Studies have shown that by adopting FDAÆs allowance of higher sentence recognition scores, more adults can benefit from cochlear implantation.
ò The study entitled ôCochlear implants in the geriatric population: benefits outweigh risksö published in the Ear Nose Throat Journal (Buchman CA, Fucci MJ, Luxford WM, 1991 Jul; 78 (7):489-94,) found that, in general, the results of cochlear implantation in the elderly have been comparable with those of younger adults.
ò A 1995 NIH Consensus Statement, Cochlear Implants in Adults and Children, NIH Consensus Statement 1995 May 15-17: 13(2):1-30, found that cochlear implantation improves communication ability in most adults with severe to profound deafness and frequency leads to positive psychological and social benefits.

It has been more than ten years since the Medicare coverage issue º65-14 was revised. CMS does not appear to have a mechanism in place to assure that Medicare beneficiaries benefit from medical and technological developments in the use of cochlear devices. We recommend that an automatic trigger be established for review by CMS whenever the FDA revises its indications for use of the cochlear device.

Please contact Mark Kander, ASHA's Director of Health Care Regulatory Analysis at 800-498-2071, ext 4139 or e-mail mkander@asha.org; or Ingrida Lusis, ASHA's Director of Health Care Regulatory Advocacy at ext. 4482 or email ilusis@asha.org.

Commenter: Mandigo, Debbie
Organization: Date: August 7, 2004 Comment:

My friend has a seven year old son who is 80% deaf in one ear due to Golden Horse Syndrome. She is income eligible and has no insurance. We are looking for an agency that would be able to help provide one hearing aid for him. Please contact me if you know of such an agency that can help.

Commenter: McReynolds, G. Walter
Organization: Houston Ear Research Foundation Date: July 16, 2004 Comment:

I am writing in support of the request for a national coverage determination (NCD) recently submitted by Cochlear Americas. I am involved as the primary surgeon with Houston Ear Research Foundation, a cochlear implant center, which has been providing cochlear implants for over 21 years. We have implanted and worked with over 750 cochlear implant recipients, both pediatric and geriatric. We have seen the technological advances in cochlear implantation during the past 20 years and have observed candidacy criteria change during this time as a result of technological advances. As a result, we have also observed more individuals benefit from the cochlear implant technology and enrich the quality of their lives. Medicare eligibility guidelines for cochlear implantation must be revised. By revamping coverage language, CMS will:

1)improve outcomes among individuals 65 years and older. At our center, we routinely evaluate cochlear implant candidates over 65 years of age, many over 70, and even over 80. After receiving the cochlear implant, these individuals once again have been able to participate in family activities. We hear from their families that we have enriched their lives and returned their family members to them.

2) Align Medicare guidelines with FDA approved indication. It is well documented that the younger we implant babies, the better is the long-term results with cochlear implants. We have seen over and over again how implanting at 12 months of age reduces the deficiency of hearing loss so by the time that child is school age, they are able to be mainstreamed without missing a beat.

3) Align more closely with audiological/medical standars generally accepted by the cochlear implant community.

4) Remove discrimination in coverage based upon payer or type of health insurance.

5) Promote enhanced quality of life, improved general health status, relief of depression and participation in health care decisions among a larger segment of the elderly with hearing loss.

Technological advances and observed, improved patient outcomes have expanded the clinical parameters of cochlear implantation. CMS last revised coverage guidelines in April 1998. Since then, criteria for candidacy associated with post-implant outcomes have undergone considerable change. Foremost among those changes is the notion that higher pre-implant speech perception scores are associated with better post-implant outcomes in the adult population. Published literature strongly supports the validity of this assertion. A related issue, and one relevant to CMS program objectives of promoting access and eliminating health disparities, is the issue of age. Published literature supports the notion that there is no difference in cochlear implantation outcomes for seniors vs a younger population, that is, age is not a predictor of outcome or benefit. Additionally, there are other important factors related to this intervention: the impact of hearing loss on general health and quality of life particularly in older patients, and the cost effectiveness of implantation. Hearing loss in elderly patients is known to contribute to depression, a subjective decrease in well-being and quality of life, social isolation and a reduction in functional capacity. Aural rehabilitation, including cochlear implantation, has been shown to decrease depression and increase a sense of self-worth in hearing impaired persons. Implantation has been found to provide cost effective benefits to recipients. I believe that Cochlear Americas' submission accurately represents current cochlear implant literature and provides a platform for change. I agree with the need to revise CMS coverage guidelines and support Cochlear Americas' request for a concomitant national coverage decision. I ask that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Meyer, Kym
Organization: The Learning Center for Deaf Children Date: Wed, Jul 14, 2004 2:51 PM Comment:

As an audiologist working with children and adults with cochlear implants, it is important that we give people the quality of life they are searching for in conjuction with what is approved by the FDA.

At present, Medicare pays for cochlear implants for people with no greater than 30% sentence recognition in the best binaurally aided condition. FDA guidelines, however, allow cochlear implantation for people with up to 60% sentence recognition in the best binaurally aided condition and up to 50% aided sentence recognition in the ear to be implanted. Therefore, elders with 30-50% sentence recognition fall within the FDA guidelines for implantation but can not get Medicare coverage for it. The FDA guidelines are based on a body of research showing that individuals with cochlear implants achieve, on the average, better than 60% correct sentence recognition. Elders with 30-50% sentence recognition scores have to hope for their hearing to deteriorate, while not hearing enough to converse in the meantime.

Please reconsider approving Medicare funding consistent with the FDA approved guidelines for cochlear implants for our elders. Thank you.

Commenter: Moland, Rene, M.S.
Organization: Atlanta Cochlear Implant Group Date: July 19, 2004 Comment:

I am writing to support the review of the cochlear implantation coverage guidelines for Medicare recipients. I have worked as a cochlear implant audiologist since 1988. I have see the numerous changes in the eligibility guidelines and the amount of benefit received by cochlear implant recipients. Today, cochlear implant patients routinely enjoy word understanding scores of 85% and better after surgery. These patients are able to live independently, make and receive telephone calls and freely communicate with friends, family and health care providers. Cochlear implant patients use this improved speech understanding ability to maintain social contacts, attend to personal business and participate in their own health care decisions. Current Medicare guidelines require a patient to have significantly poorer speech discrimination ability than is recommended by the Food and Drug Administration. There is ample data to support the use of cochlear implantation in patients with severe to profound hearing loss. The social isolation and depression can be crushing for many hearing impaired people. Patients who have been wearing hearing aids up till the time of implant surgery have a higher level of success. Also, patients with higher speech discrimination ability remain in the mainstream of society and subsequent cochlear implantaion allows them to avoid the heavy emotional toll associated with understanding less than one-third of what they hear. Further, currently most third party payors use the FDA guidelines for cochlear implantation coverage, speech discrimination ability of less than 50% of sentence material. The Medicare quideline for coverage is less than 30% word understanding of sentence material. Therefore a patient still working and covered by a employers health plan can receive a cochlear implant where a taxpayer on Medicare with the exact same audiogram and speech discrimination ability can not receive the enormous benefits of a cochlear implant. This is effectively coverage discrimination against Medicare recipients. Based upon my clinical experience,the overwhelming published data supporting cochlear implantation in patients with pre-surgical speech discrimination scores up to 50% correct, and the current FDA guidelines recognizing the benefit of implantation in patients with pre-surgical speech understanding scores up to 50& correct I strongly recommend the Centers for Medicare and Medicaid Services review and change the guidelines for cochlear implantation to mirror the FDA approved indications. Thank you for your time and thoughtful review of my comments.

Commenter: Payne, Stacy M.A., CCC-A
Organization: University of Miami Date: July 28, 2004
Comment:

I am writing regarding the issue of expanding candidacy criteria for a Medicare/Medicaid user to receive a cochlear implant. I am an audiologist who works in the field of cochlear implants and know the benefits they can provide an individual. Current criteria for your organization grossly limits those individuals who can receive a cochlear implant. Your guidelines are markedly below the FDA guidelines AND could be considered discrimination since you are not allowing individuals who have Medicare/Medicaid to receive a cochlear implant that could otherwise do so if they had another insurance. Cochlear implants not only improve hearing but also a quality of life improvement by allowing recipients to have improved social lives, better relationships with significant others as well a allowing some individuals to rejoin the workforce. Denying someone a cochlear implant because of a restricted guideline is NOT acceptable and we strongly urge you to change the candidacy criteria.

Commenter: Peters, Kimberly
Organization: Western Washington University Date: August 9, 2004 Comment:

I am writing to support the request for a national coverage determination recently submitted by Cochlear Americas. Medicare eligibility must be revised to match current FDA eligibility standards. This revision will enhance quality of life, improve general health, and increase participation in health care decisions for elderly individuals with hearing loss.

It is well supported in the literature that hearing loss in the elderly significantly contributes to perception of poor general health, feelings of depression, social isolation, and reduction in function. It has also been well-documented that cochlear implants provide speech perception benefit to individuals with severe to profound hearing loss, regardless of age. Several studies have demonstrated that quality of life is significantly improved for implanted individuals, and that cochlear implants are a cost-effective treatment for severe to profound hearing loss, even in elderly individuals.

As a rehabilitative audiologist, I have had the opportunity to work with numerous children and adults who use cochlear implants, and have seen the tremendous benefit first-hand. Patients report reduced stress during interactions, less fatigue at the end of the day due to decreased listening effort, increased confidence and greater social interaction post-implantation. Aural rehabilitation focused on "active listening" has been shown to have a positive benefit for older individuals with hearing loss. This kind of listening approach is often possible only through the use of a device such as a cochlear implant, which can provide much greater access to speech and language than traditional amplification.

I urge you to revise CMS coverage guidelines to facilitate much needed access to this beneficial technology.

Commenter: Peterson, AnnaMary
Organization: Date: August 3, 2004 Comment:

I support Cochlear America's request for a national coverage determination regarding the eligibility guidelines for cochlear implantation. I would in a large medical facility which has an active cochlear implant program. We have well over 300 patients. It is unfair to our patients to tell them that if they were just a few days younger they could have qualified for an implant but since they are now Medicare age, they no longer qualify for coverage. That is very discriminatory for our older popupation! This is sometimes also true for our Medical Assistance patients. It certainly reflects poorly on our governmently health care programs. In addition to the discrimination that this causes our elderly and low income populations, it prevents those individuals imporved hearing and increased ability to communicate. Improved communication enhances an individual's quality of life, lessens depression and allows individuals to take a more active part in their health care and financial decisions in their later years. Please look positively on this request and bring the eligibility guidelines for Medicare and Mecical Assistance into line with the FDA apprved indications. Thank you for considering this important issue.

Commenter: Peterson-Combs, Mary
Organization: Spectrum Health Butterworth Date: July 27, 2004 Comment:

As an audiologist involved in the fitting and programming of cochlear implants, I felt it was necessary that I comment on the request to bring Medicare guidelines in line with current FDA guidelines. Improved technology has greatly enhanced successful use of the device. My patients, either young or old, receive considerable benefit and tell me they "would never go back to how I was before." The cochlear implant "has given me my life back." They are able to communicate with family and friends. Young deaf children are able to develop speech and language on par with their age peers with the learning gap lessened by their use of the implant.
Current FDA guidelines state that age guidelines for children should be 12 months of age or older. These youngsters make up the language learning gap quite quickly and are able to join their normally hearing peers in regular education classes often before kindergarten.

Current adult FDA guidelines allow for better speech perception scores prior to cochlear implantation. These adults with better pre- operative speech perception outperform those with little or no speech perception. Often within a month of having their device activated they are talking on the telephone and participating in the social and occupational aspects of their lives with ease.

