

October 29, 2013

Office of Regulations and Reports Clearance
Social Security Administration
107 Altmeyer Building
6401 Security Boulevard
Baltimore, MD 21235-6401

RE: Docket No. SSA-2012-0075: Revised Medical Criteria for Evaluating Hearing Loss and Disturbances of Labyrinthine-Vestibular Function

Dear Sir or Madam:

The American Academy of Audiology (the “Academy”) is the world's largest professional organization of, by, and for audiologists, representing nearly 12,000 members. The Academy promotes quality hearing and balance care by advancing the profession of audiology through leadership, advocacy, education, public awareness, and support of research.

The Academy appreciates the opportunity to offer comments in response to the Social Security Administration’s (SSA) advance notice of proposed rulemaking (ANPRM), Docket No. SSA-2012-0075, published in the Federal Register on August 30, 2013.

The ANPRM indicates that the SSA is requesting feedback on how to revise the criteria in the Listings and Impairments (listings) for evaluating hearing loss and disturbances of labyrinthine-vestibular function in adults and children. The Academy commends the SSA on its efforts to ensure that its listing criteria accurately reflect current practice and medical knowledge. As such, we would like to propose a series of changes to the introductory text sections 2.00B and 102.00B, and the listings and other criteria in sections 2.00 and 102.00 for evaluating hearing loss (see addendum 1) and disturbances to labyrinthine-vestibular function (see addendum 2).

Thank you for your consideration of the Academy’s comment letter. If there are any questions about our recommendations, please contact Melissa Sinden, Senior Director, Government Relations at 202.544.9335 or via email at msinden@audiology.org .

Sincerely,



Bettie Borton, AuD
President, American Academy of Audiology

Addendum 1

Proposed revisions to the introductory text sections 2.00B and 102.00B and the listings and other criteria in sections 2.00 and 102.00 for evaluating hearing loss

B. How is hearing loss evaluated?

1. What evidence is needed?

a. Evidence is needed that demonstrates the presence of a hearing loss, and a medically-determinable condition that is responsible for the hearing loss. An audiometric measurement of the type, configuration, and severity of the hearing loss is also required, along with a complete otologic examination by a physician. Audiometric testing should be completed within two months of the otologic examination, or sooner if any acute changes have occurred in the status of hearing. Determination of impairment would include degree of hearing loss, along with any other relevant information about an individual's hearing, including information from outside of the test setting.

b. A complete otologic examination must be performed by a licensed physician, preferably an otolaryngologist or otologist. A medical report should include the physician's description of the appearance of the external ears (pinnae and external ear canals), evaluation of the tympanic membranes, and assessment of any middle ear abnormalities. It must also include a medical history.

c. Audiometric testing must be performed by, or under the direct supervision of, an otolaryngologist or by an audiologist qualified to perform such tests. A qualified audiologist is one who is currently licensed as a clinical audiologist by the State or U.S. territory in which he or she practices.

2. What audiometric testing is needed when the patient does not have a cochlear implant?

a. *General.* A complete audiometric evaluation must include both physiologic and behavioral testing (other than screening testing, see 102.00B2g) that is appropriate for the age of the patient. See 102.00B2c-102.00B2f. A complete audiometric evaluation should include pure tone threshold testing for both air and bone conduction, Speech Recognition Thresholds (SRT), and Word Recognition testing. Immittance testing should be included as appropriate. Testing must be conducted in a sound-treated booth or room, with calibrated equipment and must be in accordance with the most recently published standards of the American National Standards Institute (ANSI). Each ear must be tested separately.

b. A SRT is the minimum decibel (dB) level required to recognize 50 percent of words on a standard list of spondee words (two-syllable words with equal stress on each syllable.) An SRT is usually found to be within 10 dB of the average pure tone air conduction hearing thresholds at 500, 1000, and 2000 Hz. If the SRT is not within 10 dB of the average pure tone air conduction

threshold, the reason for the discrepancy must be documented. If it cannot be determined that there is an audiometric basis for the discrepancy, the results of the testing cannot be used to determine whether a hearing loss meets a given criteria.

c. Word recognition testing determines the ability to recognize a standardized list of phonetically balanced monosyllabic words in the absence of visual cues. Testing must be performed in a quiet environment. The word list must be presented via recording, and the words should be presented at a loudness level that will measure maximum word recognition ability. This level is typically at the listener's Most Comfortable Loudness level, usually 35 to 40 dB above your SRT. However, if the words cannot be delivered comfortably at 35 to 40 dB above the SRT, the word recognition testing score should be reported using the highest, allowable loudness comfortable level, and noted in the report accordingly.

d. *Testing requirements.* The testing must be conducted in accordance with the most recently published standards of the American National Standards Institute (ANSI). Hearing aids must not be worn during the evaluation. Additionally, persons described in 102.00B1c must perform an otoscopic examination of both ear canals immediately before the audiometric testing. The otoscopic examination and/or tympanometry must show that there are no conditions that would preclude valid audiometric testing, such as fluid in the middle ear, ear infection, cerumen impaction, or other obstruction in an ear canal. The person performing the test also should report on any other factors that that could affect the interpretation of the test results.

