UnitedHealthcare Community Plan

REIMBURSEMENT POLICY
CMS-1500
Policy Number 2024R7104B.LA

Otoacoustic Emissions Testing Policy, Professional for Louisiana

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Community Plan reimbursement policies uses Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS) or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.*

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms. Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general reference resource regarding UnitedHealthcare Community Plan's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare Community Plan may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare Community Plan enrollees.

Other factors affecting reimbursement supplement, modify or, in some cases, supersede this policy. These factors include, but are not limited to: federal &/or state regulatory requirements, the physician or other provider contracts, the enrollee's benefit coverage documents, and/or other reimbursement, medical or drug policies.

Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare Community Plan due to programming or other constraints; however, UnitedHealthcare Community Plan strives to minimize these variations.

UnitedHealthcare Community Plan may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

Application

This reimbursement policy applies to UnitedHealthcare Community Plan Medicaid products.

This reimbursement policy applies to services reported using the 1500 Health Insurance Claim Form (a/k/a CMS-1500) or its electronic equivalent or its successor form. This policy applies to all products and all network and non-network physicians and other qualified health care professionals, including, but not limited to, non-network authorized and percent of charge contract physicians and other qualified health care professionals.

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Policy

Overview

UnitedHealthcare Community Plan has noticed an increase in utilization for OAE (otoacoustic emissions) testing in certain markets as a tool for routine screening. This has created increasing financial payments in these markets.

The American Academy of Pediatrics (AAP) Task Force on Newborn and Infant Hearing and the Joint Committee on Infant Hearing (JCIH) endorse the implementation of universal newborn hearing screening. Also, the U.S. Preventive Services Task Force (USPSTF) recommends screening for hearing loss in all newborn infants.

Otoacoustic emissions (OAEs) are low-intensity sounds emitted by functioning outer hair cells of the cochlea. OAEs are measured by presenting a series of very brief clicks to the ear through a probe that is inserted in the outer third of the ear canal. The probe contains a loudspeaker that generates the clicks and a microphone for measuring the resulting OAEs that are produced in the cochlea and are then reflected back through the middle ear into the outer ear canal. OAE testing requires no behavioral or interactive feedback by the individual being tested.

OAEs are used as a screening test for hearing in newborns. Other potential applications of OAE testing include screening children or at-risk populations for hearing loss, and characterizing sensitivity and functional hearing loss and differentiating sensory from neural components in people with known hearing loss.

The two most common types of OAE measurements are 1) transient evoked otoacoustic emissions (TEOAEs) which are sounds emitted in response to acoustic stimuli of very short duration; usually clicks but can be tone-bursts, and 2) distortion product otoacoustic emissions (DPOAEs) which are sounds emitted in response to two simultaneous tones of different frequencies. TOAEs are used to screen infants, validate other tests, and assess cochlear function, and DPOAEs are used to assess cochlear damage, ototoxicity, and noise-induced damage. Spontaneous otoacoustic emissions (SOAEs) are sounds emitted without an acoustic stimulus (i.e., spontaneously). Sustained-frequency otoacoustic emissions (SFOAEs) are sounds emitted in response to a continuous tone. At present, SOAEs and SFOAEs are not used clinically.

The OAE test is an effective screening measure for middle-ear abnormalities and for moderate or severe degrees of hearing loss, because normal OAE responses are not obtained if hearing thresholds are approximately 30- to 40-dB hearing levels or higher. The OAE test does not further quantify hearing loss or hearing threshold level. The OAE test also does not assess the integrity of the neural transmission of sound from the eighth nerve to the brainstem and, therefore, will miss auditory neuropathy and other neuronal abnormalities. Individuals with such abnormalities will have normal OAE test results but abnormal auditory brainstem response (ABR) test results (Harlor, 2009).

Reimbursement Guidelines

UnitedHealthcare Community Plan will deny CPT codes 92558, 92587 and 92588 when not submitted with a diagnosis on the attached diagnosis list for members age 4 years and over.

Neonatal hearing screening using otoacoustic emissions (OAEs) is medically necessary for infants who are 90 days or younger.

Otoacoustic emissions (OAEs) testing is medically necessary for the evaluation of hearing loss in the following:

- infants and children age 3 years (up to, but not including, 4th birthday) or younger
- children and adults who are or who are unable to cooperate with other methods of hearing testing (e.g. individuals with autism or stroke)

Auditory screening or diagnostic testing using otoacoustic emissions (OAEs) is not medically necessary for all other patient populations and conditions including ototoxic hearing changes in individuals treated with ototoxic medications.

There is inadequate evidence that hearing screening with OAEs is superior to screening audiometry in improving health outcomes such as timely facilitation of speech, language, and communication skills in older children or adults. There is also inadequate evidence to indicate that the use of diagnostic otoacoustic emissions (OAEs) testing is superior to screening audiometry in improving health outcomes such as timely facilitation of speech, language, and communication skills) in patients with other conditions such as ototoxic hearing changes in individuals treated with ototoxic medications, noise-induced hearing loss, sudden hearing loss, tinnitus, and other suspected hearing loss.

Definitions

OAE	Otoacoustic emissions: low-intensity sounds emitted by functioning outer hair cells of the cochlea.

Questions and Answers

1	**Q:** Why doesn't UnitedHealthcare Community Plan reimburse for OET screening for members over the age of 4 years? **A:** In order to comply with newborn hearing screening requirements and to follow guidelines from the research regarding testing of children, OET screening will be allowed for members up to age 4. There is inadequate evidence that hearing screening with OAEs is superior to screening audiometry in improving health outcomes such as timely facilitation of speech, language, and communication skills in older children or adults.

Codes

CPT code section

92558	92587	92588

Attachments

Otoacoustic Emissions Testing ICD-10 Diagnosis Policy List	List of ICD-10 codes for which CPT codes 92558, 92587 and 92588 will be reimbursed on or after date of service October 1, 2015.

Resources

Individual state Medicaid regulations, manuals & fee schedules

American Medical Association, *Current Procedural Terminology (CPT®) Professional Edition* and associated publications and services

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

The American Academy of Pediatrics (AAP) Task Force on Newborn and Infant Hearing
Joint Committee on Infant Hearing (JCIH)

U.S. Preventive Services Task Force (USPSTF)

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Clinical Evidence

Otoacoustic Emissions (OAEs) for Neonatal Hearing Screening

A study which involved 53,781 newborns provided a direct comparison of hearing impairment detection rates during periods of newborn hearing screening and no screening in the same hospitals (Wessex Universal Hearing Screening Trial, 1998). Those infants born during a period of screening underwent a two-stage screening test, with transient evoked otoacoustic emissions (TEOAE) at birth, followed by automated auditory brainstem response (AABR) before discharge if the first screen was failed. If the second screen was also failed, the babies were referred to an audiologist at 6 to 12 weeks of age. In this study, 4% of infants with hearing loss were missed during the screening period, while 27% were missed during the period of no screening. This study did not provide data on clinical outcomes such as speech and language development in screened versus unscreened children.

Another group of investigators compared clinical outcomes, including speech and language development, in 25 infants who were screened as part of the Colorado Universal Newborn Screening program with outcomes in 25 matched infants who were born in a hospital without a universal newborn hearing screening program (Yoshinaga-Itano et al., 2000). This study found that children who were identified as hearing impaired through the newborn hearing screening program had significantly better scores on tests of speech and language development than did children who were identified later.

According to Hayes, there is sufficient evidence to support the use of universal neonatal hearing screening programs using either auditory brainstem response (ABR) or otoacoustic emissions (OAE) techniques, when the screening program includes a protocol for rescreening infants who failed the initial screen; referral for age-appropriate diagnostic testing for infants who fail both newborn screens; parent and community education; and a support system to ensure that diagnostic testing is performed and effective intervention provided when indicated. (Hayes, 2005)

OEA Evaluation and Screening for Hearing Loss in Children

Chiong et al. (2007) evaluated evoked otoacoustic emission (OAE) and auditory brainstem response (ABR) results for hearing screening in infants. The objective of the study was to correlate hearing screening outcomes of a cohort of infants with developmental outcomes at 6 and 12 months. A total of 565 infants had both OAE testing and ABR. Overall in 1130 ears, OAE and ABR testing showed an observed agreement of 99%, agreement due to chance of 96%, and kappa agreement of 79% in diagnosing bilateral hearing losses. OAEs had a sensitivity of 86.4% and a specificity of 99.4%.

Vatovec et al. (2001) assessed the role of otoacoustic emission testing during the assessment of auditory function in 110 infants at risk for brain damage. Auditory function was estimated by recording of otoacoustic emissions, tympanometry, pure tone audiometry and, when necessary, auditory brainstem responses. Spontaneous otoacoustic emission was detected in 38.2% of examinees. Evoked otoacoustic emissions were registered in 87.3% of infants. The testing had to be repeated in 32.7% of infants. According to the investigators, infants at risk for brain damage have more frequently impaired auditory function than their peers. For this reason, it is especially important to focus attention on the hearing condition when dealing with this population. Recording of evoked otoacoustic emissions is very helpful in pediatric audiometry, but any interpretation of the results should consider the possibility of auditory neuropathy.