Our center has implanted 43 children and 42 adults in the past 2 years. Our experience with these patients confirm that the FDA guidelines are appropriate selection criteria. Persons with better speech perception skills or shorter length of deafness do much better than those who have been deaf longer or have very poor speech perception skills.

Commenter: Portis, Terry D., Ed.D.
Organization: Self Help for Hard of Hearing People (SHHH) Date: August 9, 2004 Comment:

I am writing in support of the national coverage decision that has been requested by John McClanahan of Cochlear Corporation.

Self Help for Hard of Hearing People (SHHH) is the nationÆs largest membership organization for people with hearing loss. We have almost 300 affiliates throughout the United States, publish a national magazine, and administer a website (hearingloss.org). Through a special division, the Cochlear Implant Association, SHHH provides special services and supports for individuals who have benefited from this important technology.

SHHH is very concerned that seniors who would qualify for the medical device under FDA guidelines are being refused because they do not meet the more restrictive CMS guidelines. We find this incongruence to be confusing and frustrating to seniors.

SHHH is hopeful that better hearing will be viewed as an essential ingredient to health and well being for people with hearing loss. Interaction with peers, family members, and community participation tend to be more restricted as hearing loss worsens. Additionally, safety issues such as listening to a doctorÆs instructions and emergency alerting are at risk with hearing impairment. We ask that these quality of life issues be carefully considering in weighing this decision.

We appreciate your time and consideration for this very important issue.

Commenter: Rhoades, Julie
Organization: Penn State Milton S. Hershey Medical Center Date: July 16, 2004 Comment:

This is letter is written in support of a revision in Medicare eligibility guidelines for cochlear implantation. It is not uncommon to work with a patient who has been a part of the hearing community for their entire life and is now succumbing to depression, a decrease in wellbeing and quality of life, social isolation and a reduction in functional capacity due to their hearing loss. As an implant center it is disheartening to find that traditional amplification is no longer appropriate for them, to tell them that they are a candidate for cochlear implantation by FDA criteria, but that they are NOT a candidate by MedicareÆs criteria and therefore cannot be implanted. Advances in technology have resulted in considerable change for post-implant outcomes since the last CMS guideline revision in 1998. It is time to no longer deny hearing impaired seniors the benefits of a cochlear implant available to other ages of patients through other insurance carriers.

I believe that Cochlear AmericasÆ submission accurately represents current cochlear implant literature and provides a platform for change. I agree with the need to revise CMS coverage guidelines and support Cochlear AmericasÆ request for a concomitant national coverage decision. I ask that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Sauter, Todd
Organization: UMass Memorial Medical Center Date: August 4, 2004 Comment:

I am writing to strongly request that Medicare eligibilty guidelines for cochlear implantation be revised. Cochlear implantation has advanced technologically the past 20 years to the point where a much larger group of the hearing impaired population can benefit greatly form the device. There was once a misperception held by many, including myself, that elderly patients may not receive the same benefits from cochlear implantation as younger patients. Published literature has proven this to be incorrect and that older patients receive all of the same benefits as younger patients. Published literature also shows that untreated hearing loss can affect the overall health of patients, especially seniors, including depression and reduced functional capacity. Implantation and other aural rehabilitation have been shown to reduce or eliminate these affects. I strongly support the submission by Cochlear Americas to revise current Medicare coverage to more accurately reflect the current standard of care. Thank you.

Commenter: Roberson, Jr., Joseph B. M.D., Stidham, Katrina M.D., Tonokawa, Lisa M.S., Pitt, Cache M.S., Highlander, Rebecca M.A. Organization: Date: August 2, 2004
Comment:
We, the undersigned, are writing to you today to indicate our support for changing MedicareÆs guidelines for cochlear implants to match those of the Food and Drug Administration. This is essential if we are to provide good clinical care to our patients as the FDA guidelines are the accepted standard of practice within the cochlear implant field.

We are physicians and clinicians who work with cochlear implant patients and conduct cochlear implant research on a daily basis, and believe we are qualified to provide support for the document recently sent to you by Cochlear Americas. In our opinion, this document represents current cochlear implant literature and provides an accurate representation of what we see and experience daily with elderly patients in our clinics.

We are fortunate to witness the profound change that occurs in a personÆs life when they receive a cochlear implant. This occurs for patients of all ages; elderly patients are just as likely to demonstrate excellent speech recognition skills after receiving a cochlear implant as are younger patients. In fact, we are often amazed by the excellent speech recognition skills of our more senior patients and are also amazed by the ease at which they adapt to their device.

We have experienced first hand the reported finding that patients who demonstrate öbetterö speech recognition skills preoperatively (sentence scores ranging from 30-50% correct) perform better post-operatively, even if they are elderly. Although such patients demonstrate some useable hearing, they struggle to communicate in almost all listening situations prior to receiving a cochlear implant. Unfortunately, waiting until a patient's speech recognition falls below 30% will not only prolong their poor communication but will also increase their duration of deafness and may actually lead to decreased performance with a cochlear implant.

Senior citizens who receive a cochlear implant often demonstrate a profound improvement in their personality and outlook on life as the implant allows them to participate in important conversations with family and friends. The implant may also allow senior citizens to live a more independent lifestyle by decreasing their dependency on spouses, children, and other family members for communication with others (e.g., doctors). Importantly, improved communication enables senior citizens to be active participants in many aspects of their lives, including management of their own health care decisions.

Elderly cochlear implant candidates are required to meet the same pre-operative audiological, medical, and psychological criteria as younger candidates. In addition, they are able to manage both the post-operative fitting as well as the aural rehabilitation that are keys to success with such a device. Research, as well as our clinical experience, has shown that elderly patients receive the same benefits to speech understanding as younger patients do with a cochlear implant.

As physicians and clinicians, we believe it is extremely important for us to be able to treat all of our patients equally, and to not discriminate against a patient based on insurance coverage. That is, all patients who have sentence recognition scores up to 50% correct should be covered for cochlear implantation whether they have Medicare or traditional insurance. At the present time, if a patient has Medicare coverage, we are faced with the difficult task of explaining to the patient that the FDA guidelines do not currently apply to his/her case.

We ask that you support our request to expand MedicareÆs current cochlear implant guidelines to match those recognized by the FDA. This would mean approving cochlear implants for patients whose sentence recognition scores fall at or below 60% in the best aided condition and at or below 50% in the ear to be implanted. Doing so will enable us to provide non- discriminatory clinical care to our elderly patients, may enhance their performance with the device, and will make it possible for many of our patients to live productive, interactive lives.

Commenter: Steenerson, Ronald Leif, M.D.
Organization: Atlanta Ear Clinic Date: July 19, 2004 Comment:

To Whom it may Concern, I am writing to comment on the revision of Medicares coverage policy for cochlear implantation. I am a neuro-otologist and have performed over 500 cochlear implant surgeries in my career. I find cochlear implants to be the most emotionally rewarding area of my practice. Patients with severe to profound neurosensory hearing loss face isolation, depression and estrangement from friends and family. More and more often we see patients living productive, vital lives well into their eighth decade. My own mother lived to be over 102! Also, there are many advantages when performing surgery on a patient who is emotionally sound and able to participate in their own treatment program. The currently guidelines for cochlear implantation in adults as published by the Food & Drug Administraion is speech discrimination ability up to 50% correct using appropriate hearing aids. However, the Medicare guideline is speech discrimination ability up to 30% correct. This disparity in the guidelines means Medicare recipients must suffer the effects of severe to profound hearing loss much longer than for patients covered by private insurance. In the case of the elderly population the time waiting for the hearing to decline to 30& word understanding may also see the decline of their physical and emotional health. I strongly encourage you to amend the Medicare quidelines for cochlear implantation to reflect the FDA approved indications and give seniors the same access to cochlear implants enjoyed by patients under 65. Thank you very much for your attention to this important issue.

Commenter: Vaden, Katie
Organization: Indiana University School of Medicine Date: August 9, 2004 Comment:

I am writing in support of the request for a national coverage determination (NCD) recently submitted by Cochlear Americas. Medicare eligibility guidelines for cochlear implantation must be revised! Revising the coverage language for cochlear implantation will allow CMS to: ¶ Improve outcomes among individuals 65 years and older; ¶ Align Medicare guidelines with FDA approved indications; ¶ Align more closely with audiological/medical standards generally accepted by the cochlear implant community; ¶ Remove discrimination in coverage based upon payer or type of health insurance; ¶ Promote enhanced quality of life, improved general health status, relief of depression and participation in health care decisions among a larger segment of the elderly with hearing loss.

Technological advances and observed, improved patient outcomes have expanded the clinical parameters of cochlear implantation. CMS last revised coverage guidelines in April 1998. Since then, criteria for candidacy associated with post-implant outcomes have undergone considerable change. Foremost among those changes is the idea that higher pre-implant speech perception scores are associated with better post-implant outcomes in the adult population.

Published literature strongly supports the validity of this assertion. A related issue, and one relevant to CMS program objectives of promoting access and eliminating health disparities, is the issue of age. Published literature supports the notion that there is no difference in cochlear implantation outcomes for seniors versus a younger population, that is, age is not a predictor of outcome or benefit.

Additionally, there are other important factors related to this intervention: the impact of hearing loss on general health and quality of life particularly in older patients, and the cost effectiveness of implantation. Hearing loss in elderly patients is known to contribute to depression, a subjective decrease in well-being and quality of life, social isolation and a reduction in functional capacity. Aural rehabilitation, including cochlear implantation, has been shown to decrease depression and increase a sense of self-worth in hearing impaired persons. Implantation has been found to provide cost effective benefits to recipients.

I believe that Cochlear AmericasÆ submission accurately represents current cochlear implant literature and provides a platform for change. I agree with the need to revise CMS coverage guidelines and support Cochlear AmericasÆ request for a concomitant national coverage decision. I ask that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Williams, Andrea
Organization: Vanderbilt Bill Wilkerson Center Date: July 22, 2004 Comment:

I am writing to support the request for a national coverage determination (NCD) that was recently submitted by Cochlear Americas. I believe that it is critical that Medicare eligibility be revised in order to include cochlear implants. The benefits of doing so are numerous and include: bringing Medicare guidelines up to date with FDA approved indications and audiological and medical standards, removing discrimination in coverage based on payer or type of health insurance, and most of all, promoting a higher quality of life for the large population of the elderly that suffer from hearing loss.

Since CMS last revised coverage guidelines in April of 1998, cochlear implant technology has become available to a wider spectrum of patients thanks to studies which support the notion that higher pre-implant speech perception scores are associated with better post-implant outcomes. This has led to improved quality of life for many individuals suffering from hearing loss, including many 65 years and older. In fact, the recent literature advocates the use of cochlear implants in the elderly and asserts that there is no difference in outcome for seniors versus a younger population.

I am in strong support of Cochlear Americas submission, which I believe is based on a sound body of literature regarding the benefits and applications of cochlear implant technology. I agree with the need to revise CMS coverage guidelines and support Cochlear Americas request for a concomitant national coverage decision. I ask that you revise Medicare coverage language to reflect current eligibility standards.

Commenter: Williams, Debra E., Au.D.
Organization: Atlantic Coast Ear Specialists Date: July 28, 2004 Comment:

I am writing in support of the request for a national coverage determination (NCD) recently submitted by Cochlear Americas. This is a request to revise Medicare eligibility for cochlear implantation. Currently, the FDA guidelines suggest word recognition of less than 50% to qualify for implant. Medicare maintains a stricter guideline of 30%. This leads to discrimination against seniors with Medicare who would qualify for cochlear implantation with other insurances.