PEDIATRIC AUDIOMETRIC CRITERIA FOR DETERMINING DEGREE OF HEARING LOSS

a. *Children from birth to the attainment of age 6 months.*

(i) Behavioral testing should be accompanied by physiologic testing, such as auditory brainstem response (ABR) audiometry and otoacoustic emissions (OAEs), along with high-frequency tympanometry.

b. *Children from age 6 months to the attainment of age 2.*

(i) A behavioral audiometric assessment should, at a minimum, yield sound field air conduction thresholds. The most common evaluation form for this age group is typically Visual Reinforcement Audiometry (VRA). Otoacoustic emissions testing or auditory brainstem audiometry could be used if the behavioral assessment cannot be completed or if the results are inconclusive or unreliable. Tympanometry should be a standard aspect of a complete evaluation.

(ii) For this age group, behavioral assessments are often performed in a sound field, and separate ear information may not always be possible. In the case of sound field testing, results are considered to be those of the better ear.

c. *Children from age 2 to the attainment of age 5.*

(i) Air conduction thresholds are determined by a behavioral assessment technique, such as Conditioned Play Audiometry (CPA), or Visual Reinforcement Audiometry (VRA). ABR or OAEs test results can be used if behavioral test results cannot be completed or the results are inconclusive, or unreliable.

(ii) For this age group, behavioral assessments can be determined either in the sound field or under earphones. If testing is performed in the sound field, each ear is not tested separately. Thus, the results are considered to be those of the better ear. Immittance testing should be a standard aspect of a complete evaluation.

f. Children from age 5 to the attainment of age 18.

(i) The test battery for this age group should include pure tone air and bone conduction threshold testing, speech testing that includes a Speech Recognition Threshold (SRT), and word recognition testing bilaterally. This testing must be conducted in a sound-treated booth or room using calibrated equipment and must be in accordance with the most recently published ANSI standards. Each ear must be tested separately.

g. Tympanometry refers to an evaluation of the status of the middle ear, including middle ear mobility and ear canal volumes.

h. Auditory Brainstem Response (ABR) audiometry refers to an evoked potential generated by a brief click or tone pip transmitted from an acoustic transducer in the form of an insert earphone or headphone. The elicited waveform response is measured by surface electrodes typically placed at the vertex of the scalp and ear lobes. The amplitude (microvoltage) of the signal is averaged and charted against the time (millisecond), much like an EEG.

i. Otoacoustic Emissions testing is a measurement of sound emanating from the inner ear that can be recorded from a minute microphone placed in the external auditory canal. OAEs are thought to be produced by the outer hair cells in the cochlea. OAEs can occur spontaneously and more commonly are evoked by acoustic stimuli, and are indicative of the integrity of the auditory hair cells.

g. *Screening.* Physiologic tests, such as ABR and otoacoustic emissions (OAE), as well as screening pure tone testing can be used to screen hearing. However, since the results of these tests will not provide exact hearing thresholds, they cannot be used to determine the degree of hearing loss with certainty. Thus, the results cannot be used to determine whether a hearing loss meets, or medically equals a listing, or to assess functional limitations due to hearing loss.

3. What audiometric testing is needed for a patient with a cochlear implant?

a. For cochlear implant recipients, anyone under the age of 5, or for one year post-implantation, whichever is later, an individual will be considered disabled.

b. After that period, word recognition testing should be performed with any age-appropriate version of the Hearing in Noise Test (HINT) or the Hearing in Noise Test for Children (HINT-C) to determine whether the remaining hearing impairment meets 102.11B. As the child develops more language, standard word recognition tests can be used, such as the Northwestern University-Children's Perception of Speech (NU-CHIPS). Testing must be conducted in quiet in a sound field. The implant processor must be functioning properly and adjusted to the individual's normal settings. The sentences should be presented at 60 dB HL (Hearing Level) and without visual cues.

4. *How is word recognition evaluated in a non-fluent English speaker?*

If an individual is not fluent in English, word recognition testing should be implemented using an appropriate word list for the language in which the individual is most fluent. The tester should be fluent in the language used for the test. If an appropriate word list or a person who is fluent in the language and qualified to perform the test is not available, it may not be possible to measure true word recognition ability. If word recognition ability cannot be measured, a hearing loss cannot meet 102.10B2 or 102.11B. Instead, the facts of the case will be used to determine whether the individual has difficulty understanding words in the language in which he or she is most fluent, and if so, whether that degree of difficulty medically meets 102.10B2 or 102.11B. For example, the individual's interactions with family members, interpreters, and other persons who speak the language in which he or she is most fluent, will be assessed.