Between 1997 and 2003, a cohort of 421 infants was enrolled at birth from Minnesota Native American reservations and an urban clinic and followed to age 2 years. This study reports OAE hearing screening results related to otitis media and effusion (OME) diagnoses, as well as risk for recurrent hearing screening failure and OME in Native American infants and children. Infants were prospectively assessed at regular intervals with pneumatic otoscopy, distortion product otoacoustic emissions, and tympanometry by nurses who were trained in all procedures and validated on pneumatic otoscopy. In the newborn period, 23.5% of infants failed hearing screening in at least one ear. Hearing screening failures increased to 29.9% from 2 to 5 months of age. Technical fail results due to excessive noise occurred frequently in infants 6-24 months of age, making interpretation of true pass and fail rates questionable in older infants. OAE test result was associated with OM diagnosis, and this relationship strengthened with age, with the strongest association above 6 months of age. A high rate of hearing screening failures occurred among Native American infants in the first 5 months of age, and was significantly associated with a correspondingly high rate of otitis media. Only one infant out of 366 was identified with sensorineural hearing loss, thus essentially all of the hearing screening failures reflected either a middle ear origin or other temporary problems. OAE screening provided a valuable hearing screening measure in this population at high risk for recurrent otitis media, but due to excessive noise in infants 6 months and older, practical use of OAE screening is limited. Use of behavioral assessment is needed after 6 months of age, when high rates of OME persist in this population (Hunter et al. 2007).

Recordings of TEOAEs and visual reinforcement audiometry (VRA) were performed in a prospective study of 39 children aged 6 to 24 months recovering from purulent meningitis. Patients with no TEOAEs, or whose VRA findings were abnormal, were also tested by impedance audiometry and recording of auditory brain-stem responses (ABRs) after treatment of any secretory otitis media. A total of 29 children had TEOAEs in both ears and normal VRA findings. Ten children lacked TEOAEs in one or both ears; 9 of them had otitis media with effusion. Further examination by VRA and ABR led to the diagnosis of bilateral sensorineural hearing loss in 2.6% (1/39) of patients and unilateral sensorineural hearing loss in 7.7% (3/39) of patients. The investigators concluded that recording TEOAEs appears to be a feasible hearing screening test for infants recovered from meningitis. If TEOAEs are absent, impedance audiometry, ABR recordings, and audiometric evaluation techniques are needed to distinguish between conductive and sensorineural hearing loss and to assess hearing thresholds precisely (Francois et al. 1997).
Yin et al. (2009) conducted a study to address 3 primary aims: develop and implement an initial hearing screen using transient evoked otoacoustic emissions (TEOAEs) for at-risk preschoolers, verify speed and tolerability of the screen, and assess the test performance of TEOAEs screening compared to pure tone audiometry. A total of 744 preschool children (age range 2 to 6 years old) attending preschools in an underserved, urban community completed TEOAEs screening by a school nurse. A total of 680 children passed screening. Forty-one children (5.5%) had a "refer" result. Two-year-olds had the highest refusal rate (10.5%). Mean testing time was 43 seconds per ear. A secondary cohort of

135 children was screened first by TEOAEs and then followed by pure tone audiometry and results compared. Secondary cohort analysis revealed 1 subject did not pass either TEOAEs or pure tone screening; no subject passed TEOAEs and then did not pass pure tone audiometry. Eight children had a “refer” on TEOAE but passed pure tone screening. TEOAEs screening test sensitivity was 1.00 (95% confidence interval 0.054-1.00) and specificity 0.94 (0.88-0.97). The investigators concluded that TEOAEs screening performed by school nurses is a fast, efficient, and feasible model. Children who pass TEOAEs screening have a very high likelihood of being free from hearing impairment. Application may be particularly relevant in underserved communities.

Sideris and Glattke (2006) compared the outcome of hearing screening using conventional pure tone behavioral testing with the outcome employing measures of transient otoacoustic emissions (TEOAEs) in a preschool population under conditions typical of educational settings. Two hundred children ranging in age from 2 years 1 month to 5 years 10 months were screened. Nearly equal numbers of children were referred from the two types of screening activities. The majority of referrals from the pure tone screening were due to an inability to condition the children to respond. Only 10% of the children referred from the TEOAE screening received a referral due to an inability to cooperate. Approximately 44% of the children referred from the pure tone screening also failed the emmittance screening, whereas 62% of those who referred from the TEOAE screening also failed emmittance screening.

Eiserman et al. (2008) screened underserved children 3 years or younger for hearing loss using otoacoustic emissions (OAE) technology and systematically document multi-step screening and diagnostic outcomes. A total of 4,519 children in four states were screened by trained lay screeners using portable OAE equipment set to deliver stimuli and measurement levels sensitive to mild hearing loss as low as 25 decibels (dB) hearing level. The screening and follow-up protocol specified that children not passing the multi-step OAE screening be evaluated by local physicians and hearing specialists. Of the 4,519 children screened as a part of the study, 257 (6%) ultimately required medical or audiological follow-up. One hundred and seven children were identified as having a hearing loss or disorder of the outer, middle or inner ear requiring treatment or monitoring. Of these 107 children, 5 had permanent bilateral and 2 had permanent unilateral hearing loss. The seven children with permanent hearing loss included four who had passed newborn screening, two who were not screened at birth and one who did not receive follow-up services after referring from newborn screening. The investigators concluded that OAE screening, using a multi-step protocol, is a feasible and accurate practice for identifying a wide range of hearing-health conditions warranting monitoring and treatment among children 3 years or younger in early childhood care programs. Future studies are needed to: (1) further examine barriers to effective OAE screening in early childhood care settings and (2) explore the value of extending early childhood OAE hearing screening into health care clinics and settings where young children receive routine care. This study is limited by lack of comparison to standard hearing tests.

As the first step in determining whether emissions can be used as an efficient method of screening for hearing loss, 295 4 year old children were tested with TEOAEs. Audiometry was performed in 160 children. Audiometry was not performed if the TEOAEs were strong (> or = 10 dB SPL) in both ears. In the group with TEOAEs of 8.8dB SPL or greater, all ears tested with audiometry had a pure-tone average (PTA) of 25 dB HL or better. Twenty-one percent of the ears had TEOAEs < or = 0 dB SPL. Only 9% of the ears had a hearing threshold exceeding 25 dB HL (PTA). The investigators concluded that the number of pathological TEOAE results was much larger than the number of pathological audiograms, making TEOAEs too sensitive to use as a single screening test, but the method may be used as first-line screening (Grenner et al. 1997).

In a retrospective, cross-sectional study, evoked otoacoustic emissions (OAEs) and diagnostic auditory brainstem responses (ABRs) were determined in 379 high-risk children (mean age 41+/-47 months) referred for hearing screening. Of the 131 children whose parents gave their consent for concomitant OAE and ABR testing, agreements were observed between the two tests in terms of classifying the results as normal or abnormal of 78.9% in right and 78.6% in left ears. When the children were classified as either "with hearing loss-bilateral abnormal ABRs" or "at least one normal ABR", there was an observed agreement of 81%. OAEs had a sensitivity of 76.9% and a specificity of 90%. The investigators concluded that there is good concordance between OAE and ABR results among high-risk children referred for hearing screening (Llanes and Chiong 2004). This study is limited by lack of comparison to standard hearing tests.

Dille et al. (2007) compared transient evoked otoacoustic emissions (TEOAE) with distortion product otoacoustic emissions (DPOAE) to determine if they resulted in equivalent signal-to-noise ratios (SNRs) when used for hearing screening in a preschool population in a community setting. Thirty-three preschool children ages 4 months to 4 years, 4 months were tested using DPOAE and TEOAE. The frequencies 800-4000Hz were compared. The tympanometric

gradient was obtained from a tympanogram done on each ear. A multivariate statistic was used to compare the emission SNR from both methods. The agreement between the pass/refer rates from the OAE screens and from the tympanometric gradient were compared. TEOAE and DPOAE SNRs were significantly different in the low frequency however, there were no significant differences found in the high frequencies. There were no significant pass/refer differences found between the methods at any frequency. When comparing the agreement between the OAE methods with the tympanometry, both methods produced nearly equivalent agreement with tympanometric gradient. However, the overall correspondence between OAE findings and tympanometry was not perfect. The investigators concluded that both methods are effective and especially equivalent in the high frequencies and can be recommended for use in a preschool population in the field. Tympanometric gradient disagreed with both OAE screening results about 25% of the time. The study also found that higher refer rates can be expected when young (younger than 3 years old) preschool children are included in the screen. This study did not compare otoacoustic emissions with pure tone audiometry.