I have experience in cochlear implantation with all ages and have found that quality of life is greatly enhanced. Seniors who may also be experiencing decline in vision especially need the best hearing possible. Often, hearing loss may contribute to increased symptoms of confusion or be mistaken for memory loss. If a senior does not hear, he or she cannot be expected to remember information.

In studies done at various centers, age of post- lingually deafened adults does not predict outcome or benefit. However, length of deafness may play a role. Therefore, if seniors are required to wait longer with poorer hearing ultimate benefit from an implant may be less.

Hearing loss is known to contribute to a sense of isolation and depression, both causes of concern with seniors. With Americans living longer than ever, it is important to ensure the best quality of life possible. Cochlear implantation can help contribute to a better quality of life.

Lastly, studies have shown that implanting patientÆs with higher speech recognition scores can result in improved post-implant scores. Here again, forcing seniors to wait until scores are lower can impact the ultimate outcome.

In summary, I believe that Cochlear AmericasÆ submission represents current cochlear implant literature and provides a platform for change. I agree with the need to revise CMS coverage guidelines and support the request for a national coverage decision. I ask that you revise Medicare coverage language to reflect current FDA eligibility seniors.

Thank you for your attention to this important matter.

Commenter: Zwolan, Teresa, Ph.D., et. al
Organization: Group of Concerned Cochlear Implant Audiologists Date: July 20, 2004 Comment:

We, the undersigned, are writing to you today to indicate our support for changing MedicareÆs guidelines for cochlear implants to match those of the Food and Drug Administration. This is essential if we are to provide nondiscriminatory clinical care to our patients as the FDA guidelines are the accepted standard of practice within the cochlear implant field.

We are clinicians who work with cochlear implant patients and conduct cochlear implant research on a daily basis, and believe we are qualified to provide support for the document recently sent to you by Cochlear Americas. In our opinion, this document represents current cochlear implant literature and provides an accurate representation of what we see and experience daily with elderly patients in our clinics.

We are fortunate to witness the profound change that occurs in a personÆs life when they receive a cochlear implant. This occurs for patients of all ages; elderly patients are just as likely to demonstrate excellent speech recognition skills after receiving a cochlear implant as are younger patients. In fact, we are often amazed by the excellent speech recognition skills of our more senior patients and are also amazed by the ease at which they adapt to their device.

We have experienced first hand the reported finding that patients who demonstrate öbetterö speech recognition skills preoperatively (sentence scores ranging from 30-50% correct) perform better post-operatively, even if they are elderly. Although such patients demonstrate some useable hearing, they struggle to communicate in almost all listening situations prior to receiving a cochlear implant.

Unfortuantely, waiting until a patient's speech recognition falls below 30% will not only prolong their poor communication but will also increase their duration of deafness and may actually lead to decreased performance with a cochlear implant.

Senior citizens who receive a cochlear implant often demonstrate a profound improvement in their personality and outlook on life as the implant allows them to participate in important conversations with family and friends. The implant may also allow senior citizens to live a more independent lifestyle by decreasing their dependency on spouses, children, and other family members for communication with others (e.g., doctors). Importantly, improved communication enables senior citizens to be active participants in many aspects of their lives, including management of their own health care decisions.

Elderly cochlear implant candidates are required to meet the same pre-operative audiological, medical, and psychological criteria as younger candidates. In addition, they are able to manage both the post-operative fitting as well as the aural rehabilitation that are keys to success with such a device. Research, as well as our clinical experience, has shown that elderly patients receive the same benefits to speech understanding as younger patients do with a cochlear implant.
As clinicians, we believe it is extremely important for us to be able to treat all of our patients equally, and to not discriminate against a patient based on insurance coverage. That is, all patients who have sentence recognition scores up to 50% correct should be covered for cochlear implantation whether they have Medicare or traditional insurance. At the present time, if a patient has Medicare coverage, we are faced with the difficult task of explaining to the patient that the FDA guidelines do not currently apply to his/her case.

We ask that you support our request to expand MedicareÆs current cochlear implant guidelines to match those recognized by the FDA. This would mean approving cochlear implants for patients whose sentence recognition scores fall at or below 60% in the best aided condition and at or below 50% in the ear to be implanted. Doing so will enable us to provide non- discriminatory clinical care to our elderly patients, may enhance their performance with the device, and will make it possible for many of our patients to live productive, interactive lives.

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MEDICAL COLLEGE OF WISCONSIN

To: Centers for Medicare and Medicaid Services

From: Koss Cochlear Implant Program Team Members
Department of Otolaryngology and Communication Sciences
Medical College of Wisconsin
9200 West Wisconsin Avenue
Milwaukee, Wisconsin 53226
Email: wackym@mcw.edu or jfirszt@mcw.edu

Re: Support of Request for National Coverage Determination

Date: August 4, 2004

The team of the Koss Cochlear Implant Program at the Medical College of Wisconsin supports the request for a national coverage determination (NCD) to revise the current Medicare eligibility guidelines for cochlear implantation.

Since the inception of the Koss Cochlear Implant Program in 1999, we have implanted almost 300 patients with each of the three available FDA-approved cochlear implant devices. We have participated in all recent clinical trials with the three manufacturers and have witnessed first-hand the improvements in technology that have become available to our patients. Advances in technology have contributed to improved benefits for recipients, which has led to expanded criteria for determining cochlear implant candidacy. When determining whether an individual is an implant candidate, we must compare a candidate's pre-implant performance with that of current cochlear implant users. **The average scores of current cochlear implant users are 78% on HINT sentences (Firszt et al., 2004), which is higher than candidates with some residual hearing. FDA guidelines have thus expanded.**

Within current FDA-approved guidelines, we have observed that the better the speech perception performance is before cochlear implantation, the higher the performance is after implantation. In Figure 1 below, group mean scores on the HINT sentence test are shown for 16 subjects before implantation and at 3, 6, and 12 months post-implant intervals. Error bars represent one standard deviation from the

mean. All subjects in this sample had pre-implant HINT sentence scores of greater than 30% but less than 50%. The mean scores at each interval were 38% for pre-implant and 76%, 79%, and 97%, for 3, 6, and 12 months post-implant, respectively. Of this group, 6 subjects were implanted at age 65 years or older and were well within one standard deviation of the group mean scores. **In our experience, we have not seen a decrease in performance following cochlear implantation compared to pre-implant performance, even with moderate pre-implant scores.**

Of the patients we follow, approximately 160 are adults, of which 53 received their devices at age 65 years and older. Our elderly patients enjoy the same benefits as those adults implanted under the age of 65 years. In a recent study (Firszt et al., 2004) of 78 adult cochlear implant users conducted at four large cochlear implant centers (Medical College of Wisconsin, Washington University School of Medicine, Mayo Clinic, and University of Texas at Dallas), 26 adults were 65 years and older. Figure 2 shows the group mean scores and one standard deviation on the HINT sentence test and more difficult CNC word test for subjects above and below 65 years of age. **When compared to adults who were younger than 65 years, scores on tests of sentences and single syllable words were not significantly different. In our experience, age is not a factor in cochlear implant candidacy.**

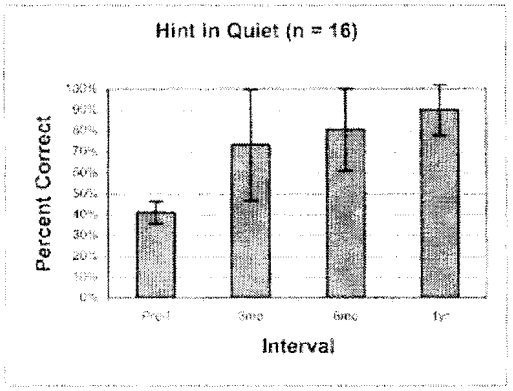

Figure 1

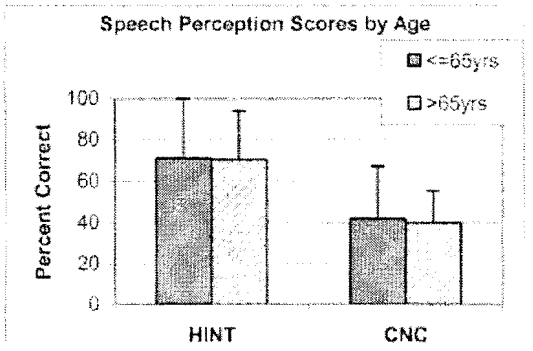

Figure 2.

Elderly patients not only obtain significant improvements in speech perception scores, but also report great gains in rejoining social interactions with family and friends, which leads to improved quality of life. In the pre-implant process, we administer a questionnaire that asks candidates about their current communication abilities and their expectations with a cochlear implant. It is very common for patients to report the following: they do not attempt to talk on the telephone, they avoid communication with unfamiliar people, they stay away from social functions, they do not initiate conversation, they rely on their partner to repeat conversations, they sit in the front and close to the speaker whenever possible, and they have great difficulty when they can not see the speaker or there is background noise present. Patients report that what they desire with a cochlear implant is improved hearing such that they may become more independent, freely communicate with family and friends, participate in social functions again, and temper feelings of isolation that often accompanies significant hearing loss. These types of comments are reported both by candidates who meet the more expanded FDA guidelines as well as those who meet the more restricted CMS guidelines. **In our experience, our cochlear**

implant candidates, regardless of pre-implant hearing status, demonstrate substantial improvements in quality of life following cochlear implantation.

The members of the Koss Cochlear Implant Program support the request for a national coverage determination to revise the Medicare eligibility guidelines for cochlear implantation.

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August 4, 2004

Madeline Ulrich, MD
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. Ulrich:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to offer the following comments in support of Cochlear America's request to revise the national coverage policy for Medicare coverage of cochlear implants. AAO-HNS represents approximately 12,000 physicians in the United States who diagnose and treat disorders of the ears, nose, throat, and related structures of the head and neck. The medical disorders treated by this specialty are the most common that afflict all Americans, old and young, including hearing loss, swallowing disorders, and head and neck cancer.

We understand that Cochlear Americas has submitted extensive evidence and cited numerous clinical studies in support of their request. These studies have indeed demonstrated improved outcomes in speech perception performance from cochlear implants, as well as an improvement in quality of life factors. In addition, they have also shown that there is no difference in those outcomes for the senior population in comparison to a younger population.

The Food and Drug Administration (FDA) has approved the use of cochlear implants in patients with a pre-implant sentence score of $\leq$ 50%, among other factors. We believe that aligning the CMS policy with the approved FDA criteria will provide Medicare beneficiaries with an opportunity to achieve better outcomes in a cost-effective manner.

Thank you for the opportunity to comment on this critical issue. If I can be of any further assistance, please call me directly at 703-519-1559.

Sincerely,

David R. Nielsen MD

David R. Nielsen, MD, FACS
Executive Vice President and CEO, AAO-HNS/F

AMERICAN OTOLOGICAL SOCIETY, INC.

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August 9, 2004

Ms. Francina Spencer
Lead Analyst
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: National Coverage Determination for Cochlear Implants

Dear Ms. Spencer:

We appreciate the opportunity to comment on the evaluation by the Centers for Medicare and Medicaid Services (CMS) of cochlear implantation criteria in Medicare recipients. Coverage of cochlear implants for Medicare beneficiaries with words-in-sentence understanding score of 30 to 50%, with binaural hearing aids, offers benefit that far outweighs associated risks and costs.

