OTOACOUSTIC EMISSIONS TESTING

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INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products
This policy applies to Oxford Commercial plan membership.

Benefit Type
General benefits package

Referral Required
Yes - Office

(Does not apply to non-gatekeeper products)

Authorization Required
Yes - Outpatient

(Precertification always required for inpatient admission)

Precertification with Medical Director Review Required
No

Applicable Site(s) of Service
Office, Outpatient

(If site of service is not listed, Medical Director review is required)

Special Considerations

1Precertification is required for services performed in an outpatient setting only.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.
Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Neonatal hearing screening as a preventive service using otoacoustic emissions (OAEs) is proven and/or medically necessary for infants who are 90 days or younger.

Otoacoustic emissions (OAEs) testing as a diagnostic service is proven and/or medically necessary for the evaluation of hearing loss in one or more of the following:

- Infants over 90 days old and children up to 4 years of age
- Children and adults who are or who are unable to cooperate with other methods of hearing testing (e.g., individuals with autism or stroke)
- Children with developmental or delayed speech or language disorders
- Individuals with tinnitus, acoustic trauma, noise induced hearing loss, or sudden hearing loss
- Individuals with abnormal auditory perception
- Individuals with sensorineural hearing loss
- Individuals with abnormal auditory function studies or failed hearing exam
- Individuals who may be feigning a hearing loss
- Monitoring of ototoxicity in individuals before, during, and after administration of agents known to be ototoxic (e.g., aminoglycosides, chemotherapy agents)

Auditory screening or diagnostic testing using otoacoustic emissions (OAEs) is unproven and/or not medically necessary for all other populations and conditions other than those listed as proven and medically necessary.

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 individuals with other conditions other than those indicated as proven and medically necessary.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>92558</td>
<td>Evoked otoacoustic emissions, screening (qualitative measurement of distortion product or transient evoked otoacoustic emissions), automated analysis</td>
</tr>
<tr>
<td>92587</td>
<td>Distortion product evoked otoacoustic emissions; limited evaluation (to confirm the presence or absence of hearing disorder, 3-6 frequencies) or transient evoked otoacoustic emissions, with interpretation and report</td>
</tr>
<tr>
<td>92588</td>
<td>Distortion product evoked otoacoustic emissions; comprehensive diagnostic evaluation (quantitative analysis of outer hair cell function by cochlear mapping, minimum of 12 frequencies), with interpretation and report</td>
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Coding Clarification:

- CPT code 92558 should be used for screening. CPT codes 92587 and 92588 are used for diagnostic evaluations to confirm the presence or absence of hearing disorders.
- For more information, see the following website: [American Speech-Language-Hearing, New and Revised Otoacoustic Emissions (OAE) CPT Codes for 2012](http://leader.pubs.asha.org/article.aspx?articleid=2280157) (Accessed March 1, 2018)
Otoacoustic emissions (OAEs) are low-intensity sounds emitted by functioning outer hair cells of the cochlea. OAEs are measured by acoustic stimuli such as 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 loudspeakers that generate the clicks and a microphone for measuring the resulting OAEs. 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.

OAE devices use either transient evoked OAE (TEOAE) or distortion product EOE (DPOAE) technology. TEOAE devices emit a single brief click that covers a broad frequency range. DPOAE devices emit two brief tones set at two separate frequencies. TEOAEs 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). Stimulus-frequency otoacoustic emissions (SFOAEs) are sounds emitted in response to a continuous tone. At present, SOAEs and SFOAEs are not used clinically.

The OAE measures are effective for screening middle-ear abnormalities and 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. 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. 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)

**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.

Akinpelu et al. (2014) reviewed ten articles on eligible studies published from January 1990 until August 2012 involving a total of 119,714 newborn participants. The main objective of this review was to determine the effects of different screening protocols on the referral rates and positive predictive values (PPV) of the OAE newborn screening test. Data extracted included the number of newborns screened, age at screening, OAE pass criteria, frequencies screened, number of retests, referral rates, and the number of newborns identified with permanent congenital hearing loss. The results found that the pooled referral rate was 5.5%. Individual referral rates ranged from 1.3% to 39%; with positive predictive values (PPS) from 2 to 40%. Increasing the age at initial screening and performing retests reduced the referral rate. The authors concluded that delaying newborn hearing screening improves test results but may not be practical in all contexts. The use of higher frequencies and more sophisticated OAE devices may be useful approaches to ensure better performance of the OAE test in newborn hearing screening.
Professional Societies and Guidelines
U.S. Preventive Services Task Force (USPSTF)
The USPSTF recommends that newborn hearing screening programs include (USPSTF, 2014):
- A one-step or two-step validated protocol which frequently involves otoacoustic emissions (OAEs) followed by auditory brainstem response (ABR) in those who failed the first test;
- Protocols to ensure that infants with positive screening-test results receive appropriate audiologic evaluation and follow-up after discharge;
- Screening and follow-up should be in place for newborns delivered at home, birthing centers, or hospitals without hearing screening facilities; and
- Hearing screening before one month of age. Those infants who do not pass the newborn screening should undergo audiologic and medical evaluation before 3 months of age.