In a prospective trial, Krueger et al. (2002) compared the findings of 3 different hearing screening methods in second and third grade school-aged children. Three hundred children were screened by using 3 test modalities, pure-tone audiometry, distortion product otoacoustic emissions (DPOAE), and tympanometry. All of the tests were normal in 532 ears (89%), and all were abnormal in 12 ears (2%). Tympanometry yielded the most abnormalities (8.3%), and pure-tone testing demonstrated the fewest (3.3%), with a positive rate of 6.3% for DPOAE testing. False-positive rates were 1.2%, 4.2%, and 6.4% for pure tones, DPOAE, and tympanometry, respectively, when normal results on pure-tones or DPOAE were taken to represent true hearing. Based on the results of the study, the investigators continue to recommend pure-tone testing as an effective screening method, with follow-up by using otoacoustic emissions in those who fail the pure-tone test.

Five hundred eighty-three grade school children in four separate school populations were screened for hearing loss using the standard pure tone four-frequency protocol and transient evoked otoacoustic emissions. Students failing either test received a comprehensive audiogram by an audiologist that served as the "gold standard." Sensitivity and specificity of both tests were compared. The sensitivity and specificity of pure tone screening was 87% and 80%, respectively, compared with 65% and 91% for transient evoked otoacoustic emissions. The investigators concluded that pure tone screening is a statistically significant better screening test for detecting hearing loss in this population of grade school children (Sabo et al. 2000).

Lyons et al. (2004) examined the test performance of distortion product otoacoustic emissions (DPOAEs) when used as a screening tool in the school setting. A total of 1003 children (mean age 6.2 years) were tested with pure-tone screening, tympanometry, and DPOAE assessment. Optimal DPOAE test performance was determined in comparison with pure-tone screening results using clinical decision analysis. The results showed hit rates of 0.86, 0.89, and 0.90, and false alarm rates of 0.52, 0.19, and 0.22 for criterion signal-to-noise ratio (SNR) values of 4, 5, and 11 dB at 1.1, 1.9, and 3.8 kHz respectively. DPOAE test performance was compromised at 1.1 kHz. In view of the different test performance characteristics across the frequencies, the use of a fixed SNR as a pass criterion for all frequencies in DPOAE assessments is not recommended. When compared to pure tone plus tympanometry results, the DPOAEs showed deterioration in test performance, suggesting that the use of DPOAEs alone might miss children with subtle middle ear dysfunction. However, when the results of a test protocol, which incorporates both DPOAEs and tympanometry, were used in comparison with the gold standard of pure-tone screening plus tympanometry, test performance was enhanced. The investigators concluded that In view of its high performance, the use of a protocol that includes both DPOAEs and tympanometry holds promise as a useful tool in the hearing screening of schoolchildren, including difficult-to-test children.

In a cross-sectional, preliminary screening study, Georgalas et al. (2008) assessed the role of otoacoustic emissions in a screening program for middle-ear disorders and hearing loss in school-age children. One hundred and ninety-six children were evaluated using transient evoked otoacoustic emissions. Twenty per cent failed in both ears, while in 32 per cent otoacoustic emissions could not be produced in at least one ear. Younger children had higher rates of absent transient evoked otoacoustic emissions. The absence of otoacoustic emissions was highly correlated with tympanic membrane changes seen on otoscopy and the presence of a type B tympanogram. As a single screening modality, otoacoustic emissions had 100 per cent sensitivity in diagnosing hearing loss worse than 30 dB, and a 90 per cent sensitivity and 64 per cent specificity in diagnosing hearing loss worse than 25 dB, which did not improve by adding tympanometry to the screening protocol. According to the investigators, these results strongly suggest the potential usefulness of otoacoustic emission testing in screening school-age children for hearing loss. The validity of this study is limited by lack of a control group.

In a transversal-prospective study, Vasconcelos et al. (2008) evaluated 451 first grade school children. Otoscopic exams with the removal of wax and the TEOAE and DPEOAE exams were performed on all school children. Audiometry and acoustic impedance were performed on the children who presented alterations at any point during the TEOAE and/or DPEOAE exams. Regarding the TEOAE and DPEOAE triage, no significant statistic difference was found when comparing the results of the exams which failed only in the TEOAE and DOEOAE with audiometric exam data, nonetheless, when comparing this failure data to both of these exams there was a significant difference. The investigators concluded that both EOAE procedures responded well to the hearing triage in school children. The validity of this study is limited by lack of a control group.

Sixty-six children (ages 5 to 10 year) participated. TEOAEs, pure-tone hearing screening, acoustic emmittance (single-frequency and multi-frequency tympanometry), and an otoscopic exam were done on each child under typical school hearing screening conditions. Performance of the TEOAE screening was determined based on the pediatrician's determination of middle ear status and the pure-tone hearing screening as the gold standards. Of the 66 subjects, 61 completed the study. Fifty-six children passed the hearing and otoscopic screenings bilaterally, and five children did not pass either or both the hearing screenings or otoscopic examination in at least one ear. A variety of TEOAE criteria were examined with respect to their ability to identify ears with either hearing impairment and/or middle ear disease. Several different otoacoustic emission criteria performed well according to our diagnostic criteria. Correlations between TEOAE variables and emmittance measures of middle ear function were all low. In addition, tympanometric data were used to compare the TEOAE screening with the American Speech-Language-Hearing Association's (ASHA) recommended protocol for the same ears. The ASHA protocol, as recommended, did not do as well as the TEOAE screening. Using slightly modified criteria, the ASHA protocol did as well as TEOAEs. The investigators concluded that there were some screening criteria based on TEOAE measurement that produced good sensitivity and specificity. A TEOAE screening for hearing impairment and middle ear disease performed as well as or better than the ASHA-recommended protocol, which requires a minimum of two different tests, even when the ASHA protocol was modified to optimize performance. The results suggest that the TEOAE test has the potential to be incorporated successfully into hearing screening programs for school-age children and may have advantages over current screening protocols. No relationship between TEOAEs and middle ear function, as measured using single-frequency and multifrequency tympanometry, could be determined in ears with normal hearing and normal middle ear function (Nozza et al. 1997). The validity of this study is limited by lack of a control group.

Driscoll et al. (2001) investigated whether Transient Evoked Otoacoustic Emission testing provides a more accurate and effective alternative to a pure tone screening plus tympanometry protocol. Pure tone screening, tympanometry and transient evoked otoacoustic emission data were collected from 940 subjects, with a mean age of 6.2 years. The Transient Evoked Otoacoustic Emission failure rate for the group was 20.3%. The failure rate for pure tone screening was found to be 8.9%, whilst 18.6% of subjects failed a protocol consisting of combined pure tone screening and tympanometry results. In essence, findings from the comparison of overall Transient Evoked Otoacoustic Emission pass/fail with overall pure tone screening pass/fail suggested that use of a modified Rhode Island Hearing Assessment Project criterion would result in a very high probability that a child with a pass result has normal hearing (true negative). However, the hit rate was only moderate. Selection of a signal-to-noise ratio (SNR) criterion set at > or =1 dB appeared to provide the best test performance measures for the range of SNR values investigated. Test performance measures generally declined when tympanometry results were included, with the exception of lower false alarm rates and higher positive predictive values. The exclusion of low frequency data from the Transient Evoked Otoacoustic Emission SNR versus pure tone screening analysis resulted in improved performance measures. According to the investigators, the present study poses several implications for the clinical implementation of Transient Evoked Otoacoustic Emission screening for entry level school children. Transient Evoked Otoacoustic Emission pass/fail criteria will require revision. The findings of the current investigation offer support to the possible replacement of pure tone screening with Transient Evoked Otoacoustic Emission testing for 6-year-old children. However, they do not suggest the replacement of the pure tone screening plus tympanometry battery.

Richardson et al. (1995) studied the feasibility of using TEOAEs as a screening test for hearing loss in children. TEOAE recordings were attempted in 56 children (median age of 4 years, range .2 to 15 years of age) attending an audiology clinic. TEOAE was successfully done in over 90% of the children. Thirty two ears were classified as having a hearing loss; 10 ears (from six patients) had sensorineural impairment and 22 ears (from 13 patients) had a conductive loss. According to the WHO classification, 17 ears had a mild or moderate loss (averaged threshold 26-55 dB), six ears had a moderately severe or severe loss (56-91 dB), and four ears had a profound hearing loss (>91 dB). The remaining five ears had average hearing thresholds of less than 26 dB but did have a raised threshold at a single auditory frequency. A

total of 10 ears from six children had hearing losses limited to either high or low frequencies. Six ears, including four with a sensorineural hearing loss, showed impairment limited to the 4 and 8 kHz frequencies. Four ears with a conductive defect had hearing loss limited to the 0 5 kHz frequency. In all of these 10 ears the auditory threshold at the affected frequency lay between 40 and 60 dB HL. Hearing status was compared with the results of six TEOAE screening criteria. All criteria had a sensitivity of 1.00. Four standard TEOAE criteria yielded specificities of 0.46-0.58. Two new criteria derived from analysis of limited frequencies from the TEOAE waveform gave specificities of 0.76 and 0.82. The investigators concluded that when appropriate pass/fail criteria are employed, TEOAEs are a feasible screening test in children. This study was limited by a small sample size.