As an organization that represents over 300 senior clinicians who address hearing loss on a daily basis, the American Otological Society asks that you consider the following:

- **Clinical indicators can forecast implant performance and suggest that a cochlear implant offers significant benefits to patients whose aided word scores fail to reach 50%**
  - We encourage CMS to review the rigorously derived conclusions offered by NIH supported research on a key issue: the prediction of how an individual will perform with a cochlear implant. NIH funded studies[1-3] indicate that the best predictors of how seniors perform with a cochlear implant are a short duration of hearing loss and a reserve of hearing prior to implantation. The implication of the strength of these two predictors is clear. The shorter the duration of hearing loss that yields speech understanding below 50% and the closer a patient is to a 50% level of residual speech understanding (without sinking to extremely low levels of testable hearing), the greater the likelihood of success. Our ability to access the nervous system while some low level of auditory function remains appears to be key to success. We also note that the age of implantation in adult-onset deafness is *not* significantly associated with success or failure with a cochlear implant.[1-4] Seniors demonstrate consistently high performance with cochlear implants when the above observations are incorporated into clinical guidelines.[5-12] Withholding the opportunity to regain hearing awaiting a progression of hearing loss to reach prior, more stringent guidelines, fails to incorporate new research findings and potentially undermines ultimate outcomes for some CMS participants.
- **Health related quality of life is undercut by hearing loss**
  - American physicians have become increasingly aware of the importance of continued engagement with social networks and daily activities that involve relating to others.[13-15] We urge our patients to remain communicatively active as a matter of maintaining general and emotional health and in preventing global cognitive declines.[16] We urge CMS to consider the fact that those seeking cochlear implantation who understand

fewer than half of the words that come to them through hearing aids are no longer able to effectively connect with the hearing and speaking world. As elective surgery, such individuals and their clinicians consider the cochlear implantation only after other rehabilitative approaches have been exhausted. This is a prudent approach to selected patients who are seriously hampered by an advanced level of hearing loss and have turned to cochlear implantation as their only remaining alternative.

- **The Social Security Administration recognizes advanced sensorineural hearing loss as disabling; affected individuals are fully eligible for benefits**
  - We are struck by a disparity not only between current CMS and FDA guidelines and between CMS implant criteria and NIH research, but also by an inconsistency between CMS guidelines and SSI/SSDI criteria.[17] Social Security claimants are deemed unable to engage in substantial gainful activity and are therefore eligible for the full monthly SGA limit when, in the better ear, pure tone average thresholds are at or beyond 90 dB HL and speech discrimination scores are 40% or less, *without* a hearing aid. This policy recognizes the disabling effects of hearing loss even at this level. Conservatively, Social Security Administration criteria for hearing-related disability represent 55 dB HL thresholds and words-in-sentence scores of better than 60% *with* a hearing aid.

We believe the disparity between current indications and Medicare's coverage guidelines is inconsistent with the mission of CMS to assure health care security for its beneficiaries. For those relatively few candidates seeking cochlear implantation whose hearing loss is in the 30 to 50% word understanding range, current policy seems arbitrary, and potentially denies prospects for successful aging. The American Otological Society believes that awaiting further declines in hearing and prolonging the experience of substantial hearing loss before restoring sensitive hearing with a cochlear implant in selected seniors is no longer justified.

Sincerely,

Clough Shelton, MD, FACS
Secretary-Treasurer
American Otological Society

References:

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JAMES T. WALSH
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25TH DISTRICT, NEW YORK

ASSISTANT MAJORITY WHIP

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Washington, DC 20515–3225

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MILITARY CONSTRUCTION

July 23, 2004

Sean Tunis, MD
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CAG – 00107N - CMS Request for Public Comments on National Coverage Determination Request (NCD) regarding the expanded use of the cochlear implant, i.e., the use of the cochlear implant for the expanded indications for adults and children, patient selection criteria, and appropriate screening needed. (Revisions to Coverage Issues Manual 65-14; Cochlear Implantation)

Dear Dr. Tunis:

We are writing on behalf of the Congressional Hearing Health Caucus to express our strong interest in this NCD request recently accepted for review by the CMS.

We believe that the recently submitted analysis of published, peer-reviewed literature is compelling and calls for a timely revision of Medicare's coverage criteria for cochlear implantation. Further, updating Medicare coverage criteria will establish parity with the younger, non-Medicare population who already benefit from this intervention.

As you are aware, Medicare has covered cochlear implantation since 1985. Since then, measures used to determine eligibility and gauge outcome have changed and improved. The Food and Drug Administration (FDA) has approved expanded indications because, based upon clinical trials, clinical experience and well-documented outcomes, it is clear that more pre-implant residual hearing is associated with better outcomes for cochlear implant patients.

Medicare's national coverage language for cochlear implants has not been updated since 1998. The latest FDA approved indications for cochlear implantation include speech-understanding scores measurably higher than current Medicare coverage language. Medicare coverage language should, but does not, conform to the updated FDA and Veteran's Administration (VA) eligibility standards in effect since 2000.

In addition to better hearing and oral communication, cochlear implants have been demonstrated to have a significant positive impact on the general health and health-related quality of life for seniors with significant hearing loss. For seniors living alone or with poor vision, the improved hearing provided by a cochlear implant may be critical to independent living.

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It is our concern that the disparity between current indications and Medicare coverage parameters fail to assure health care security for aged candidates. Current Medicare guidelines require a degree of deafness that potentially delays or substantially compromises successful use of this technology. Forcing senior citizens to delay cochlear implantation until there are further declines in hearing loss implantation cannot be justified based upon available clinical data or stated CMS objectives to eliminate health disparities.

We strongly urge you to carefully review the full range of data, analysis and comments submitted and to proceed with a timely revision of Medicare's coverage criteria for cochlear implantation.

Sincerely,

James T. Walsh
Member of Congress

Jim Ryun
Member of Congress

Carolyn McCarthy
Member of Congress

Lois Capps
Member of Congress

cc: Secretary Thompson
cc: Mark McClellan

4/1

From: "Thomas Walsh" <tom.walsh@advancedbionics.com>
To: "CAG Inquiries" <caginquiries@cms.hhs.gov>
Date: Fri, Aug 6, 2004 7:07 PM
Subject: Public Comment for Cochlear Implantation

First Name: Thomas
Last Name: Walsh
Email: tom.walsh@advancedbionics.com
Comment: August 4, 2004

Madeline Ulrich, M.D.
Francina Spencer
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CAG-00107N: Revisions to CIM 65-14
Cochlear Implantation

Dear Dr. Ulrich and Ms. Spencer:

On behalf of Advanced Bionics Corporation, I am pleased to submit the following comments on the National Coverage Analysis for Cochlear Implantation (CAG-00107N).

Background
Medicare provided national coverage for cochlear implants in postlinguistically deafened adults effective October 1986 (CIM 65-14). Since that time, this national coverage policy has been expanded in 1992 and 1998 to provide updated coverage consistent with changes in the technology and with Food and Drug Administration (FDA) labeling for these products in children and adults.
Current Medicare coverage policy for cochlear implantation includes the following coverage restriction that was consistent with FDA labeling in 1998 when the policy was last updated:

ôCochlear implants may be covered for adults (over age 18) for prelinguistically, perilinguistically, and postlinguistically deafened adults. Postlinguistically deafened adults must demonstrate test scores of 30 percent or less on sentence recognition scores from tape recorded tests in the patientÆs best listening condition (emphasis inserted).ö

Coverage Request
Advanced Bionics requests that CMS expand the Medicare coverage eligibility criteria for cochlear implants in postlinguistically deafened

adults in such a manner that links the coverage threshold to the contemporaneous FDA labeling for approved cochlear implants. Thus, if FDA labeling changes in the future, CMS would not have to revisit the coverage criteria for cochlear implantation. As an alternative, we request that coverage criteria be changed to include candidates who meet the current FDA criteria of demonstrating test scores of 50 percent or less on a test of open set sentence recognition in the best aided condition. As explained in more detail below, this update to the existing coverage policy is supported both by current FDA labeling and clinical evidence published in peer-reviewed journals.

FDA Labeling
The progression of FDA approved labeling for Advanced Bionics cochlear implants in adults is summarized in the table below:

Year	Pure-Tone Average Threshold	Open-Set Sentence Test Score
1996	90 dB HL	≤ 20% (CID)
2000	70 dB HL	≤ 40% (HINT)
2002	70 dB HL	≤ 50% (HINT)

The current FDA labeling for this product for adults defines the population eligible for the device as those candidates with test scores of 50 percent or less on a test of open-set sentence recognition in the best-aided listeningcondition. (See attached Package Insert.)

These expansions in FDA labeling are a result of technology improvements that have enabled a broader patient population to benefit from cochlear implantation. The benefit experienced with cochlear implants, especially with continued technological advances, provides a higher level of benefit than hearing aids for individuals with severe-to-profound sensorineural hearing loss. Such technological gains include advances in hardware design and signal processing, and in software-based sound processing strategies.

Clinical Evidence and Applicability to the Medicare Population
There is substantial published clinical evidence supporting the effectiveness of cochlear implantation consistent with FDA-approved labeling in adults and the elderly. Numerous clinical studies of cochlear implantation in elderly adults have demonstrated that older individuals experience substantial benefits from cochlear implants that are similar to other

adults1-5, 7-10. In all published studies, adults implanted after age 65 show significant pre-implant to post-implant improvement in speech recognition and quality of life 1-5, 7-10. In eight studies, implant benefits were found to be similar for elderly individuals compared to adults implanted under 65 years of age1, 3-5, 7-10.

Advanced Bionics believes that the published evidence strongly indicates that elderly patients are likely to experience benefits similar to younger adults, and treatment outcomes are unlikely to differ according to age. Moreover, because elderly patients and younger patients undergo the same pre-implant testing, evaluations and counseling processes used to determine cochlear implant candidacy, identical factors will used to identify patients in both groups who are likely to benefit from cochlear implantation from those who are not appropriate candidates.

The authors of one large retrospective study of 749 cochlear implant patients recently concluded that ôage at implantation has no significant effect on post-operative performance for subjects over the age of 65. The observation that a shorter percentage of life spent in severe-to-profound SNHL [sensorineural hearing loss] suggests that a foundation of acoustic/auditory processing in the elderly cohort may mitigate potential physiologic effects associated with advanced age.ö This finding confirms and extends prior observations that the duration of profound deafness and residual speech recognition carry a higher clinical predictive value than patient age for cochlear implants. 6

Summary
We request that CMS expand the indications and limitations of national coverage for cochlear implants in postlinguistically deafened adults in such a manner that links the coverage threshold to the contemporaneous FDA labeling for approved cochlear implants. As an alternative, we request that coverage criteria be changed to include candidates who meet the current FDA criteria of demonstrating test scores of 50 percent or less on a test of open set sentence recognition in the best aided condition. The clinical evidence demonstrates that cochlear implants are associated with significant improvements in patient outcomes for adults over the age of 65 years.

Advanced Bionics Corporation appreciates the

agencyÆs recognition of the impact of coverage restrictions on patient access to cochlear implants and requests your careful consideration of these comments. If you require further information, please do not hesitate to contact me (661-362-1721 or Tom.Walsh@bionics.com).