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. 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 Pediatrics (AAP)
In February 1999, the American Academy of Pediatrics endorsed the implementation of universal newborn hearing screening. (AAP, 1999)

National Institutes of Health (NIH)
In 1993, the National Institutes of Health (NIH) held a consensus conference, sponsored by the National Institute on Deafness and Other Communication Disorders (NIDCD), on identifying hearing loss in infants and young children. In its consensus statement, the NIH recommended that all newborns be tested for hearing loss at birth or within the first 3 months of life. Two common screening techniques were advocated: auditory brain response (ABR) testing, which examines the brain's electrical response to sound to determine whether the ear is functioning properly, and evoked otoacoustic emissions (EOAE) testing, which monitor sounds produced by the inner ear in response to stimulation. The NIH confirmed as recently as February 2017 that ABR and EOAE are standard tests in diagnosing auditory neuropathy.

OAE Evaluation for Hearing Loss in Children
Rowe et al (2016) Assessment of hearing in children is important because early identification of hearing loss results in better developmental and educational outcomes. In the UK slightly more than 1 in 1000 children have significant permanent hearing loss diagnosed by the Neonatal Hearing Screening Programme (NHSP). This is based on Otoacoustic Emission (OAE) testing and Auditory Brainstem Response Testing (ABR). OAE testing is performed in the first few weeks of life and identifies infants who warrant further testing with automated ABR. Automated ABR uses an encephalogram to monitor response to sounds. Infants who meet the ‘high risk’ criteria will be referred directly for automated ABR testing. If automated ABR suggests abnormality the child is referred for diagnostic ABR testing, which is a more detailed investigation capable of giving actual hearing thresholds and differentiating between conductive and sensorineural hearing loss.

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%.

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. 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.

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 concluded that higher refer rates can be expected when young (younger than 3 years old) preschool children are included in the screen.

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.

Balatsouras et al. (2012) evaluated transiently evoked otoacoustic emissions in the diagnosis of otitis media with effusion as compared to tympanometry in 38 children (ranging in age from 4 to 15 years, with a mean age of 8.3 years) with bilateral otitis media with effusion. Forty normal children of similar age and sex were used as controls. All subjects underwent pneumatic otoscopy, standard pure-tone audiometry, tympanometry, and transiently evoked otoacoustic emissions. In the group of children with bilateral otitis media, transiently evoked otoacoustic emissions were absent in 51 ears (67%). In the remaining 25 ears (33%) the mean emission amplitude was reduced, as compared to the mean value of the control group. The authors concluded that transiently evoked otoacoustic
emissions should be included in the diagnostic workup of otitis media with effusion because it is a fast, reliable, and objective test. Transiently evoked otoacoustic emissions should always be used in conjunction with tympanometry, because a more meaningful interpretation of transiently evoked otoacoustic emissions measures is possible. Conclusions from this study are limited by small sample size. Further studies with larger patient populations are needed to confirm this conclusion.

Foust, et al. (2013) evaluated using otoacoustic emissions to screen young children for hearing loss in primary care settings. Three federally funded clinics serving low-income and uninsured people in a metropolitan area participated in the 10-month study. Subjects included 846 children (842 in the target population < 5 years of age and 4 older siblings) who were screened during routine visits to their primary care providers using a distortion product OAE instrument. A multistep screening and diagnostic protocol, incorporating middle ear evaluation and treatment, was followed when children did not pass the initial screening. Audiological evaluation was sought for children not passing a subsequent OAE screening. Of the 846 children screened, 814 (96%) ultimately passed the screening or audiological assessment and 29 (3%) exited the study. Three children (1 was younger than 5 years of age and 2 were older than 5) were identified with permanent hearing loss. OAE screening holds the potential for being an effective method for helping to identify young children with permanent hearing loss in primary care settings.