Richardson et al. (1998) studied the efficacy of otoacoustic emissions (OAEs) as a screening test for hearing impairment in children with acute bacterial meningitis in 21 centers. In the 48 hours before discharge from the hospital, all patients underwent a thorough audiologic assessment consisting of transient evoked OAEs, auditory brainstem responses (ABRs), otoscopy, and tympanometry. Hearing loss was defined as ABR threshold >/=30 dB. The results of OAE screening were compared with the gold standard of ABR threshold. Of 124 children recruited, OAEs and ABRs were performed on 110 children. Seven (6.3%) of the 110 children had ABR threshold >/=30 dB; 2 had sensorineural hearing loss and 5 had conductive hearing loss. At follow-up, hearing loss persisted in both cases of sensorineural hearing loss and no new cases were identified. All 7 children with hearing loss failed the OAE screening test. Ninety-four children with normal hearing thresholds passed the test, and 9 failed. Thus, the screening test had a sensitivity of 1.00, a specificity of 0.91, a positive predictive value of 0.44, and a negative predictive value of 1.00. The investigators concluded that OAE screening in children recovering from meningitis was found to be feasible and effective. The test was highly sensitive and reasonably specific. Inpatient OAE screening should allow early diagnosis of postmeningitic hearing loss and prompt auditory rehabilitation. This study is limited because there was no comparison to pure tone audiometry.

Kirkim et al. (2005) evaluated pediatric patients with auditory neuropathy with regard to diagnostic criteria and audiological test results. Hearing assessment was made in five children with auditory neuropathy. The patients were tested with the use of acoustic emmittance measures, transient evoked otoacoustic emissions (TEOAE), behavioral audiometry, and auditory brainstem responses (ABR). Transient otoacoustic emissions were recorded in all the patients in contrast to the lack of auditory evoked brainstem responses (i.e. there were no identifiable waves in all recordings). Another common feature was the absence of correlation between ABR, TEOAE, and behavioral test results. According to the investigators, otoacoustic emissions and the auditory brainstem responses, when used together, offer insight into pre-neural as well as neural function in the auditory system and thus, may form the necessary combination for the evaluation of hearing in children.

OEA Evaluation and Screening for Hearing Loss in Adults

Jupiter (2009) determined whether distortion product otoacoustic emissions (DPOAEs) could be used as a hearing screening tool with elderly individuals living independently and to compare the utility of different screening protocols: (a) 3 pure-tone screening protocols consisting of 30 dB HL at 1, 2, and 3 kHz; 40 dB HL at 1, 2, and 3 kHz; or 40 dB HL at 1 and 2 kHz; (b) the Hearing Handicap Inventory for the Elderly-Screening version (HHIE-S); (c) pure tones at 40 dB HL at 1 and 2 kHz plus the HHIE-S; and (d) DPOAEs. A total of 106 elderly individuals age 65-91 years were screened using the above protocols. Pass/fail results showed that most individuals failed at 30 dB HL, followed by DPOAEs, the 40-dB HL protocols, the HHIE-S alone, and the combined pure-tone/HHIE-S protocol. All screening results were associated except the HHIE-S and 30 dB HL and the HHIE-S and DPOAEs. A McNemar analysis revealed that the differences between the correlated pass/fail results were significant except for the HHIE-S and 40 dB at 1 and 2 kHz. The investigators concluded that DPOAEs can be used to screen the elderly, with the advantage that individuals do not have to voluntarily respond to the test. This study is limited by small sample size.

Stenkley (2003) analyzed the changes in transient evoked otoacoustic emissions (TEOAEs) with age. The study included 232 subjects above 60 years of age with a battery of audiological tests, including TEOAEs. The criterion for the presence of TEOAEs was based on a cut-off at overall wave reproducibility 55% or overall response level 4 dB SPL. The prevalence of TEOAEs in left ears was 55.6%. No TEOAEs were found in subjects with a pure-tone average (PTA) above 40 dB HL. In the subgroup with TEOAEs, a significant decrease in overall wave reproducibility with age was found. We compared 45 normal-hearing elderly subjects with TEOAEs with a control group of 20 normal-hearing young adults The elderly had significantly lower mean overall response levels and mean overall wave reproducibility. Average hearing level was significantly higher in the elderly than in controls. The investigators concluded that the prevalence of TEOAEs decreases with age, **a**nd that the overall response level and overall reproducibility decrease with age.

Uchida et al. (2008) evaluated 331 adults (age range, 41 to 80 years) who took part in the Longitudinal Study of Aging. Analysis of variance was performed on DPOAE amplitudes and noise estimates at 22 test frequencies, as well as on the PTT. According to the investigators, the present analyses substantiated the hypothesis DPOAEs deteriorate with age independently of hearing sensitivity. The investigators concluded that DPOAE measurements in normal-hearing elderly as determined by standard audiometry may provide early indications of cochlear damage because of aging.

In a prospective study of adult 64 patients, Wang et al. (2002) evaluated the validity of hearing screening by means of the portable screening pure-tone audiometer and distortion-product otoacoustic emissions (DPOAE) measurement. The 64 study participants underwent hearing tests performed with screening pure-tone audiometer, DPOAE and conventional pure-tone audiometer. The results of conventional pure-tone audiometry were used for "gold standards" and the normal auditory function was defined as the threshold less than or equal to 20 dB. Compared with the "gold standards: For screening pure-tone audiometry, the kappa values at the 5 tested frequencies (0.5, 1, 2, 4, 8 kHz) ranged from 0.79 to 0.93 and the agreement with the gold standards was classified as "excellent." The sensitivity, specificity and test accuracy values ranged from 91.8-98.5%, 88.0-96.3% and 89.8-96.9%, respectively. For DPOAE measurement, the kappa values at the 3 tested frequencies (1, 2, 4 kHz) ranged from 0.62 to 0.78. The agreement was classified as "good" at 1, 4 kHz and "excellent" at 2 kHz. The sensitivity, specificity and test accuracy values ranged from 91.7-98.5%, 62.3-86.8% and 81.3-89.1%. The investigators recommend a hearing screening measured at 0.5, 1, 2, 4, 8 kHz with screening pure-tone audiometer in a simple-type soundproof chamber and performed by a screening assistant. The DPOAE measurement may be used as an auxiliary tool to provide more information for early identification and differential diagnosis of hearing loss in clinical application. This study is limited by small sample size.

Engdahl et al. (2005) evaluated the association between otoacoustic emissions (OAEs) and pure-tone hearing thresholds (PTTs) in an unscreened adult population (N =6415), to determine the efficiency by which TEOAEs and DPOAEs can identify ears with elevated PTTs, and to investigate whether a combination of DPOAE and TEOAE responses improves this performance. Associations were examined by linear regression analysis and ANOVA. Test performance was assessed by receiver operator characteristic (ROC) curves. The relation between OAEs and PTTs appeared curvilinear with a moderate degree of non-linearity. Combining DPOAEs and TEOAEs improved performance. Test performance depended on the cut-off thresholds defining elevated PTTs with optimal values between 25 and 45 dB HL, depending on frequency and type of OAE measure. According to the investigators, the best efficiency in identifying ears with elevated PTTs is obtained when using TEOAE measures that take background noise into account (signal to noise rations and reproducibility);. DPOAEs and TEOAEs variables are combined and the TEOAE stimulus levels are included; and the cut-off for defining elevated PTTs is optimized. The optimal cut-off is higher for TEOAEs than for DPOAEs and higher at high frequencies than at low.

In a prospective, clinical, observational study, Hamill et al. (2003) assessed hearing impairment in adults admitted to a university surgical intensive care unit in order to identify patients at risk for impaired receptive communication. Patients included in the study were 442 adult patients admitted to the surgical intensive care unit for trauma, a critical illness, or postoperative monitoring. As part of a continuing quality improvement protocol, adults admitted to the surgical intensive care unit were screened for hearing loss. Screening included otoscopy, tympanometry, and distortion product otoacoustic emissions. Almost two thirds of patients studied failed the screening protocol. The investigators concluded that screening with otoscopy, tympanometry, and DPOAE is an efficient and sensitive way to identify patients at risk for impaired auditory acuity. The validity of this study is limited by lack of a control group.

Wagner et al. (2008) evaluated the test-retest repeatability for distortion product otoacoustic emissions (DPOAE). Measurements of DPOAE were performed in triplicate in 40 subjects. The investigators concluded that although the measurements were conducted under practical conditions resembling the clinical setting, repeatability was generally good. The widely used minimum SNR of 6 dB seems to be a recommendable criterion when considering both practicability and measurement quality under clinical conditions. The current findings underline the suitability of DPOAE as a monitoring tool of cochlear status over time. This study is limited by small sample size.