Sincerely,

Thomas P. Walsh
Manager, Strategic Reimbursement

cc: Steve Phurrough, M.D., M.P.A., Director Coverage and Analysis Group
Sean Tunis, M.D., Chief Medical Officer for CMS and Director, Office of Clinical Standards and Quality

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Attachment:
1
The HiResolutionTM Bionic Ear System is a cochlear implant designed to provide useful hearing to individuals with severe-to-profound hearing loss. It consists of internal and external components. The internal components include a receiver (HiResTM 90K) and electrode array (HiFocus«) that are implanted surgically under the skin behind the ear. The external components include a sound processor (bodyworn or ear-level), a headpiece, and a cable. The system converts sound into electrical energy that activates the auditory nerve. The auditory nerve then sends information to the brain, where it is interpreted as sound.
INDICATIONS: The HiResolution Bionic Ear System is intended to restore a level of auditory sensation to individuals with severe-to-profound sensorineural hearing loss via electrical stimulation of the auditory nerve.
Adults
ò 18 years of age or older.
ò Severe-to-profound, bilateral sensorineural hearing loss (>70 dB HL).
ò Postlingual onset of severe or profound hearing loss.
ò Limited benefit from appropriately fitted hearing aids, defined as scoring 50% or less on a test of open-set sentence recognition (HINT Sentences).
Children
ò 12 months through 17 years of age.
ò Profound, bilateral sensorineural deafness (>90 dB HL).
ò Use of appropriately fitted hearing aids for at least 6 months in children 2 through 17 years of age, or at least 3 months in children 12 through 23 months of age. The minimum duration of hearing aid use is waived if x-rays indicate ossification of the cochlea.
ò Little or no benefit from appropriately fitted hearing aids. In younger children (< 4 years of age), lack of benefit is defined as

a failure to reach
developmentally appropriate auditory milestones
(such as spontaneous response
to name in quiet or to environmental sounds)
measured using the Infant-Toddler
Meaningful Auditory Integration Scale or
Meaningful Auditory Integration Scale
or <20% correct on a simple open-set word
recognition test (Multisyllabic
Lexical Neighborhood Test) administered using
monitored live voice (70 dB
SPL). In older children (>4 years of age), lack
of hearing aid benefit is defined
as scoring <12% on a difficult open-set word
recognition test (Phonetically
Balanced-Kindergarten Test) or <30% on an open-
set sentence test (Hearing In
Noise Test for Children) administered using
recorded materials in the soundfield
(70 dB SPL).
CONTRAINDICATIONS: Deafness due to lesions of the
acoustic nerve or
central auditory pathway; active external or
middle ear infections; cochlear
ossification that prevents electrode insertion;
absence of cochlear development;
tympanic membrane perforations associated with
recurrent middle ear infections.
WARNINGS:
ò Bacterial meningitis has been reported in users
of the system and other cochlear
implants, especially in children under the age of
5. The cause of meningitis in
these cases has not been established. A small
percentage of deaf patients may
have congenital abnormalities of the cochlea
(inner ear) which predispose them to
meningitis even prior to implantation. Patients
who become deaf as a result of
meningitis are also at increased risk of
subsequent episodes of meningitis compared
to the general population. Other predisposing
factors may include young
age (<5 years), otitis media, immunodeficiency,
or surgical technique. The
cochlear implant, because it is a foreign body,
may act as a nidus for infection
when patients have bacterial illnesses.
The incidence rate, although low, appears to be
higher than the age-adjusted rate
for the general population. The fatality rate as
a result of meningitis also appears
to be higher. Adequate epidemiological data are
not available to determine
whether the incidence and fatality rates are, in
fact, definitively different from

the general population, whether there are special risk factors in the cochlear implant population, or whether different cochlear implant models pose different risks.

Adults and parents of children who are considering a cochlear implant or who have received cochlear implants should be advised of the risk of meningitis.

They should also be informed of the availability of vaccines that have been shown to substantially reduce the incidence of meningitis in the general population resulting from the organisms that commonly cause bacterial meningitis (Streptococcus pneumoniae, Haemophilus influenzae, Meningococcus). National health agencies frequently provide updated information on the safety and utility of specific vaccines and offer recommendations reflecting local or regional conditions. Physicians or patients should refer to the applicable authorities for this information. These vaccines can be administered by pediatricians, primary care/family physicians, and infectious disease specialists.

Adults and parents of children who have received cochlear implants should be counseled on the symptoms of meningitis, the need to seek immediate medical care if any symptoms appear, and the need to advise the treating physicians of the presence of the cochlear implant and of the possibility of increased risk of meningitis associated with implant. They should also be counseled to obtain medical care at the first signs of otitis media.

ò Extreme direct pressure on the implanted device, up, down, left or right may cause the implant to move and possibly dislodge the electrode array.

ò A direct impact to the implant site may damage the implant and result in its failure to function. There have been instances of CLARION« device failure as a result of a child hitting his/her head at the site of the implanted device. None of these reported incidents have resulted in a concussion or fracture of the skull In all cases, the failed device was explanted and a new device reimplanted with no further complications.

ò The long term effects of chronic electrical stimulation are unknown. Clinical experience with the system since 1991 has shown

no adverse effects of chronic
electrical stimulation on patient performance,
electrical thresholds, or dynamic
range.
ò Exposure of the cochlear implant to a Magnetic
Resonance Imaging (MRI)
device may cause deleterious effects to the
implant and to the patient.
Individuals with a HiRes 90K implant cannot
undergo an MRI procedure or be in
the same room with an MRI system, regardless of
whether the system is in
operation or not. The inability to undergo an MRI
procedure prevents access to
that important diagnostic procedure.
ò Electrode displacement can occur if the
electrode is not inserted properly.
Surgeons should be proficient in the use of the
electrode insertion tool. Failure
to follow the recommended surgical procedure for
placement and
stabilization of the HiRes 90K implant increases
the risk of device migration
or extrusion, and of damage resulting from impact
trauma, including
breakage of the electrode lead wires. Creating a
recessed bed or well for the
implant and securely stabilizing the device in
place with sutures are critical
elements of the surgical procedure.
ò Electrosurgical instruments must not be used
within the vicinity of the implant
or electrode. Electrosurgical instruments are
capable of producing radiofrequency
voltages of such magnitude that a direct coupling
might occur between
the cautery tip and the electrode. Induced
currents could cause damage to the
cochlear tissues or permanent damage to the
implant.
ò Diathermy must never be applied over the
implant or electrode. High currents
induced into the electrode can cause tissue
damage to the cochlea or permanent
damage to the implant.
ò Electroconvulsive therapy must never be used on
a cochlear implant patient.
Electroconvulsive therapy may cause tissue damage
to the cochlea or permanent
damage to the implant.
ò Ionizing Radiation Therapy cannot be used
directly over the implant as it may
damage the device.
ò The effects of cobalt treatment and linear
acceleration techniques on the
implant are unknown.

ò Insertion of a cochlear implant electrode will likely result in the loss of any residual hearing in the implanted ear.

PRECAUTIONS:

ò Electrostatic Discharge (ESD): Although there have been no cases of damage to the internal electronics of the Advanced Bionics system due to static electricity, it is known that static electricity can potentially damage sensitive electronic components such as the ones used in the external hardware of a cochlear implant system. Care should be taken to avoid situations in which high levels of static electricity are generated. Those conditions are detailed in the user manual of the system. If static electricity is present, static electrical potential of the cochlear implant recipients can safely be reduced by the patients touching any person or object with their fingers prior to that person or object contacting the implant system (processor and/or cabling).

ò Digital Cellular Phones: Using or being in close vicinity to someone using some digital cellular phones may cause interference with the system. If such interference occurs, patients can turn off the sound processor or move a greater distance from the phone. Before purchasing a digital cellular phone, patients should evaluate whether it will interfere with their system. No such interference has been noted with cellular phones using analog technology.

ò Ingestion of Small Parts: The external components of the implant system contain small parts that may be harmful if swallowed.

ò Airport/Security Metal Detectors: Metal detectors, x-ray machines, and security scanners will not damage the implant or sound processor. However, individuals with a cochlear implant should be advised that passing through security metal detectors may activate the detector alarm. It is advised that patients carry their "Patient Emergency Identification Card" with them at all times. Cochlear implant users also might hear a distorted sound caused by the magnetic field around the security scanner door or hand-held scanning wand. Turning the sound-processor volume down before passing through security

screening will ensure that those sounds, if they occur, are not too loud or uncomfortable.
ò Use of Another Person's Sound Processor: Implant recipients should use only the sound processor that has been specifically programmed for them by their clinician. Use of a different sound processor may be ineffective in providing sound information and may cause physical discomfort.
ò Physical Activity: When engaging in physical activities that include the possibility of trauma or impact, precautions should be taken, such as wearing a protective helmet, to reduce the risk of damage to the internal device.
CLINICAL STUDIES:
Safety Results: The HiRes 90K is a repackaging of the commercially available CLARION« CII Bionic EarTM (CII) implantable electronics into new housing to reduce the size of the implanted components and to simplify the surgical procedure.
Clinical data from 41 HiRes 90K patients (37 adults and 4 children) implanted in Canada and Europe indicated no safety concerns with the new smaller implant.
The following adverse events occurred.
Leakage of Cerebrospinal Fluid during Surgery: One adult patient with a cochlear anomaly experienced moderate leakage of cerebrospinal fluid. No further leakage occurred following routine packing of the cochleostomy.
Complications at the Implant or Magnet Site: Complications occurred at the implant incision site during the immediate postoperative period in three patients (two adults and one child). The symptoms resolved in two patients (one adult and the child) and are resolving in the third patient following antibiotic treatment. Two patients experienced complications at the magnet site that resolved in one of the patients. Device removal was ultimately required in the other patient because a pressure ulcer developed, resulting in protrusion and subsequent removal of the magnet. The patient will be reimplanted in the same ear following resolution of the ulcer.
Vestibular Effects: One elderly patient with a history of significant episodes of imbalance and numerous other medical problems reported severe vestibular

symptoms postoperatively that have resolved.
Tinnitus: Two patients reported postoperative tinnitus. One patient, whose symptoms resolved, also experienced the symptoms preoperatively. The other patient had no history of preoperative tinnitus and has not yet been seen for the next follow-up evaluation.
No device failures or major device malfunctions occurred in this study group.
In summary, the incidence of medical and surgical complications was comparable to that observed in the CII-HiRes IDE clinical trial.
Efficacy Results: The HiRes 90K is a repackaging of the CII implant electronics and delivers the same stimulation strategies and programming parameters as the CII. Because the electronics of the HiRes 90K implant are essentially the same as those of the CII implant, patient outcomes with the HiRes 90K were expected to be similar to those obtained with the CII implant.
To verify that outcomes were similar between implant packages, clinical data were collected from 41 HiRes 90K patients (37 adults and 4 children) in Canada and Europe. The results demonstrated that HiRes 90K speech-perception benefit was similar to the benefit shown during the clinical trial of the CII with HiResolution Sound (HiRes) processing, as well as to the benefit experienced by patients participating in an ongoing post-market surveillance study of the CII and HiRes sound processing.
A subset of adult patients with the HiRes 90K were matched to a subset of adult patients who participated in the CII HiRes IDE clinical trial on the basis of onemonth word recognition abilities (CNC scores). Speech-perception results for the HiRes 90K subset after one month (n = 23) and three months (n = 13) were similar to those of the matched patients in the CII HiRes IDE (n = 23). The distribution and range of benefit for the subset of HiRes 90K patients and the matched group of CII-HiRes IDE patients were indistinguishable across test measures and time. In addition, the distribution and range of benefit for the subset of HiRes 90K patients was similar to that of 20 consecutively implanted adults with follow-up results in the ongoing postmarket study of the CII and HiRes sound