**Professional Societies and Guidelines**

**American Academy of Audiology (AAA)**
The American Academy of Audiology (AAA, 2011) endorses the detection of hearing disorders in early childhood and school-aged populations using evidence-based hearing screening methods. OAEs are recommended for preschool and school age children for whom pure tone screening is not developmentally appropriate (ability levels less than 3 years).

**OAE Testing in Individuals Who Cannot Cooperate with Other Methods of Hearing Testing**

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 otoacoustics, tympanometry, and DPOAE is an efficient and sensitive way to identify patients at risk for impaired auditory acuity.

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 operand conditioning audiometry, and conditioned play audiometry) and physiological measures (auditory brain stem response audiometry, distortion product otoacoustic emissions, and acoustic reflexes). 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)

OAE Testing for Ototoxicity

Among patients receiving cisplatin for the treatment of cancer, Reavis et al. (2011) sought to (1) identify the combination of DPOAE metrics and ototoxicity risk factors that best classified ears with and without ototoxic-induced hearing changes; and (2) evaluate the test performance achieved by the composite measure as well as by DPOAEs alone. The odds of experiencing hearing changes at a given patient visit were determined using data collected prospectively from 24 veterans receiving cisplatin. The investigators concluded that DPOAEs alone and especially in combination with pre-exposure hearing and cisplatin dose provide an indication of whether or not hearing has changed as a result of cisplatin administration.

Al-Noury (2011) measured otoacoustic emissions in patients treated with a first dose of cisplatin in a prospective study of 26 patients (mean age at treatment, 11.3 years). Audiograms and transient-evoked otoacoustic emissions (TEOAEs) and distortion-product otoacoustic emissions (DPOAEs) were measured before and after the first dose of cisplatin. Baseline readings were compared with those recorded after the administration of the first dose of cisplatin. Two patients showed a loss of TEOAEs at high frequencies above 4 kHz, and this was consistent with the 25-dB hearing loss of the high frequencies detected in their audiograms; there was a significant threshold shift for DPOAEs at a frequency >3 to 4 kHz. The authors concluded that DPOAE testing appears to be a more sensitive method to detect cochlear damage than conventional pure-tone audiometry. The authors stated that the measurement of DPOAE thresholds is a useful approach to detect the early auditory changes induced by cisplatin therapy.

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.

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.

Professional Societies and Guidelines

American Academy of Audiology (AAA)

In a position statement and clinical practice guideline on ototoxicity monitoring, the American Academy of Audiology states that over the past decade, three main approaches have emerged for monitoring the effects of ototoxic medications on hearing loss: basic audiologic assessment, high frequency audiometry (HFA; 10-18 kHz), and OAEs.

Using OAEs to monitor ototoxic medications requires a baseline evaluation so that later results have the clearest basis for interpretation. Ototoxic drugs exert their effect on outer hair cells (OHC) function (although not solely on OHCs), and OAEs are OHC dependent. With ototoxicity, OAEs have been shown to decrease simultaneously with changes in HFA thresholds and before changes appear in the conventional audiometric frequencies. Although both TEOAEs and DPOAEs can be used to monitor the effects of ototoxic medications, DPOAEs have some distinct advantages over TEOAEs. First, DPOAEs test higher frequencies than TEOAEs, making them more sensitive to the frequency area affected first. Second, DPOAEs can be recorded in the presence of more hearing loss than TEOAEs. Therefore, if a hearing loss already exists, that patient is still able to be monitored (so long as their hearing loss is not too great), which means DPOAEs can monitor more people. Third, using DPOAEs can provide some indication of degree and configuration of the hearing loss. (AAA Position Statement, 2009)
OAE Testing for Early Identification of Noise-Induced Hearing Loss

Fetoni et al. (2009) evaluated whether distortion product otoacoustic emissions (DPOAEs) can discriminate normal subjects with a risk of damage induced by sound exposure, the effectiveness of OAEs in monitoring the protective effects of Coenzyme Q10 tercitratrate (QTer), and the role of blood parameters in monitoring preventive therapies. Twenty volunteers were randomized to two groups: the first (n=10) was treated with Q-Ter (200 mg orally once daily) for 7 days before noise exposure and the second group was treated with placebo using the same schedule. All participants were exposed to white noise of 90 dBL for 15 minutes. DPOAEs and pure-tone audiometry (PTA) were measured before and 1 h, 16 h, and 7 and 21 days after exposure. Inflammatory and oxidative stress parameters were measured before and 2 and 24 h after exposure. In the placebo group, DPOAE amplitudes were reduced 1 and 16 h after exposure compared with the baseline values. In the Q-Ter group, DPOAEs did not show any significant difference between baseline and post-exposure. PTA threshold values in the Q-Ter and placebo groups did not differ before and after exposure. No significantly different levels of the inflammatory markers were observed in the Q-Ter and placebo groups at the different time points. The investigators concluded that this pilot study confirms that DPOAEs represent a sensitive test for monitoring the effects of noise in preclinical conditions and pharmacological treatment.