Engdahl et al. (1996) investigated the applicability of transient evoked otoacoustic emissions (TEOAEs) as a method of screening for hearing losses among recruits attending obligatory military service. TEOAEs, tympanometry and pure tone audiometry were recorded in 95 male recruits. Based on study results, the investigators concluded that TEOAEs were highly repeatable and had a higher sensitivity than pure-tone audiometry to detection of small changes in cochlear function under conditions normally found when testing recruits. This study is limited by small sample size.

Well-designed trials with larger sample sizes are needed to demonstrate that OAE testing used as a method for hearing screening in adults has an impact on clinical outcomes such as increasing communication skills in these patients.

OAE Testing in Individuals with Developmental Disorders

Tas et al. (2007) evaluated hearing in autistic children by using transient evoked otoacoustic emission (TEOAE) and auditory brainstem response (ABR). Tests were performed on 30 children with autism and 15 typically developing children, following otomicroscopy and tympanometry. The children with autism were sedated before the tests. Positive emissions and normal hearing level at ABR were obtained in both ears of all children in the control group and of 25 children with autism. TEOAE and ABR results varied in the remaining five children with autism. The mean III-V interpeak latencies (IPLs) in both ears of children with autism were longer than those in the control group. According to the investigators, hearing loss may be more common in children with autism than in typically developing children.

Tharpe et al. (2006) described the auditory characteristics of children with autism relative to those of typically developing children and described the test-retest reliability of behavioral auditory test measures with this population of children with autism. Audiometric data were obtained from 22 children diagnosed with autism and 22 of their typically developing peers. The audiologic test battery consisted of behavioral measures (i.e., visual reinforcement audiometry, tangible reinforcement operant conditioning audiometry, and conditioned play audiometry) and physiological measures (auditory brain stem response audiometry, distortion product otoacoustic emissions, and acoustic reflexes). Children with autism had physiologic test results equivalent to their typically developing counterparts. That is, no differences in auditory brain stem response audiometry, distortion product otoacoustic emissions, or acoustic reflex results were noted between the children with autism and typically developing children. However, behavioral measures revealed that about half of the children diagnosed with autism presented pure-tone averages outside of normal limits (i.e., >20 dB HL), although their response thresholds to speech were within normal limits. All behavioral test results were within normal limits (i.e., </=20 dB HL) for the typically developing children. In addition, test-retest variability was typically 15 dB or greater for children with autism as compared with variability of 10 dB or less for most of the typically developing children. The investigators concluded that children with autism demonstrated essentially equivalent results on a battery of physiological auditory tests as those obtained from typically developing children. However, on average, behavioral responses of children with autism were elevated and less reliable relative to those of typically developing children. Furthermore, approximately half of the children with autism demonstrated behavioral pure-tone averages outside of the normal hearing range (i.e., >20 dB HL) despite having normal to near-normal hearing sensitivity as determined by other audiometric measures.

During the German Special Olympics Summer Games 2006, 552 athletes with intellectual disabilities (ID) had their hearing screened according to the international protocol of Healthy Hearing, Special Olympics. This screening protocol includes otoscopy, measurement of distortion product otoacoustic emissions, and, if necessary, tympanometry and pure tone audiometry (PTA) screening at 2 and 4 kHz. Additionally, 195 athletes underwent a full diagnostic PTA. The results of the screening and diagnostic PTA were compared. Of the 524 athletes who completed the screening protocol, 76% passed and 24% failed it. Ear wax was removed in 48% of all athletes. 42% of the athletes were recommended to consult an otolaryngologist or an acoustician. Of the 99 athletes whose screening-based suspicion of a hearing loss was confirmed with diagnostic PTA, 74 had an undetected hearing loss. The correlation (Cramer's V) between screening and diagnostic PTA was .98. The sensitivity of the screening was 100% and the specificity 98%. The investigators concluded that the screening reliably detects hearing disorders among persons with ID. The prevalence of hearing impairment in this population is considerably higher than in the general population, and the proportion of undetected hearing impairments is large, even among people with only mild and moderate ID, as examined in this study. Therefore, a screening is highly recommended for persons with ID (Hild, 2008). The screening protocol includes otoscopy, measurement of distortion product otoacoustic emissions, tympanometry, and pure tone audiometry (PTA) screening.

Hassmann et al. (1998) investigated the features of hearing impairment in subjects with Down syndrome. Forty-seven children and 14 adults with Down syndrome were included in the study. Depending on age, intellectual level and middle ear status the following examinations were performed: pure-tone 'play audiometry', tympanometry, acoustic reflex, auditory brain response (ABR) and distortion products otoacoustic emissions (DPOAE). The results were compared with age matched control groups. Tympanometry of B and C type was detected in 56% of ears. The amplitude of DPOAE was lower in children with Down syndrome than in the control group. This difference was more expressed in adults with Down syndrome. Pure-tone audiometry was carried out in all patients except one. The pure-tone average hearing loss was 32.3 dB HL in this group. Two patients had normal hearing, at PTA 15 dB HL, considered as within the normal range and four had normal hearing at PTA 25 dB HL, also considered as within the normal range. Severe hearing loss

was reported in one case - PTA 56 and 82 dB HL. According to the investigators, DPOAE examination results in subjects with Down syndrome without conductive hearing loss indicate early age related inner ear impairment.

OEA Testing for Other Conditions

Ototoxcity

Hotz et al. (2000) investigated the action of midazolam and its active metabolite alpha-hydroxy-midazolam on different parts of the auditory pathway in six healthy volunteers in a randomized, double-blind, three-way cross-over study. Acoustically evoked short (SLP) and middle (MLP) latency potentials, transitory evoked otoacoustic emissions (TEOAE), and EEG power spectra were analyzed after short i. v. injections of placebo, or 0.15 mg kg-1 midazolam, or alpha-hydroxy-midazolam, respectively. SLP showed a significant transient increase of Jewett wave V 10 min after injection for midazolam and alpha-hydroxy-midazolam while the latency of wave I was unchanged. Both benzodiazepines induced a marked and long-lasting MLP amplitude decrease for 240 min with slow recovery over the following 360 min. No changes of TEOAE were observed. In agreement with earlier reports, increases in EEG beta activity and decreases in alpha activity were observed after administration of either drug. The investigators concluded that systemically administered benzodiazepines modulate the auditory pathway above the level of the cochlea. While SLP changes were closely associated with sedation and high plasma benzodiazepine concentrations, MLP effects persisted for hours after sedation even at low benzodiazepine plasma levels. Evoked potentials may therefore be more sensitive than EEG as a tool to monitor benzodiazepine effects. This study is limited by its small sample size.

Yilmaz et al. (2009) investigated cisplatin ototoxicity by using the transient evoked otoacoustic emission (TEOAE) test and the pure tone audiometer. Twenty adult lung cancer patients and 20 control group patients were included in the study. The investigators compared the hearing of the patients who received 100 mg/m(2) 4-cycle cisplatin for lung cancer, with pure tone audiometer and transient evoked otoacoustic emission test in 1,000, 2,000 and 4,000 Hz. A 55% hearing decrease with pure tone audiometer was found in patients that are receiving 100 mg/m(2) 4-cycle cisplatin for lung cancer. An established emission amplitude decrease with TEOAE test was found in 85% of the patients. When the patients' pure tone audiometer in 1,000, 2,000 and 4,000 Hz and TEOAE amplitude changes were compared, there were no statistically significant results, but when the patients' TEOAE amplitude changes in 1,000, 2,000 and 4,000 Hz was compared with the control group, statistically significant results were found. The investigators concluded that the study results demonstrate that cisplatin ototoxicity could be find out with TEOAE test before it is seen with pure tone audiometer. This study is limited by its small sample size.

Delehaye et al. (2008) compared the efficacy of otoacoustic emissions (distortion-product otoacoustic emissions) with that of pure-tone audiometry as method of audiological monitoring in 60 patients undergoing Deferoxamine therapy. Distortion-product otoacoustic emissions were obtained as DP-grams. Threshold changes from baseline were found to be statistically significant from 4 to 8kHz in 68.4% of the subjects. Distortion-product otoacoustic emissions demonstrated a significant threshold shift and a decreased amplitude in the frequencies >3kHz. Furthermore, DP-gram amplitude also reduced significantly at 3kHz without any similar change in pure-tone audiometry. According to the investigators, ototoxicity screening tool DP-gram was extremely sensitive and superior to pure-tone audiometry. Their use is recommended for regular monitoring of cochlear function, aiming in prevention of permanent damage. This study is limited by its small sample size.