processing. Thus, these results indicate that the efficacy of the HiRes 90K and CII are comparable.
In summary, the clinical comparability of safety and efficacy between the HiRes 90K and the CII precluded the need for a separate clinical trial of the HiRes 90K device in the United States.
Mean speech-perception scores for low, medium, and high performers at one and three months postimplant for the HiRes 90K adults, the matched group of CII IDE adults, and adults in the ongoing HiRes postmarket study.
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Email:asiapacific@advancedbionics.com
Low (<20%) 5% 5% 2%
Moderate (20-40%) 24% 26% 27%
High (>40%) 53% 53% 42%
n 23 23 20
CNC Words One Month
Performance Group 90K PMS CII IDE
2
Clinical trials have been conducted with two previous CLARION cochlear implant systems: the CLARION CII Bionic Ear ("CII") with HiResolution Sound Processing (HiRes) and the first-generation CLARION implant ("CI") and its corresponding sound-processing strategies. A clinical trial of the CII implant was conducted in adults with postlingual onset of

severe-to-profound hearing loss.
Clinical trial results for children, 12 months through 17 years of age, were obtained with the first-generation CI implant. A clinical trial of the CII with HiRes sound processing was not conducted in children.
During the clinical trials, the HiFocus Electrode was implanted with an ancillary component called the Positioner. With the CI implant, the Positioner was inserted behind the electrode array for the intended purpose of placing the electrode closer to the auditory nerves. A modified design was used with the CII Bionic Ear implant in which the Positioner was attached to the electrode to simplify the surgical procedures. Comparison of safety and efficacy data showed that electrode type (with Positioner inserted separately or attached to the electrode) had no significant effect on safety or efficacy results.
The CLARION CII Bionic Ear implant is no longer being distributed with the Positioner, and the HiResolution Bionic Ear System does not include a Positioner.
Data obtained from HiFocus and HiRes clinical trial patients who did not receive the Positioner (20 adults and 37 children), and retrospective data from other patients implanted with HiFocus Electrode without the Positioner (from Advanced Bionics patient registry, 33 adults and 45 children) indicate that there are no unusual safety and efficacy concerns associated with absence of the Positioner.
(Patients were intended to receive a Positioner but, in most cases, cochlear anomalies and conditions encountered at the time of surgery precluded its use.)
Specifically, the incidence of medical/surgical or device related complications is similar to HiFocus clinical trial patients implanted with a Positioner. Moreover, efficacy results from No-Positioner patients are indistinguishable from HiFocus clinical trial patients implanted with a Positioner, thereby indicating that there is no systematic reduction in efficacy associated with absence of the Positioner. Similar to all clinical trial populations, patients implanted without the Positioner derived clinical benefit from their implants consistent with their demographics at the time of implantation. However, the independent effect of the Positioner has not been established. Postmarket study is currently

underway.
Safety Results in Adults
Patients received the CII Bionic Ear implant, which was initially approved for commercial distribution when programmed to operate as the first-generation CI implant. A subsequent clinical trial was conducted to evaluate the software that enables HiResolution sound processing and signal delivery capabilities of the CII Bionic Ear implant.
Safety data are based on 80 adults implanted in North America with the CII Bionic Ear implant (HiFocus Electrode with attached Positioner) during the clinical trial.
The following adverse events occurred in relation to the use of the device.
Medical/Surgical Complications
ò Vestibular Effects: Five patients (5/80, 6.3%) reported vestibular symptoms (dizziness and or spinning sensation) after surgery. Two of the five patients also experienced those symptoms preoperatively. Symptoms are improving in one patient, while no further reports have been received for the second patient who experienced severe symptoms approximately six months post-implant. Three of the five patients had no symptoms preoperatively. Two patients had mild symptoms that have resolved, and the third patient had severe symptoms with current status unknown because the patient withdrew from the study.
ò Tinnitus: Thirty-eight patients (38/80, 47.5%) experienced tinnitus preoperatively in the ear to be implanted. No postoperative tinnitus was reported by 35 of these patients (35/38, 92.1%). The status is unknown in the remaining patients because they withdrew from the study following surgery.
Forty-two patients (42/80, 52.5%) reported no preoperative tinnitus in the implant ear. Three patients (3/42, 7.1%) reported tinnitus postoperatively. The symptoms were initially reported as severe in one of the patients but resolved.
The symptoms also resolved in another patient and are reported as intermittent in the third patient.
ò Facial Nerve Involvement: Two patients (2/80, 2.5%) demonstrated post operative facial nerve paralysis and were treated with steroids and antiviral medication. Symptoms are partially resolved in

one patient with no further
reports received on the second patient. One
patient (1/80, 1.3%) experienced
facial nerve stimulation that is controlled with
device programming.
ò Postoperative Complications at Surgical Site:
Four patients (4/80, 5.0%)
experienced inflammation at the surgical site
that resolved with topical
antibiotics. One of these patients also
experienced an infection in the external
auditory canal which is resolving following
antibiotic treatment. Another patient
(1/80, 1.3%) experienced redness and swelling at
the surgical site following
trauma that resolved without medical
intervention. One patient (1/80, 1.3%)
experienced superficial skin sloughing with
unknown resolution because the
patient withdrew from the study.
ò Electrode Displacement: One patient (1/80,
1.3%), who had a partial insertion
of the electrode array during the initial surgery
because of extensive cochlear
ossification, required revision surgery because
the non-inserted portion of the
array appeared to have migrated into the middle
ear space. During revision
surgery, it was noted that the part of the array
originally inserted into the
cochlea was still in place, and thus, the array
was not repositioned or removed.
Because the patient derived limited benefit from
the original device, the
contralateral ear was reimplanted. The patient
only uses the second device.
Device-Related Complications
Two patients (2/80, 2.5%) experienced device
failures that required device
replacement. One patient withdrew from the study
and the other patient derives
comparable benefit from the replacement device.
HiResolution Sound Processing (HiRes),
Stimulation Waveform, Number of
Electrode Contacts, and Stimulation Rate.
HiResolution Sound Processing offered by the CII
Bionic Ear implant is different
from the sound-processing strategies implemented
by the earlier-generation CI
implant, which had 8 independent output circuits
and 16 contacts on the electrode
array. In contrast, the CII has 16 independent
output circuits to deliver
information to 16 contacts on the electrode array.
For HiRes sound processing in the clinical trial,
all 16 independent output circuits

and all 16 electrode contacts were used, thereby doubling the number of independent pathways for conveying frequency information to the auditory nerve.

HiRes sound processing also delivered pulses at high stimulation rates on each contact. High stimulation rates are intended (1) to represent the fine timing information in the sound signal and (2) to induce a more natural pattern of responses in the hearing nerve, which may convey more information about sound to the brain.

During the clinical trial, the CII was initially programmed to operate like a CI device using conventional sound processing strategies (SAS, MPS, or CIS) and patients were evaluated after three months using these strategies. Patients then switched to HiRes sound processing and were evaluated after three months of HiRes use. When programmed with HiRes sound processing during the clinical trial, all patients used pulsatile stimulation with monopolar coupling of the 16 electrode contacts. The number of contacts used, the pulse width and grouping of contacts all determined the stimulation rate (pulses per second per contact) used by each patient.

Fifty-one of the 80 patients reached the six-month CII Bionic Ear clinical trial test interval (three-month HiRes interval). The number of stimulation contacts used and the rate of stimulation are summarized in the table below. Notably, 92% of the patients used 13 or more contacts, thereby giving them access to the greater independent spectral resolution provided by the 16 output circuits. Seventy-five percent of patients used stimulation rates exceeding 2900 pulses per second per contact. Such high stimulation rates are designed to induce a more natural response pattern in the hearing nerve than the lower rates used in earlier generation cochlear implants.

HiRes Stimulation Parameters for Adult Patients (n = 51)

HiRes Efficacy Results in Adults

Efficacy results are based on data from 51 of the 80 patients who had reached the six-month test interval. Patients were initially fit with previous-generation (conventional) sound processing strategies and evaluated after three months of use,

after which they were fit with HiRes sound processing and again evaluated after three months of use (approximately six months of device experience). Word recognition, easy sentence recognition, and difficult sentence recognition in quiet and noise (all without lipreading) were evaluated after six months of device use (three months of HiRes use).
The mean age at implant for the 51 postlingually deafened adults was 55 years.
Mean duration of severe-to-profound hearing loss was 12 years.
Word Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of HiRes Use): Consonant-Nucleus-Consonant (CNC) Words
After six months of implant use (three months HiRes use):
ò Almost half (25/51, 49%) recognized 50% or more of these difficult words.
ò Over one-third (20/51, 39%) of the adults recognized 60% or more of the words.
Easy Sentence Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of HiRes Use): CID Everyday Sentence Test
After six months of implant use (three months HiRes use):
ò Ninety percent of the adults (46/51) recognized 50% or more of the words.
ò Three quarters of the adults (38/51, 75%) recognized 80% or more of the words
Difficult Sentence Recognition in Quiet, Hearing Only (no lipreading) After Six Months of CLARION Use (Three Months of HiRes Use): Hearing in Noise Test (HINT)
After six months of implant use (three months HiRes use):
òNinety percent of the adults (46/51) recognized 50% or more of the words.
òTwo thirds of the adults (32/51, 63%) recognized 80% or more of the words.
Difficult Sentence Recognition with Background Noise, Hearing Only (no lip reading) After Six Months of CLARION Use (Three Months of HiRes Use):
Hearing in Noise Test (+10 dB signal-to-noise ratio)
After six months of implant use (three months HiRes use):
ò More than two thirds of the adults (35/51, 69%)

recognized 50% or more of the
words in this difficult listening situation.
ò Almost one-third of the adults (16/51, 31%)
recognized 80% or more of the
words in this difficult listening situation.
Sound-Processing Preference
A preference questionnaire was completed by 50 of
51 patients after six months of
implant use (three months of conventional sound
processing and three months of
HiRes use).
ò 90% (45/50) of the patients preferred HiRes
sound processing to conventional
sound processing.
ò Patients showed a stronger preference for HiRes
sound processing than for
conventional sound processing. On a scale of 1
(weak preference) to 10 (strong
preference), the mean preference rating for the
patients who preferred HiRes
sound processing was 8.5 (range 4-10) compared
with a mean rating of 5.3 for
the patients who preferred conventional sound
processing (range 1-8).
Low (<40%) 15% 11% 9%
Moderate (40-70%) 54% 52% 57%
High (>70%) 89% 89% 82%
n 23 23 20
HINT Sentences in Quiet: One Month
Performance Group 90K PMS CII IDE
Low (<40%) 10% 17% 18%
Moderate (40-70%) 56% 48% 55%
High (>70%) 92% 82% 84%
n 13 13 13
HINT Sentences in Quiet: Three Months
Performance Group 90K PMS CII IDE
Low (<40%) 9% 5% 11%
Moderate (40-70%) 46% 56% 61%
High (>70%) 95% 72% 86%
n 23 22 18
HINT Sentences in Noise (+10 dB SNR): One Month
Performance Group 90K PMS CII IDE
Low (<40%) 11% 13% 18%
Moderate (40-70%) 50% 43% 47%
High (>70%) 82% 76% NA
n 13 12 11
HINT Sentences in Noise (+10 dB SNR): Three Months
Performance Group 90K PMS CII IDE
Number of
Stimulation
Contacts
< 2900 pps
per contact
2900-5000 pps
per contact
> 5000 pps

per contact
Total
6 2% 2% 4%
8 2% 2%
10 2% 2%
13 4% 4% 8%
14 2% 8% 4% 14%
15 2% 2% 2% 6%
16 15% 41% 8% 64%
Total 25% 57% 18%
Mean Median Standard Deviation Range n
50% 48% 25% 0-94% 51
Mean Median Standard Deviation Range n
84% 95% 26% 0-100% 51
Mean Median Standard Deviation Range n
80% 89% 25% 0-100% 51
Mean Median Standard Deviation Range n
61% 65% 28% 0-100% 51
Low (<20%) 5% 10% 5%
Moderate (20-40%) 27% 28% 27%
High (>40%) 60% 49% 49%
n 13 13 13
CNC Words Three Months
Performance Group 90K PMS CII IDE
3
ò Of the 45 patients who preferred HiRes sound processing:
- 91% reported that the quality of speech was better
- 84% reported that speech was easier to understand in a quiet situation while conversing with one person
- 80% reported that they were better able to converse on the telephone
- 78% reported that speech was easier to understand while conversing in a small group
- 71% reported that speech sounded more natural
- 60% reported music sounded better
- 47% reported that speech was easier to understand in noise

At the 12-month follow-up visit, three of the five patients who initially preferred conventional sound processing stated a preference for HiRes. Thus, 96% (48/50) of the patients preferred HiRes sound processing to conventional sound processing.