5. *What is meant by a 'marked limitation' in speech or language as used in 102.10B3?*

a. An individual is considered to have a marked limitation in speech production if:

(i) Entire phrases or sentences in conversation are unintelligible to unfamiliar listeners at least 50 percent (half) of the time, but no more than 67 percent (two-thirds) of the time on a first attempt; and

(ii) The sound production or phonological patterns (the ways in which speech sounds are combined) are atypical for the individual's age.

b. A marked limitation in both expressive and receptive language is defined as a current and valid test score on an appropriate comprehensive, standardized test of overall language functioning that is at least two standard deviations below the mean. In addition, the evidence of an individual's daily communication functioning must be consistent with his or her test score. If an individual is not fluent in English, it may not be possible to test language performance. If language performance cannot be tested, an individual's hearing loss cannot meet 102.10B3. Instead, the facts of the case will be considered in determining whether the individual's hearing loss is medically equal to 102.10B3.

HEARING LOSS CRITERIA FOR ALL ABOVE AGE CATEGORIES

To determine whether a hearing loss meets 102.10A, an average of an individual's hearing thresholds at 500, 1000, 2000, and 4000 Hertz (Hz) will be determined. If no response is determinable at a particular frequency, a threshold of 5 decibels (dB) over the limit of the audiometer will be used.

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In addition to offering revisions to listing and criteria in sections 2.00 and 102.00 for evaluating hearing loss, the Academy also wishes to address a number of the sample questions posed by the SSA in the ANPRM. Our responses are enumerated below.

1. Do the rules for evaluating hearing loss or disturbances of labyrinthine- vestibular function contain technical language or jargon that is not clearly explained? If not clearly explained, what technical language or jargon needs further explanation?

Further definition of testing techniques needs to be expanded for each age group (see revisions above).

2. Are the requirements for otological examinations and audiometric testing provided in sections 2.00B and 102.00B clearly stated? If not clearly stated, what requirements need further clarification?

The requirements are clearly stated, but the intent was not clear.

3. What types of testing should we consider when evaluating hearing loss in adults or children who cannot cooperate in behavioral testing?

As noted in our suggested revisions, physiological testing methods, that require minimal patient cooperation, are included and defined, e.g. ABR, OAE, tympanometry.

4. Would it be helpful to add a sample audiogram that contains all the requirements necessary for evaluation of hearing loss in adults or children?

Only a conventional audiogram could be included since an audiogram developed using pediatric test methods such as VRA or play audiometry could be varied.

5. What word recognition tests other than the Hearing in Noise Test (HINT) or the Hearing in Noise Test—Children (HINT-C) should we consider when we evaluate hearing loss treated with cochlear implantation?

As implanted children develop receptive language, conventional word recognition tests such as the NU-CHIPS could be used. Adults may be tested using some form of minimal auditory

capabilities testing that ultimately leads to testing using a conventional, monosyllabic word test such as the NU-6.

6. Should we provide examples of medical reasons for a discrepancy between the speech reception threshold and the pure tone average?

Possibly, but there are audiometric explanations for this discrepancy as well, e.g. poor word recognition.

7. What else could we do to make the rules for evaluating hearing or disturbances in labyrinthine-vestibular function easier to understand?

The Academy recommends that the SSA outline separate sections for audiometric testing paradigms vs. hearing loss categorization/criteria.

8. Would a different format make the rules easier to understand (for example, changing the grouping or ordering of sections; use of headings; paragraphing; use of diagrams; use of tables)?

Yes (see suggested changes in proposed revisions to sections 2.00 and 102.00). As noted in our comments, the Academy recommends designating audiometric testing strategies separately from hearing loss designation criteria as they clearly serve different purposes.

9. Experts who study disability believe that many personal, environmental, educational, and social factors contribute in significant ways to the relationship between a person's hearing ability and the ability to work. Rather than providing criteria for evaluating hearing loss in adults under the listings, should we evaluate all hearing loss using residual functional capacity?

Yes, however, developing a single tool to determine capacity will be challenging.