Biro et al. (2006) studied the characteristics and risk factors of the long-term ototoxic effect of cisplatin in testicular cancer patients by measuring distortion product otoacoustic emissions (DPOAEs). A total of 223 patients who received cisplatin were assessed by DPOAE. The control group consisted of 40 testicular cancer patients who did not undergo chemotherapy. Symptomatic ototoxicity was observed in 20% of the patients. In patients receiving <or=300 mg/m2 cisplatin, no amplitude changes were detected. Beyond this dose, hearing impairment proved to be dose dependent. In patients receiving >or=400 mg/m2, DPOAE could detect significant hearing impairment at lower frequencies that are important for speech perception. At 400 mg/m2, significant amplitude change was detected at 3,000 Hz; at 500-600 mg/m2, significant amplitude change was detected at 1,500, 2,000 and 3,000 Hz, and at 700 mg/m2 significant amplitude change was detected at 3,000 Hz. The investigators concluded that DPOAE is a fast, noninvasive and reliable method in detecting late ototoxicity in testicular cancer patients. The limitation of this study is that there is no comparison to standard hearing tests.

Dhooge et al. (2006) evaluated an audiometric protocol for identifying ototoxicity in a retrospective study of 16 children treated with cisplatin and/or carboplatin. Audiometric testing was done by means of pure-tone threshold audiometry (PTA), high-frequency audiometry (HFA), and distortion product otoacoustic emissions (DPOAEs). An excellent correlation was found between DPOAE levels and results obtained by audiometry. The investigators concluded that

because of the several advantages of DPOAEs (noninvasive, objective, rapid, easy to use, sensitive) this method should be added in the audiological follow-up in infants and toddlers. This study is limited by its small sample size.

Reavis et al. (2008) analyzed 53 patients receiving ototoxic medications and showing significant hearing changes in at least one ear. The investigators concluded that DPOAEs are a useful screening tool for ototoxicity in adults with pre-exposure hearing loss, but are less sensitive compared with a behavioral test method that targets thresholds near the upper limit of a subject's audible frequency range. Ears successfully monitored for ototoxicity with DPOAEs are those with better pre-exposure hearing, greater postexposure hearing changes, and baseline DPOAEs near the highest behavioral test frequencies and present at high f2's. Results suggest that successful monitoring of ototoxicity with DPOAEs may be predicted clinically by assessing the measurable DPOAE f2 frequency range and its relation to the highest behavioral test frequencies.

Ress et al. (1999) compared the efficacy of screening with distortion-product otoacoustic emissions (DPOAEs) with the outcome of both conventional and ultra-high-frequency (UHF) audiometry. Baseline audiometric and DPOAE testing was performed in 66 patients, 33 of whom met criteria for inclusion in the final database. Comparisons were made between baseline measurements and those recorded before subsequent cisplatinum (CP) infusions. Outcomes were analyzed clinically and with paired repeated-measures analysis of variance. Results indicated that DPOAEs and UHF were better measures than conventional audiometry. Further, DPOAEs may be better suited for screening older patients receiving CP chemotherapy because DPOAEs are as sensitive as UHF and are present in a greater number of these patients. Screening with DPOAEs may be enhanced by testing only in the 3- to 5.2-kHz range, thus decreasing testing time.

Stavoulaki et al. (2002) investigated whether transient-evoked and distortion-product (DP) otoacoustic emissions (OAEs) are more sensitive than pure-tone audiometry (PTA) in revealing gentamicin-induced ototoxicity in children with cystic fibrosis (CF) in a prospective case-control study. The study group consisted of a consecutive sample of 12 audiologically normal children with CF and a history of gentamicin exposure (CF-gentamicin group). The control groups consisted of 8 age-matched children with CF and 11 age-matched healthy volunteers. The investigators found that Otoacoustic emissions measurement (especially of DP OAEs) proved more sensitive than PTA in revealing minor cochlear dysfunction after gentamicin exposure. They should be used for monitoring patients receiving ototoxic factors such as aminoglycosides. This study is limited by its small sample size.

Arora et al. (2009) conducted a prospective, randomized and observational study to evaluate the effects of different doses of cisplatin on hearing in 57 patients. All patients were divided into three groups depending on the dose of cisplatin infused in 3 weeks. Subjective hearing loss was found in seven patients, while six patients had tinnitus during the chemotherapy. The hearing loss was sensorineural, dose dependent, symmetrical, bilateral and irreversible. Higher frequencies were first to be affected in cisplatin chemotherapy. According to the investigators, high-frequency audiometry should be used to evaluate hearing loss in patients undergoing cisplatin-based chemotherapy.

Well-designed trials with larger sample sizes are needed to demonstrate that OAE testing is as effective as standard hearing tests or has an impact on clinical outcomes such as increasing speech, language, and communication skills in patients with a risk of developing ototoxicity.

Suspected Hearing Loss
Pure-tone thresholds were used as the reference and compared with extrapolated distortion product otoacoustic emission input/output-functions and auditory steady state responses (ASSR) in hearing-impaired adults, using the Cochlea-Scan and Audera devices. Fifty-three subjects presenting with sensorineural deficits were included in the study. The DPOAE data were recorded using the detailed Cochlea-Scan threshold modality, and ASSR responses were assessed at 1.0, 2.0, and 4.0 kHz. The comparison between DPOAE and ASSR threshold values indicated significant mean differences across all tested frequencies. Significant relationships were observed between the behavioral and the DPOAE measurements in the lower frequencies (1.5 and 2.0 kHz). The Cochlea-Scan algorithm seems to overestimate hearing threshold. Logistic regression models (probability of DPOAE response p = 0.9), suggested that the identifiable hearing levels are less than 34 dB HL (at 2.0 and 4.0 kHz) and less or equal to 38 and 40 dB HL at 1.5 and 6.0 kHz respectively. According to the investigators, the Cochlea-Scan DPOAE protocols can be used in cases presenting mild hearing deficits (i.e. less than 40 dB HL) (Hatzopoulos et al. 2009). The study was limited by small sample size.

Ellison et al. (2005) assessed how well stimulus-frequency otoacoustic emissions (SFOAEs) identify hearing loss, classify hearing loss as mild or moderate-severe, and correlate with pure-tone thresholds in a population of adults with normal middle ear function. Based on the study results, the investigators concluded that although SFOAEs were

significantly correlated with hearing threshold, they do not appear to have clinical utility in predicting a specific behavioral threshold. Information on middle ear status as assessed by acoustic transfer function measures offered minimal improvement in SFOAE predictions of auditory status in a population of normal and impaired ears with normal middle ear function.

The performance of distortion product otoacoustic emissions (DPOEs) as a frequency-specific test of sensorineural hearing loss was evaluated in 142 ears of human adults with normal middle-ear function. The DPOE was measured with the stimulus levels of the two tones equal to 65 dB SPL and the ratio between the two frequencies 1.2. In the DPOE test, the cochlear function of an ear at a test frequency was predicted to be normal or abnormal depending upon whether the DPOE level with the geometric mean of the two stimulus frequencies at the test frequency was greater or less than a criterion. The DPOE test outcomes were evaluated against the pure-tone hearing threshold as the standard. The sensitivity, specificity and predictive efficiency of the test was found to be 85-89% at 6000 and 4000 Hz, 82-83% at 2000 Hz and 78-79% at 1000 Hz, respectively. The performance was also evaluated using decision theory in terms of the area under the receiver operating characteristics. The latter was found to range from 0.90 (for 1000 Hz) to 0.94 (for 6000 Hz). According to the investigators, these findings support the conclusion that the DPOEs can form a useful frequency-specific objective test of cochlear function (Kim, 1996). This study is limited by its small sample size.

Bertoli et al. (1997) investigated the clinical value of measuring TEOAEs in the routine audiological evaluation of older people reasoning that a finding of hearing loss in the presence of TEOAEs could indicate a form of presbycusis with a primary central component. Click-evoked otoacoustic emissions (CEOAEs) were measured in 201 subjects without middle ear problems aged 60 years and older (range 60 to 97 years) who volunteered for the study because of complaints concerning their hearing. Audiological procedures included a pure-tone audiogram, modified Speech Perception in Noise test, and the Hearing Handicap Inventory for the Elderly. Results from ears with a pure-tone average (PTA) at 0.5, 1, and 2 kHz of < or = 30 dB HL were further analyzed with respect to the presence or absence of CEOAEs. In addition, tone burst evoked otoacoustic emissions (TbOAEs) were tested in ears with responses to click stimuli. CEOAEs were not detectable in ears with a PTA > 30 dB HL. The prevalence of CEOAEs in ears with a PTA < or = 30 dB HL was 60%. Response levels decreased as hearing thresholds became poorer, but there was no apparent influence on TEOAE level due to age alone. The audiological measures from ears with and without CEOAEs and with PTAs < or = 30 dB HL were similar with the exception of small between group differences at lower frequencies. The TbOAE results showed no differences in linear superposition and suppression when results were compared with those of younger subjects tested previously. According to the investigators, the lower overall amplitudes of TEOAEs and the lower prevalence of 60% in comparison to results from younger subjects with normal hearing imply that cochlear changes do occur with aging. However, the preservation or loss of TEOAEs does not separate subjects with presbycusis into distinct audiological categories or handicaps. Tone burst results suggest that frequency processing within the cochlea is not affected by age alone. The investigators concluded that TEOAEs add no relevant information in the routine clinical evaluation of elderly persons with hearing problems.