Pre-Implant to Post-Implant Improvement after Six Months of CLARION Use

Word recognition, easy sentence recognition, and difficult sentence recognition in quiet and in noise (all without lipreading) were evaluated preoperatively with hearing aids and after six months of CLARION use (3 months of HiRes use). A positive difference between post-implant and pre-

implant scores was considered a clinically significant improvement if the difference equaled or exceeded 20%. Similarly, a decrease between pre- and post-implant scores that equaled or exceeded 20% was considered a clinically significant decrement. A difference between the pre- and post-implant scores less than 20% was considered no change in performance.

* Either pre- or postoperative score not available.

All but two patients showed clinically significant improvement on one or more of the speech measures. One of the two patients showed a significant decrement on CID sentences, with non-significant improvement on the other three tests. The decrease in CID sentence recognition ability does not reflect a decrement in performance of the implanted ear, but the absence of the contribution of the nonimplanted ear, which likely augmented preoperative performance. The other patient is elderly, has a long duration of deafness, and has only a partial insertion of the electrode because of cochlear ossification.

Improvement from Conventional Sound Processing to HiResolution Sound Processing

Word recognition, easy sentence recognition, and difficult sentence recognition in quiet and in noise (all without lipreading) were evaluated after using conventional sound processing strategies for three months and after using HiRes sound processing for three months. The mean improvement in performance from conventional sound processing to HiRes sound processing was statistically significant on all measures, although the study design does not allow determination of whether HiRes sound processing was solely responsible for the improvement.

Safety and Efficacy Data in Children

Pediatric safety and efficacy data are based on clinical trial results obtained with the first-generation CLARION implant (CI) and electrode technology and HiFocus Electrode with Positioner. Two consecutive clinical trials were conducted in the pediatric population with CLARION CI HiFocus I Electrode with Positioner: (a) children implanted between 18 months and 17 years of age, and (b) children implanted between 12 months and 17 months of age.

Pediatric safety and efficacy data are based on clinical trial results obtained with the previous-generation device and electrode technology--CLARION CI with HiFocus I Electrode with Positioner--which was the predecessor to the CII HiFocus II Electrode. The HiFocus II Electrode is a design change in which the Electrode Positioner is attached to the HiFocus I Electrode, a modification made to streamline and simplify the surgical procedure. The HiFocus II Electrode was evaluated with the CLARION CI device only in postlingual adults, and a clinical trial was not conducted in the pediatric population. Two consecutive clinical trials were conducted in the pediatric population with CLARION CI HiFocus I Electrode with Positioner: (a) children implanted between 18 months and 17 years of age, and (b) children implanted between 12 months and 17 months of age.

Safety Results: Children Implanted Between 18 Months and 17 Years of Age

Safety results are based upon data from 150 children implanted in North America with the CLARION CI implant and HiFocus Electrode with Positioner. Among this group, the following adverse events occurred in relation to the use of the device.

Medical/Surgical Complications

ò Vestibular Effects: Two patients (2/150, 1.3%) experienced postoperative vestibular symptoms. One patient experienced balance problems immediately following surgery. Another patient experienced minor positional vertigo. Symptoms resolved in both patients without medical intervention.

ò Tinnitus: One patient (1/150, 0.7%) reported mild tinnitus in the implanted ear on several occasions following surgery. The tinnitus resolved without medical intervention.

ò Facial Nerve Involvement: One patient (1/150, 0.7%) experienced facial nerve weakness and ear pain 6 days after surgery which resolved following medical treatment.

ò Postoperative Complications at Surgical Site: Three patients (3/150, 2.0%) experienced a complication at the surgical site. Two patients experienced infection which resolved in one patient following medical treatment. The infection in the other patient did not respond to

medical treatment and required
surgery to replace the device. The patient was
reimplanted without incident.
Another patient experienced a hematoma at the
surgical site following head
trauma. The hematoma resolved following treatment
and the device continues to
function normally.
ò Electrode Displacement: One patient (1/150,
0.7%) experienced electrode
displacement due to excessive intracochlear bone
growth (ossification) and
required reimplantation. The device was explanted
and the patient was
reimplanted without incident.
Device-Related Complications
ò One patient (1/150, 0.7%) experienced a device
failure as a result of electrode
breakage and required surgery to replace the
device. The patient was reimplanted
without incident.
Efficacy Results: Children Implanted Between 18
Months and 17 Years of Age
Efficacy results are based on 52 of the 150
children with six-month follow-up data.
Children were implanted with the CLARION CI
implant with HiFocus Electrode
with Positioner.
Because of developmental differences in cognitive
and linguistic skills, children
were classified into two groups by age at time of
implant: (1) children between 18
months and 3 years 11 months of age (n = 25), and
(2) children 4 years of age
and older (n = 27). For both age groups, parental
ratings of the child's response to
sound in everyday listening situations
[Meaningful Auditory Integration Scale
(MAIS) or Infant-Toddler Meaningful Auditory
Integration Scale (IT-MAIS)] were
made pre-implant with hearing aids and at six
months post-implant. For the older
group, closed-set and open-set word recognition
also were evaluated pre-implant
with hearing aids and at six months post-implant
using monitored live voice (70 dB
SPL). Effectiveness was assessed by comparing
post-implant scores after six
months of device use to pre-implant scores on
each test.
A positive difference between post-implant and
pre-implant scores was considered a
clinically significant improvement if the
difference equaled or exceeded 20%.
Similarly, a decrease between pre-implant and
post-implant scores that equaled or

exceeded 20% was considered a clinically significant decrement. A difference between the pre-and post-implant scores less than 20% was considered a nonsignificant change in performance because of the long-time course over which auditory skills emerge in children.

Children 18 Months to 3 Years 11 Months of Age

Response to Sound in Everyday Situations After Only Six Months of Device Use

Test: Meaningful Auditory Integration Scale (MAIS) or Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)

During a structured interview, parents rated the frequency of occurrence of 10 auditory behaviors using the scale: 0 (never), 1 (rarely), 2 (occasionally), 3 (frequently), 4 (always). Composite scores (sum of 10 items divided by the total number of possible points) were calculated.

* Three children did not have six-month scores.

ò Approximately one-third (7/22, 32%) of the children attained a composite score of 80% or higher after six months of device use.

Results also were analyzed for the percentage of children who "frequently" or "always" demonstrated a specific auditory behavior.

ò Preoperatively with hearing aids only, 4% (1/25) of the children frequently or always responded to their name in quiet. Postoperatively with the implant, 73% (16/22) of the children frequently or always responded to their name in quiet.

ò Preoperatively with hearing aids only, 4% (1/25) of the children frequently or always responded to environmental sounds. Postoperatively with the implant, 68% (15/22) of the children frequently or always responded to environmental sounds.

ò Preoperatively with hearing aids only, 8% (2/25) of the children frequently or always differentiated between speech and non-speech sounds. Postoperatively with the implant, 68% (15/22) of the children frequently or always differentiated between speech and non-speech sounds.

Children 4 Years of Age and Older

Pre-Implant to Post-Implant Improvement in Individual Patients

All children 4 years of age and older showed clinically significant improvement on one or more of the efficacy measures.

Response to Sound in Everyday Situations After Only Six Months of Device Use

Test: Meaningful Auditory Integration Scale (MAIS)
During a structured interview, parents rated the frequency of occurrence of 10 auditory behaviors using the scale: 0 (never), 1 (rarely), 2 (occasionally), 3 (frequently), 4 (always). Composite scores (sum of all 10 items divided by total number of possible points) were calculated.
* One child did not have a six-month score.
** Two children did not have preoperative or six-month scores.
ò More than one-third (10/26, 38%) of the children attained a composite score of 80% or higher.
Results also were analyzed for the percentage of children who "frequently" or "always" demonstrated a specific auditory behavior.
ò Preoperatively with hearing aids only, 23% (6/26) of the children frequently or always responded to their name in quiet. Postoperatively with the implant, 88% (23/26) of the children frequently or always responded to their name in quiet.
ò Preoperatively with hearing aids only, 23% (6/26) of the children frequently or always responded to environmental sounds. Postoperatively with the implant, 85% (22/26) of the children frequently or always responded to environmental sounds.
ò Preoperatively with hearing aids only, 31% (8/26) of the children frequently or always differentiated between speech and non-speech sounds. Postoperatively with the implant, 81% (21/26) of the children frequently or always differentiated between speech and non-speech sounds.
Closed-Set Word Recognition in Quiet, Hearing Only (no lipreading) After Only Six Months of Device Use
Test: Early Speech Perception (ESP) Test (Monosyllable Word Identification Subtest)
* One child did not have a six-month score.
ò Approximately one-third (9/26, 35%) of the children recognized 90% or more of the closed-set words.
Open-Set Phoneme Recognition in Quiet, Hearing Only (no lipreading) After Only Six Months of Device Use
Test: Phonetically Balanced-Kindergarten Word Test (scored for phonemes correct)
* Three children did not have six-month scores.
** Four children did not have either preoperative

or six-month scores.
ò One-third (8/24, 33%) of the children recognized 60% or more of the phonemes in words after six months of device use.
Open-Set Word Recognition in Quiet, Hearing Only (no lipreading) After Only Six Months of Device Use
Test: Phonetically Balanced-Kindergarten Word Test (scored for words correct)
* Two children did not have six-month scores.