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). A total of 105 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.

OAE Testing for Sudden Hearing Loss

Mori et al. (2011) investigated whether distortion product otoacoustic emissions (DPOAEs) can be a prognostic indicator of hearing outcomes in 78 patients with idiopathic sudden sensorineural hearing loss (ISSNHL). Based on the results of the study, the authors concluded that there was significant correlation between hearing recovery and DPOAEs measured before treatment. The authors stated that DPOAEs are a potentially useful means of predicting hearing prognosis in ISSNHL.

OAE Testing for Tinnitus

Park et al. (2013) evaluated whether abnormalities in outer hair cell (OHC) function were related to tinnitus through interaural comparison of distortion product otoacoustic emissions (DPOAEs) in a cross-sectional study. The study included 27 patients with unilateral tinnitus and pure-tone average of both ears ≤25 dB hearing loss. Pure-tone thresholds observed at 500 to 16,000 Hz and DPOAE amplitudes at f2 frequencies of 1001 to 6348 Hz were compared between the tinnitus ears and non-tinnitus ears in patients with unilateral tinnitus. The pure-tone averages in the non-tinnitus ears were similar to those in the tinnitus ears. There were no differences in pure-tone averages at all frequencies tested. While the DPOAE amplitudes measured at f2 frequencies of 1001 to 3174 Hz in tinnitus ears were not different from those in the non-tinnitus ears, the tinnitus ears showed significantly reduced DPOAE amplitudes when compared with the non-tinnitus ears at frequencies of 4004 to 6348 Hz. The authors concluded that OHC dysfunction was correlated with tinnitus at high frequencies, and DPOAE amplitudes can provide additional information about cochlear dysfunction, which is complementary to pure-tone audiometry.

Zhou et al. (2011) assessed cochlear function, perceptual thresholds and distortion product otoacoustic emissions (DPOAEs) that were measured with high frequency resolution for patients with tinnitus and non-tinnitus control subjects (n = 29 and n = 18) with and without hearing loss. For 19 of 29 of subjects, perceptual thresholds were correlated with the tinnitus likeness ratings across frequencies and this correlation was significantly improved when low input-level DPOAE were included as an additional variable. According to the authors, cochlear function is strongly associated with the tinnitus percept and measures of cochlear function using DPOAEs provide additional diagnostic information over perceptual thresholds alone.

OAE Testing for Other Indications

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.

The clinical evidence was reviewed on January 31, 2018 with no additional information identified that would change the conclusion.
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 published position statements 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 dysynchrony 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/dysynchrony: automated ABR measurement. (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 otoacoustic emissions (OAE) 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)

The ASHA Practice Portal lists the following recommendations:
- **Newborn Infant Hearing Screening** indicates OAE - either transient-evoked OAEs (TEOAEs) or distortion product OAEs (DPOAEs)—are recommended for use in newborns. Because OAEs are sensitive to outer ear debris and middle ear fluid that may be present at birth, most OAE screening protocols involve an outpatient rescreening of those newborns who fail the screening at hospital discharge. Newborns who have initially passed a hearing screening are rescreened if readmitted to the hospital or if risk factors for hearing loss develop over the infant’s hospital stay following the initial screening.
- **Childhood Hearing Screening** indicates the use of OAE technology may be appropriate for screening children who are difficult to test using pure-tone audiometry (those who cannot respond to traditional pure tone or conditionined play techniques; Stephenson, 2007). Multiple OAE screenings may be needed/used to limit false positive findings.
and medical referrals for children who fail the initial OAE screen, but who do not actually need treatment. (Eiserman et al., 2008)

- Adult Hearing Screening cites a three-pronged approach for audiologic screening for hearing disorders, impairments, or disabilities including:
  - A brief case history with a visual or otoscopic inspection to identify any significant otologic history or obvious anatomic abnormalities of the ear;
  - Pure tone screening; and
  - Use of self-report questionnaires to identify perceived difficulties related to hearing.

### 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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm). [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. (Accessed January 31, 2018)

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.

### REFERENCES


Otoacoustic Emissions Testing
UnitedHealthcare Oxford Clinical Policy

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