Early Identification of Noise-Induced Hearing Loss

Korres et al. (2009) evaluated noise-induced hearing loss in a group of industrial workers, using distortion product otoacoustic emissions (DPOAEs) in conjunction with standard pure tone audiometry (PTA). One hundred and five subjects were included in the study. PTA, tympanometry, and DPOAEs were performed. Statistically significant lower DPOAE levels were found in the noise-exposed group as compared to the control group. Based on the results of the study, the investigators concluded that DPOAEs and PTA are both sensitive methods in detecting noise-induced hearing loss, with DPOAEs tending to be more sensitive at lower frequencies. This study is limited by its small sample size.

In a longitudinal study with 338 volunteers, audiometric thresholds and otoacoustic emissions were measured before and after 6 months of noise exposure on an aircraft carrier. The investigators found significant changes in group audiometric thresholds along with changes in OAEs, but there was little consistency between changes in thresholds and OAEs in individual ears. The study failed to show that OAEs were more sensitive than audiometric thresholds (Lapsley Miller 2006).

In a prospective controlled trial, Shupak et al. (2007) evaluated changes in transient evoked and distortion product otoacoustic emissions (TEOAEs, DPOAEs) as they relate to pure-tone audiometry thresholds during the first 2 years of occupational noise exposure. Pure-tone audiometry thresholds, TEOAE and DPOAE amplitudes, and contralateral medial olivocochlear reflex strength were repeatedly evaluated during 2 years and compared between and within a cohort of 135 ship engine room recruits and a control group of 100 subjects with no noise exposure. Based on the

results of the study, the investigators concluded that although TEOAEs changes after 1 year showed high sensitivity in predicting NIHL after 2 years of exposure, they cannot be recommended as an efficient screening tool due to high false-positive rates.

Audiometric thresholds and otoacoustic emissions (OAEs) were measured in 285 U.S. Marine Corps recruits before and three weeks after exposure to impulse-noise sources from weapons' fire and simulated artillery, and in 32 non-noise-exposed controls. A subgroup of 60 noise-exposed volunteers with complete data sets for both ears showed significant decreases in OAE amplitude but no change in audiometric thresholds. According to the investigators, the analysis showed an increased sensitivity of OAEs in comparison to audiometric threshold. The investigators also concluded that low-level OAEs indicate an increased risk of future hearing loss by as much as ninefold (Marshall et al. 2009). Although promising, the results of this study cannot be generalized to a larger population because all study participants were young men and the study duration of 13 weeks was too short for aging to have any measurable impact.

Jansen et al. (2009) assessed the hearing status of 241 musicians of professional symphony orchestras to determine if OAEs have an added value in the diagnosis of noise induced hearing loss (NIHL) in musicians. The musicians were subjected to an extensive audiological test battery, which contained testing of audiometric thresholds, loudness perception, diplacusis, tinnitus, speech perception in noise, and otoacoustic emissions. Most musicians could be categorized as normal hearing, but their audiograms show notches at 6 kHz, a frequency that is associated with NIHL. Musicians often complained about tinnitus and hyperacusis, while diplacusis was generally not reported as a problem. Based on the study results, the investigators concluded that otoacoustic emissions were more intense with better pure-tone thresholds, but due to large individual differences it can still not be used as an objective test for early detection of NIHL.

Job et al. (2009) evaluated whether low distortion product otoacoustic emissions (DPOAEs) in normal hearing ears are risk markers for subsequent early hearing loss when subjects are exposed to noise in a 3-year follow-up study that was carried out on a population of pilots aged 20-40 years (n=521). Data collection consisted of tonal audiograms, DPOAEs measurements with a calculation of an index of abnormality (the IaDPOAE). Of the 521 pilots enrolled, 350 (67%) had follow-up data 3 years later. The investigators found that in adults with a normal audiogram, ear vulnerability to noise could be elicited by the use of objective DPOAE measurements. A high IaDPOAE that corresponded to reduced DPOAE levels constitutes a risk for early hearing loss. This study failed to show the clinical utility of otoacoustic emissions testing in patients who are exposed to noise.

Sudden Hearing Loss
Otoacoustic emissions (OAE) and pure tone audiogram (PTA) were examined in 25 patients suffering from sudden hearing loss from the 1st day to up to 505 days following the drop of hearing to test the hypothesis whether the OAEs are capable of delivering predictive information about the recovery process. Transitory evoked otoacoustic emissions (TEOAE) and distortion product otoacoustic emissions (DPOAE) were measured under constant stimulus and recording conditions in three to nine sessions. The relation between OAE level and actual pure tone threshold was subject to a regression analysis. The correlation between both parameters is small but significant. Even smaller correlations are observed if the OAE level is related to former hearing loss, whereas the correlation improves if the OAE level is compared to the pure tone threshold measured in a later session. The comparison of the OAE levels measured at an early stage with later audiograms shows that there are only a small number of cases with small initial emissions and good final threshold or large initial emissions and bad final threshold. This means that small initial OAEs end up with a remaining final hearing deficit, whereas a high OAE level immediately after drop of threshold correlates with good outcome. According to the investigators, the reliability of an individual prediction based on the OAE level combined with the threshold after sudden hearing loss and the consequences for the physiologic mechanisms underlying the sudden hearing loss remain to be proved in further investigations (Hoth, 2005).

Canale (2005) assessed whether OAEs could be considered as a reliable prognostic test in low frequency sudden hearing loss (LFSHL). The study group consisted of 20 patients presenting with a unilateral LFSHL. Each patient was submitted to spontaneous otoacoustic emissions (SOAEs), transient otoacoustic emissions (TEOAEs) and distortion products (DPOAEs) recording and then treated with glycerol administrated intravenously in 3-h intervals for 4 days. Pure tone audiometry (PTA) threshold was evaluated again 1 hour after the last administration of glycerol. After osmotic therapy 12 patients (60%) showed a significant PTA improvement with a mean improvement of 11 dB; modifications were significant at the Student's t test for paired data. The relationship between the pretherapy presence or absence of SOAEs, TEOAEs and DPOAEs and PTA modification was not significant at the exact Fisher's test. The investigators concluded that even if the results of the study supports the use of OAEs as an indicator of the inner ear functional state,

they cannot be utilized as a prognostic test in LFSHL in relation to the efficacy of osmotic therapy. Among the other parameters evaluated, only the precocity of therapy seems to be related to prognosis in LFSHL.

Tinnitus and Acoustic Trauma
Santaolalla et al. (2007) investigated otoacoustic emissions (OAEs) in 44 patients with tinnitus using Spontaneous Otoacoustic Emissions (SOAEs) and Transitory Evoked Otoacoustic Emissions (TEOAEs). A correlation was determined between the OAEs results and the results obtained using hearing thresholds. Statistically significant differences at 500, 1000, 2000, 4000 and 8000 Hz frequencies were not found at mean hearing thresholds between the sample of ears with tinnitus and the sample of ears without tinnitus. Based on the results of the study, the investigators concluded that there is no significant relation between tinnitus and OAEs registration.

Nottet et al (2006) evaluated the possible predictive value of hearing thresholds and otoacoustic emissions during the first 24 hours after acoustic trauma. A group of 24 young military subjects without any otologic problem before the acoustic trauma were examined at three time intervals after an accidental acoustic trauma caused by the discharge of a firearm: 24 hours, 72 hours, and 15 days. Pure tone audiometry was performed from 1 to 8 kHz per half octave. Transiently evoked otoacoustic emissions were recorded in the nonlinear mode at 80 dB pSPL, and distortion product otoacoustic emissions were recorded from 1 to 6 kHz, using a distortion product-gram type procedure, at 65/55 dB SPL, with f2/f1 = 1.22. Two groups of subjects were defined: group 1 (n = 8) represented subjects with short-lasting tinnitus (less than72 hours) and group 2 (n = 16) subjects with long-lasting tinnitus (greater than 72 hours). Hearing thresholds did not differ significantly between these two groups 24 hours after the acoustic trauma. However, otoacoustic emissions showed significantly lower amplitudes 24 hours after the acoustic trauma in subjects showing a longer lasting tinnitus. The investigators concluded that otoacoustic emissions appear to be a better predictor of the persistence of tinnitus than hearing thresholds alone 24 hours after an acute acoustic trauma. This study is limited by a small sample size.

Otoacoustic emissions (OAEs) testing has also been used for other indications such as evaluating pseudohypacusis (Balatsouras, 2003), facioscapulohumeral muscular dystrophy (Balatsouras, 2007), diagnosing endolymphatic hydrops (Rotter, 2008), and evaluating vestibular schwannoma (Ferri, 2009). The evidence is insufficient to determine the usefulness of OAE testing to diagnose or manage these conditions.