	Significant Improvement (%, n)	No Change	Significant Decrease (%, n)	Could Not Calculate(n)*
CNC Words	85% (40/47)	15% (7/47)	0% (0/47)	4
CID Sentences	90% (43/48)	8% (4/48)	2% (1/48)	3
HINT Sentences in Quiet	94% (48/51)	6% (3/51)	0% (0/51)	0
HINT Sentences in Noise	84% (36/43)	16% (7/43)	0% (0/43)	8
Mean	59%	Significant Improvement(%, n)	82% (18/22)	
Median	66%	Non-Significant Improvement(%, n)	14% (3/22)	
S.D.	30%	No Change(%, n)	0% (0/22)	
Range	0-98%	Non-Significant Decrement(%, n)	5% (1/22)	
n	22*	Significant Decrement(%, n)	0% (0/22)	
Mean	71%	Significant Improvement (%, n)	76% (19/25)**	
Median	71%	Non-Significant Improvement(%, n)	16% (4/25)**	
S.D.	19%	No Change (%, n)	4% (1/25)**	
Range	38-100%	Non-Significant Decrement (%, n)	4% (1/25)**	
n	26*	Significant Decrement (%, n)	0% (0/25)**	
Mean	60%	Significant Improvement(%, n)	50% (13/26)	
Median	71%	Non-Significant Improvement(%, n)	4% (1/26)	
S.D.	37%	No Change(%, n)	19% (5/26)	
Range	8-100%	Non-Significant Decrement(%, n)	19% (5/26)	
n	26*	Significant Decrement(%, n)	8% (2/26)	
Mean	37%	Significant Improvement(%, n)	49% (11/23)**	
Median	33%	Non-Significant Improvement(%, n)	26% (6/23)**	
S.D.	31%	No Change(%, n)	26% (6/23)**	
Range	0-90%	Non-Significant Decrement(%, n)	0% (0/23)**	

n 24* Significant Decrement(%, n) 0% (0/23)**
Mean 23% Significant Improvement(%, n) 28% (7/25)
Median 16% Non-Significant Improvement(%, n) 40% (10/25)
S.D. 26% No Change(%, n) 32% (8/25)
Range 0-100% Non-Significant Decrement(%, n) 0% (0/25)
n 25* Significant Decrement(%, n) 0% (0/25)
4
ò Slightly more than one-fourth (7/25, 28%) of the children recognized 48% or more of these difficult words.
Stimulation Strategy and Pulse Rate
Several sound-processing strategies are implemented with the CLARION CI implant and HiFocus Electrode. There are 8 independent output circuits and 16 electrode contacts in the cochlea. In the Simultaneous Analog Strategy (SAS), the 16 electrode contacts are bipolar coupled and analog waveforms are delivered to the resulting 8 channels simultaneously. In the Continuous Interleaved Sampler (CIS), monopolar coupling (even or odd) is used and pulsatile waveforms are sent to the resulting 8 sites sequentially. In the Multiple Pulsatile Sampler (MPS), pulsatile waveforms are sent to two electrodes at the same time (partially simultaneous stimulation). The table below indicates the strategies, the number of channels, and the stimulation rates (for pulsatile strategies only) used by the 52 children. Approximately two-thirds of the children used SAS with 7 or 8 channels. The remaining patients used pulsatile stimulation with 7 or 8 channels.
Safety Results: Children Implanted Between 12 Months and 17 Months of Age
Safety results are based on 29 children implanted between 12 and 17 months of age in North America with the CLARION CI implant and HiFocus Electrode with Positioner. The following adverse events occurred:
Medical/Surgical Complications
ò Leakage of Cerebrospinal Fluid during Surgery: Three children (3/29, 10.3%) with malformed cochleae experienced leakage of cerebrospinal fluid during surgery. Routine packing terminated the leaks. One patient also required a lumbar drain and two additional days of hospitalization for observation. All three patients stabilized after surgery and no further complications were reported.
ò Middle Ear Complications: Two patients (2/29,

6.9%) had acute ear infections at six months postimplantation that resolved after antibiotic treatment. One patient (1/29, 3.4%) had a small dry perforation of the tympanic membrane 12 months after implantation. No further complications were reported for the three patients.

ò Electrode/Device Displacement: Two patients (2/29, 6.9%) experienced migration of the electrode or receiver/stimulator. One patient experienced device migration due to head trauma resulting from a fall seven months following surgery. The receiver/stimulator was repositioned surgically without disturbing the electrode array or requiring device replacement. The other patient was reimplanted without incident after demonstrating unusual responses to sound six weeks after initial stimulation. The electrode had migrated partially and was kinked due to unknown cause.

Device-Related Complications

ò No device failures or major device malfunctions among this study group.

Efficacy Results: Children Implanted Between 12 Months and 17 Months of Age

Results from 20 of 29 children who had reached the six-month test interval were used to determine the effectiveness of the CLARION CI HiFocus I Electrode with Positioner in children 12-17 months of age. Parental ratings of the child's response to sound in everyday listening situations [Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)] were made pre-implant with hearing aids and at six months post-implant. Effectiveness was assessed by comparing post-implant scores after six months of device use to pre-implant scores. A positive difference between post-implant and pre-implant scores was considered a clinically significant improvement if the difference exceeded 20%. Similarly, a decrease between pre-implant and post-implant scores that exceeded 20% was considered a clinically significant decrement.

Response to Sound in Everyday Situations After Only Six Months of Device Use

Test: Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS)

During a structured interview, parents rated the frequency of occurrence of 10

auditory behaviors using the scale: 0 (never), 1 (rarely), 2 (occasionally), 3 (frequently), 4 (always). Composite scores (sum of all 10 items divided by the total number of possible points) were calculated.
ò More than one-third (8/20, 40%) of the children attained a composite score of 80% or higher after six months of device use.
Results also were analyzed for the percentage of children who "frequently" or "always" demonstrated a specific auditory behavior.
ò Preoperatively with hearing aids only, 15% (3/20) of the children frequently or always showed a change in their vocalizations. Postoperatively with the implant, 100% (19/19) frequently or always showed a change in their vocalizations.
ò Preoperatively with hearing aids only, 0% (0/20) of the children frequently or always responded to their name in quiet. Postoperatively with the implant, 84% (16/19) of the children frequently or always responded to their name in quiet.
ò Preoperatively with hearing aids only, 0% (0/20) of the children frequently or always responded to their name in noise. Postoperatively with the implant, 68% (13/19) of the children frequently or always responded to their name in noise.
ò Preoperatively with hearing aids only, 0% (0/20) of the children frequently or always responded to environmental sounds. Postoperatively with the implant, 74% (14/19) of the children frequently or always responded to environmental sounds.
ò Preoperatively with hearing aids only, 0% (0/20) of the children frequently or always recognized sounds in the environment. Postoperatively with the implant, 68% (13/19) of the children frequently or always responded spontaneously to everyday sounds.
ò Preoperatively with hearing aids only, 5% (1/20) of the children frequently or always differentiated between speech and non-speech sounds. Postoperatively with the implant, 74% (14/19) of the children frequently or always differentiated between speech and non-speech sounds.
Stimulation Parameters
Several sound-processing strategies are implemented with the CLARION CI implant and HiFocus Electrode with Positioner. There are 8 independent output

circuits and 16 electrode contacts in the cochlea. In the Simultaneous Analog Strategy (SAS), the electrodes are bipolar coupled and analog waveforms are delivered to the resulting 8 sites simultaneously. In the Continuous Interleaved Sampler (CIS), monopolar coupling (even or odd) is used and pulsatile waveforms are sent to the resulting 8 sites sequentially. In the Multiple Pulsatile Strategy (MPS), pulsatile waveforms are sent to two electrodes at the same time (partially simultaneous stimulation). Two thirds of the very young children (13/20) used analog stimulation and one third (7/20) used pulsatile stimulation. All children used 6-8 channels.

Stimulation Parameters for Children 12-17 Months of Age (n = 20)

POSSIBLE ADVERSE EVENTS: The following risks associated with cochlear implantation and ear surgery also can occur.

ò Implant patients incur the normal risks of surgery and general anesthesia.

ò Major ear surgery may result in numbness, swelling or discomfort about the ear, disturbance of taste or balance, or neck pain. If these events occur, they are usually temporary and subside within a few weeks of surgery.

ò Rarely, cochlear implantation may cause a leak of the inner ear fluid, which may result in meningitis.

ò Skin infection in the area of the implant may require additional medical treatment or removal of the internal device.

PATIENT COUNSELING INFORMATION

Prospective cochlear implant candidates must be counseled appropriately on expected outcomes prior to surgery. Patients demonstrate a range of cochlear implant benefit.

Although it is not possible to predict post-implant performance preoperatively for individual patients, research and clinical experience have shown that age at implant, duration of severe-to-profound hearing loss, and preoperative speech perception skills have a significant effect on post-implant performance. Ear selection for implantation is left to the discretion of the patient, surgeon, and audiologist. There is no consensus in the field regarding implantation of the better versus poorer ear. If the poorer ear is implanted, patients should be counseled that

postoperative performance ear may not equal that
of the better non-implanted ear,
especially if there also is long duration of
deafness and negligible residual hearing
preoperatively.
Communication mode (oral versus total
communication) and the patient's auditory
environment can affect outcomes in children.
Implant-center professionals should
counsel parents about the impact of communication
mode and auditory environment
on potential implant benefit in the pediatric
population.
TELEMETRY: The HiResolution Bionic Ear System
incorporates bi-directional
telemetry that verifies system function and
continuously monitors the system during
normal use.
STORAGE: The HiResolution Bionic Ear System
should be stored at temperatures
in the range of 0 to 50 Centigrade (32 to 122
Fahrenheit).
HANDLING: The HiRes 90K implant package should be
handled with care. An
impact that damages the storage pack also could
rupture the sterile packaging.
SHELF LIFE: A "Use Before" date is located on the
HiRes 90K implant
packaging. This date is two years from the date
of sterilization. The cochlear
implant itself is not subject to aging.
STERILIZATION: The HiRes 90K implant is supplied
in ethylene oxide sterile
packaging with indicators of sterilization.
Sterile packs should be inspected
carefully to confirm that they have not been
ruptured. Sterility cannot be
guaranteed if the sterile package is damaged or
opened.
INFORMATION FOR USE AND REQUIRED TRAINING: A
Surgeon's
Manual and a video describing the surgical
procedure and insertion of the electrode
are provided to all physicians prior to
implantation. Physicians must be well versed
in mastoid surgery and the facial recess approach
to the round window. Advanced
Bionics conducts periodic training courses on the
recommended surgical procedure
to implant HiRes 90K and strongly recommends that
surgeons who implant adults
receive training.
All physicians implanting the HiRes 90K in
children must be trained in the
implantation procedure. Failure to obtain the
appropriate training will result in a

higher incidence of surgical and medical complications.
Surgeons should work with an audiology professional who has been trained fully on the proper fitting and adjustment of the system.
Device and Fitting Manuals are provided to all clinical centers with the Clinician's Programming System. Audiologists must be highly skilled in administering test procedures used to determine cochlear implant candidacy. They should be knowledgeable about state-of-the-art hearing aid technology and fitting procedures.
In addition, at least one audiologist from a clinical center should be fully trained and qualified in the fitting of the CLARION cochlear implant in both adults and children. Advanced Bionics conducts periodic training courses for audiologists and strongly recommends that audiologists attend a training course. Failure to obtain the appropriate training will result in less-than-optimal patient performance.
An instructional video and sound processor user guides are provided to all HiResolution Bionic Ear System recipients upon delivery of the system. Patient counseling materials are made available to all implant centers upon request. These materials provide detailed information about the system, indications for use, benefits, risks, and what is involved in patient selection, surgery, and follow-up procedures.
CAUTION: Federal law restricts this device to sale, distribution and use by or on the order of a physician. For use in children, federal law restricts this device to sale, distribution and use by or on the order of a physician who is trained in the pediatric implantation procedures for the HiResolution Bionic Ear System.
Number of Channels
SAS CIS MPS
Analog Percentage of Users
Pulses per Second per Channel
Percentage of Users

Pulses
per
Second
per
Channel
Percentage
of Users
3
Continuous
Simultaneous
Stimulation
2167 3250
4 1625 3250
5 1300 2167
6 1083 2167
7 8% 929 1625 2%
8 56% 813 15% 1625 19%
Total 64% 15% 21%
Mean 70% Significant Improvement(%, n) 95% (19/20)
Median 75% Non-Significant Improvement(%, n) 5%
(1/20)
S.D. 22% No Change(%, n) 0% (0/20)
Range 15-95% Non-Significant Decrement(%, n) 0%
(0/20)
n 20 Significant Decrement(%, n) 0% (0/20)
Number
of
Channels
SAS CIS MPS
Analog
Percentage
of Users
Pulses
per
Second
per
Channel
Percentage
of Users
Pulses
per
Second
per
Channel
Percentage
of Users
3
Continuous
Simultaneous
Stimulation
2167 3250
4 1625 3250
5 1300 2167
6 5% 1083 2167
7 929 5% 1625 5%
8 60% 813 10% 1625 15%

Total 65% 15% 20%
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