Addendum 2

Comments and proposed revisions to introductory text sections 2.00B and 102.00B, and the listings and other criteria in sections 2.00 and 102.00 for evaluating disturbances of labyrinthine-vestibular function

1. The only specific disorder mentioned in listings and criteria is Meniere's disease, which can present as fluctuating periods of vertigo, tinnitus, and hearing loss. However, there are numerous other disorders that can cause symptoms of vertigo/imbalance, and do not always present with hearing loss and/or tinnitus. For this reason, hearing loss should NOT be part of the criteria for determining whether an individual has a vestibular disorder. Whereas the audiogram should be part of the standard assessment and can provide useful information, hearing loss is not always present in vestibular disorders.
2. Meniere's disease is a common cause for vestibular dysfunction, but it is not the only clinically recognized diagnosis for vestibular dysfunction. In some cases, vestibular dysfunction can be a result of numerous other disease processes/etiologies. For this reason, a complete assessment should be completed to determine the appropriate diagnosis for vestibular disorders.
3. Other common causes of vestibular dysfunction include, but are not limited to:
 - a. Vestibular neuritis or labyrinthitis
 - b. Vestibular migraine
 - c. Vestibular ototoxicity
 - d. Benign Paroxysmal Positional Vertigo (BPPV)
 - e. Progressive auto-immune disorder
 - f. Acoustic neuroma (vestibular schwannoma)
 - g. Traumatic Brain Injury
 - h. Bilateral vestibular dysfunction
 - i. Diabetes-related vestibular dysfunction
 - j. Superior Semicircular Canal Dehiscence
4. CT scans should be eliminated from vestibular assessments. CT scans are often misleading and rarely add any useful information to the diagnosis. If any imaging studies are indicated, MRIs should be considered, as they have been proven to be much more sensitive in identifying vestibular lesions.

5. Bekesy audiometry should be eliminated from a vestibular assessment protocol. This is an outdated test, and is no longer performed in the clinical setting to evaluate patients.
6. Vestibular disorders can be peripheral, central or both. One goal of vestibular assessment is to determine the etiology of vestibular dysfunction. This will help to establish a diagnosis and to determine the best course of treatment. Peripheral vestibular disorders are often easier to diagnose and treat. However, even with appropriate treatment and rehabilitation, these disorders can cause permanent functional disability. Central vestibular disorders are normally progressive in nature and can lead to significant impairment and malfunction.
7. Once dysfunction has occurred, the brain begins to adapt to the altered sensory information, ultimately leading to elimination of the perception of dizziness/imbalance. This is called vestibular compensation. This can occur slowly on its own, and can be hastened with specialized exercises and rehabilitation in vestibular rehabilitation. This process can take a few days to a few months, depending on what activities are completed.
8. In some people, full compensation never occurs, and lingering symptoms can continue on for the rest of their lives. There are certain activities and movements that are difficult for these people to complete, and can result in frequent imbalance.
9. Vestibular assessment should begin with a thorough case history by a licensed audiologist, neurologist, or otolaryngologist who has the required training in vestibular assessment. This should include determining the frequency/intensity of symptoms, whether these are related to head movement, the presence of blurred vision, and/or other pertinent symptoms. Patients with vestibular disorders will often be able to describe subjective symptoms accurately. This, along with a measurably objective abnormality on vestibular function testing, and abnormal functional assessment, is enough to diagnose a patient with a vestibular disorder.
10. An audiometric evaluation should also be completed including tympanometry, acoustic reflexes, acoustic reflex decay, air and bone conduction thresholds, and speech audiometry. Auditory Brainstem Response (ABR) testing can also be beneficial.
11. Functional assessments should be completed to determine an individual's perceived handicap and functional performance. This can include, but is not limited to, the Dizziness Handicap Inventory, Computerized Dynamic Posturography, and Visual Acuity Testing. Functional testing should be supplemented with objective evidence.

12. Objective measurements should include, but are not limited to, videonystagmography (VNG) or electronystagmography (ENG), rotary chair testing, caloric testing, and/or vestibular-evoked myogenic potentials (VEMP).

Key Statement:

A functional deficit of vestibular function is evidenced by abnormal objective measurements on one or more of the following tests: Videonystagmography or electronystagmography, Rotary Chair Testing, Caloric Testing, Computerized Dynamic Posturography, vHIT or Head Impulse testing, and/or VEMP

AND

Is supported by functional measurements using one or more of the following tests: Computerized Dynamic Posturography, or Dynamic Visual Acuityⁱ.

References:

Vestibular System and Vertigo - Maryland Hearing and Balance Center | University of Maryland Medical Center <http://umm.edu/programs/hearing/services/vertigo#ixzz2gyV0xav1>
University of Maryland Medical Center – Accessed October 6, 2013

How Are Vestibular Disorders Diagnosed - Vestibular Disorders Association
<http://vestibular.org/understanding-vestibular-disorder/diagnosis> - Accessed October 6, 2013

ⁱ Some transient vestibular disorders such as vestibular migraine and Meniere's disease, objective testing may show normal vestibular function on the day of testing. For this reason, the examiner's judgment and case history should be heavily relied upon to determine whether symptoms correlate to a specific disorder.