Professional Societies and Guidelines

American Academy of Pediatrics (AAP)

In a clinical report for hearing assessment in infants and children, the AAP states that ABR and OAEs are tests of auditory pathway structural integrity but are not true tests of hearing. Even if ABR or OAE test results are normal, hearing cannot be definitively considered normal until a child is mature enough for a reliable behavioral audiogram to be obtained. Behavioral pure-tone audiometry remains the standard for hearing evaluation. According to the AAP, a failed infant hearing screening or a failed screening in an older child should always be confirmed by further testing. Audiologists may repeat the audiometric tests in a sound booth and using a variety of other tests. ABR can also be used for definitive testing of the auditory system. Diagnostic ABR is often the definitive test used by audiologists in children and infants who are unable to cooperate with other methods of hearing testing. A diagnostic ABR is usually performed under sedation or general anesthesia in children aged approximately 3 to 6 months and older. Diagnostic ABR provides information that is accurate enough to allow for therapeutic intervention. According to the AAP, the OAE test also does not assess the integrity of the neural transmission of sound from the eighth nerve to the brainstem and, therefore, will miss auditory neuropathy and other neuronal abnormalities. Infants with such abnormalities will have normal OAE test results but abnormal auditory brainstem response (ABR) test results. A failed OAE test only implies that a hearing loss of more than 30 to 40 dB may exist or that the middle-ear status is abnormal (Harlor, 2009).

In a policy statement for the pediatrician’s role in the diagnosis and management of autistic spectrum disorder in children, the AAP states that any child who has language delays should be referred for an audiologic and a comprehensive speech and language evaluation. If the child is uncooperative, diagnostic otoacoustic emissions or sedated brainstem auditory evoked responses should be obtained (AAP, 2001).

The Joint Committee on Infant Hearing (JCIH)

The JCIH which includes organizations such as the American Academy of Pediatrics (AAP), the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), the American Academy of Audiology (AAA), and American Speech-Language-Hearing Association (ASHA), has a published position statement on principles and guidelines for early hearing detection and intervention programs. According to the JCIH, all infants, regardless of newborn hearing-screening outcome, should receive ongoing monitoring for development of age-appropriate auditory behaviors and communication skills. Any infant who demonstrates delayed auditory and/or communication skills development, even if he or she passed newborn hearing screening, should receive an audiological evaluation to rule out hearing loss. The JCIH recommends that subsequent audiologic assessments for infants and children from birth to 36 months of age should include OAE testing. The JCIH indicates that infants with hearing loss related to neural conduction disorders or auditory neuropathy/auditory dyssynchrony may not be detected through the use of otoacoustic emission [OAE] testing alone. Because these disorders typically occur in children who require NICU care, the JCIH recommends screening this group with the technology capable of detecting auditory neuropathy/dyssynchrony: automated ABR measurement (JCIH, 2007).
The JCIH endorses early detection of and intervention for infants with hearing loss. To maximize the outcome for infants who are deaf or hard of hearing, the hearing of all infants should be screened at no later than 1 month of age. Those who do not pass screening should have a comprehensive audiological evaluation at no later than 3 months of age. Infants with confirmed hearing loss should receive appropriate intervention at no later than 6 months of age from health care and education professionals with expertise in hearing loss and deafness in infants and young children. Separate protocols are recommended for NICU and well-infant nurseries. NICU infants admitted for more than five days are to have auditory brainstem response (ABR) included as part of their screening so that neural hearing loss will not be missed. For infants who do not pass automated ABR testing in the NICU, referral should be made directly to an audiologist for re-screening and, when indicated, comprehensive evaluation including ABR (JCIH, 2007).

American Academy of Neurology (AAN)

In a practice parameter for the evaluation of the child with global developmental delay, the AAN recommends that audiometric assessment for children with global developmental delay can include behavioral audiometry or brainstem auditory evoked response testing when feasible (Level C; class III evidence). The AAN also states that early evidence from screening studies suggests that transient evoked otoacoustic emissions should offer an alternative when audiometry is not feasible (Level A; class I & II evidence). Level A rating requires at least one convincing class I study or at least two consistent, convincing class II studies. According to the AAN, global developmental delay is a subset of developmental disabilities defined as significant delay in two or more of the following developmental domains: gross/fine motor, speech/language, cognition, social/personal, and activities of daily living. The term global developmental delay is usually reserved for younger children (i.e., typically less than 5 years of age) (Shevell, 2003).

American Speech-Language-Hearing Association (ASHA)

In the Audiologic screening section of the Preferred Practice Patterns for the Profession of Audiology, ASHA indicates that OA may be used to monitor for toxicity before, during, and after administration of or exposure to agents known to be toxic (e.g., aminoglycosides, chemotherapy agents, and heavy metals) (ASHA, 2006). In a Guideline for Audiologic Screening, the ASHA indicates that evoked otoacoustic emissions (OAE) are suggested as an alternative procedure for infants and children (through age 2) when behavioral audiologic methods are ineffective (ASHA, 1997).

In a 2004 Guideline for the Audiologic Assessment of Children from Birth to 5 Years of Age, the ASHA specified the following assessment protocols for children (ASHA, 2004):

- Assessment Protocol for Children Who Are Chronologically/Developmentally Birth Through 4 Months of Age (Age Adjusted for Prematurity): At these very young ages, or for children with severe developmental delays or multiple health conditions, the suggested methods for comprehensive assessment rely primarily on physiologic measures of auditory function: ABR [and/or auditory steady-state response (ASSR)] using frequency-specific stimuli are used to estimate the audiogram; ABR using click stimuli is used to assess VIIIth nerve integrity. OAEs and acoustic emmittance measures are used to supplement and corroborate the evoked-potential findings. The results of these physiologic measures should always be considered in combination with case history, parent/caregiver report, and behavioral observation of the infant's responses to a variety of auditory stimuli. The behavioral observation is intended for corroboration of parent/caregiver report of the child's auditory behavior rather than for threshold estimation.

- Assessment Protocols for Children Who Are Chronologically/Developmentally 5 through 24 Months of Age (Age Adjusted for Prematurity): *OAEs and auditory brainstem response (ABRs).* When behavioral audiometric tests are judged to be unreliable, ear-specific thresholds cannot be obtained, or when results are inconclusive regarding type, degree, or configuration of hearing levels, (evoked) EOAEs and/or ABR testing should be completed. In addition, if the neurological integrity of the auditory system through the level of the brainstem is in question, ABR testing should be conducted.

Assessment Protocol for Children Who Are Chronologically/Developmentally 25 to 60 Months of Age (Adjusted for Prematurity): OAE and ABR are recommended when the validity or adequacy (ear-specific information) of behavioral test results is limited or if the neurologic integrity of the auditory pathways to the level of the brainstem is in question. When ear-specific information cannot be obtained, EOAE testing should be completed for each ear. If EOAE (TEOAE or DPOAE) responses are not present at expected levels across the frequency range, ABR testing should be conducted.

U.S. Preventive Services Task Force (USPSTF)

The USPSTF recommends that newborn hearing screening programs include (USPSTF, 2008):

- a 1- or 2-step validated protocol which includes otoacoustic emissions (OAEs) followed by auditory brainstem response (ABR) in those who failed the first test
- quality-control programs in place to reduce avoidable false-positive test results
- protocols to ensure that infants with positive screening-test results receive appropriate audiologic evaluation and follow-up after discharge
- hearing screening before 1 month of age. Those infants who do not pass the newborn screening should undergo audiologic and medical evaluation before 3 months of age for confirmatory testing

National Institutes of Health (NIH)

An NIH Consensus Statement concluded there is no ideal method for screening hearing (NIH, 1993). In the absence of an ideal screening program, the NIH recommends universal two-stage EOAE and ABR screening of all infants prior to hospital discharge, or within the first 3 months of life for infants born at an alternate birthing site. The NIH also states that universal hearing screening is superior to a hearing protocol that screens only neonates with high-risk indicators; a high-risk protocol identifies only 50% of hearing-impaired infants.

U.S. Food and Drug Administration (FDA)

There are a number of diagnostic auditory brainstem response (ABR), automated ABR, transient evoked otoacoustic emissions (EOAE), and distortion EOAE devices currently approved for marketing by the FDA. These devices are designated by the FDA as Class II medical devices suitable for infant and adult hearing assessment.

See the following Web site for more information: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed April 2010. Use product codes GWJ (evoked response auditory stimulator) or EWO [(audiometer); otoacoustic emission test]. Note that not all of these clearances are for otoacoustic emission testing.

Note that devices in product category EWO (audiometer) are 510(k) exempt devices. Although manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement. All manufacturers are, however, required to register their establishment and submit a “Device Listing” form.

History	
11/17/2024	Policy version updated. Resource Section: Updated New American Academy of Pediatrics link in resource section. Update history section: Entries prior to 11/17/2022 archived
2/16/2024	Policy version update Logo updated in Header. Change in Code Table to remove the code description. Format change to the attachment Update history section: Entries prior to 2/16/2022 archived
8/15/2011	Policy implemented by UnitedHealthcare Community Plan

