Electroretinography

Number: 0854

Aetna considers electroretinogram or electroretinography (ERG) an acceptable alternative adjunctive modality useful in establishing loss of retinal function and distinguishing retinal from optic nerve lesions.

Aetna considers ERG experimental and investigational for all other indications including the following (not an all-inclusive list):

- Diagnosis / evaluation of glaucoma
- Diagnosis of psychiatric disorders (including but not limited to attention deficit hyperactivity disorder, eating disorder, major depressive disorder, panic disorder, schizophrenia, and substance use disorder)
- Evaluation of autism spectrum disorder
- Evaluation of childhood brain tumor survivors
- Evaluation of rhegmatogenous retinal detachment.

Aetna considers multi-focal ERG (mfERG) medically necessary for detecting chloroquine (Aralen) and hydroxychloroquine (Plaquenil) toxicity.
Aetna considers multi-focal ERG experimental and investigational for all other indications including the following (not an all-inclusive list):

- Diagnosis/evaluation of glaucoma
- Evaluation of idiopathic epiretinal membrane
- Evaluation of poppers maculopathy
- Prediction of visual acuity decline in age-related macular degeneration.

Aetna considers pattern electroretinography experimental and investigational for the diagnosis of glaucoma and all other indications.

**Background**

The retina is composed of rod and cone cells in the photoreceptive layer of tissue at the back of the inner eye. It acts like the film in a camera -- images come through the eye’s lens and are focused on the retina. The retina then converts these images to electric signals and sends them via the optic nerve to the brain. The macula, composed mainly of cones, is used primarily for central and color vision (photopic vision) while the remaining retina, composed mainly of rod photoreceptors, is utilized primarily for peripheral and night (scotopic) vision.

The electroretinogram or electroretinography (ERG) records the electrical response evoked from the entire retina by a brief flash of light and consists of an “A” wave, a photoreceptor response, and a “B” wave that emanates from the Muller and bipolar cells. The ERG provides information about the performance of the rods and cones. The ERG helps to distinguish retinal degeneration and dystrophies. Multi-focal electroretinography (mfERG) measures the photoreceptors’ activity. It is an advanced form of ERG in that it produces...
images with higher resolution than ERG. It involves stimulating areas of the retina using an electrical signal and mapping the response. Multi-focal ERG also allows the stimulation of multiple spots simultaneously, producing a changing pattern that is supposed to give more diagnostic information.

An assessment conducted by the Australian Medical Services Advisory Committee (MSAC, 2001; Johnston et al, 2003) concluded that mfERG is experimental. The report reached the following conclusions regarding mfERG: “All the studies of multifocal ERG were classified as level IV evidence. They did not present diagnostic characteristics or sufficient data to compute them. Although the studies showed that the multifocal ERG was able to discriminate between some visual parameters of patients with disease and controls with normal vision, they had little consistency and comparability. It is apparent from the available studies that much of the attention is focused on the mechanics of the technique and issues concerned with averaging signals and presentation of results. Thus, the clinical benefits of this technique are not yet apparent”,

Feigl et al (2005) investigated the cone- and rod-mediated mfERG in early age-related maculopathy (early ARM). A total of 17 eyes of 17 subjects with early ARM and 16 eyes of 16 age-matched control subjects with normal fundi were examined. These researchers concluded that their findings show a functional impairment of the rods in early ARM subjects. As there is histopathological evidence showing earlier rod than cone impairment in early ARM, following the rod function with the mfERG might be helpful in diagnosis or for monitoring the progression of early ARM.

In a prospective cohort study, Lai and colleagues (2005) assessed the longitudinal changes in mfERG in patients receiving hydroxychloroquine (HCQ) and examined the effects of cumulative HCQ dose on mfERG. A total of 24 eyes in 12
patients receiving HCQ underwent mfERG recordings at baseline and 1 to 2 years later. The first negative (N1) and first positive (P1) response amplitudes and peak latencies were compared with normal controls. Serial changes in the pattern of mfERG abnormalities and in response amplitudes and peak latencies were also compared between eyes in which HCQ therapy was continued or stopped. Correlation analyses were performed to assess the effects of a cumulative dose of HCQ on mfERG. These investigators concluded that patients receiving HCQ showed a longitudinal decline in retinal function; patients who stopped HCQ therapy showed improvement. Although these data are insufficient to demonstrate the sensitivity of mfERG for evaluating early HCQ toxicity, the results suggested that serial mfERG assessment may help detect early retinal changes associated with HCQ therapy. They stated that further studies with long-term results will be useful in clarifying the value of mfERG in evaluating early retinal toxicity due to HCQ.

Lai et al (2007) stated that mfERG is an investigation that can simultaneously measure multiple electroretinographic responses at different retinal locations by cross-correlation techniques. Thus, mfERG allows topographic mapping of retinal function in the central 40 to 50 degrees of the retina. The strength of mfERG lies in its ability to provide objective assessment of the central retinal function at different retinal areas within a short duration of time. Since the introduction of mfERG in 1992, mfERG has been applied in a large variety of clinical settings. Multi-focal ERG has been found to be useful in the assessment of localized retinal dysfunction caused by various acquired or hereditary retinal disorders. The use of mfERG also enabled clinicians to objectively monitor the treatment outcomes as the changes in visual functions might not be reflected by subjective methods of assessment. By changing the stimulus, recording, and analysis parameters, investigation of specific retinal electrophysiological
components can be performed topographically. Further developments and consolidations of these parameters will likely broaden the use of mfERG in the clinical setting.

Moon et al (2012) conducted a study to investigate the association between automated perimetry, mfERG, and optical coherence tomography (OCT) measurements in patients with advanced retinitis pigmentosa (RP). In 25 patients with advanced RP central visual field sensitivity (VFS) was evaluated using an average of visual sensitivity value at central four test points during central 30-2 static automated perimetry. When OCT imaging was conducted the inner and outer segment (IS/OS) line was classified into three groups: Group 1, absence; Group 2, partially intact; and Group 3, intact. Central retinal thickness (CRT), defined as the retinal thickness of central 3.0 mm, was also evaluated. Average amplitude and implicit time of N1 and P1 in ring 1 and 2 were measured on mfERG and comparisons of VFS, mfERG and OCT among the three subgroups were performed following IS/OS integrity. The relationship between VFS, mfERG and CRT was evaluated by regression analysis. The authors reported that group 3 patients with an intact IS/OS line showed a better VFS, and amplitude of mfERG response than those of Group 1 and 2. VFS and amplitudes of mfERG were correlated significantly with CRT in linear regression analysis. The authors concluded that disrupted IS/OS integrity was associated with visual dysfunction which was shown by decreased amplitude of mfERG response and reduced central VFS. CRT was significantly correlated with amplitude of mfERG response and central VFS and an eye with the more reduced CRT was associated with the worse amplitude of mfERG response and central VFS.

Narayanan et al (2013) conducted a prospective study of mfERG in patients with type 2 MacTel to characterize the electroretinography response of the macula by mfERG. The study was conducted from April 2009 to November 2009 and mfERGs were recorded using a visual evoked response
imaging system (MonElec2, Metrovision, Perenchies, France). The International Society for Clinical Electrophysiology of Vision (ISCEV) guidelines were followed and the study included patients with type 2 MacTel confirmed by fundus fluorescein angiography without subretinal neovascularisation. Individual mfERG responses for the hexagons were grouped into concentric rings centered on the fovea for analysis (less than 2, 5 to 10, 10 to 15 and greater than 15°). A total of 28 eyes of 14 patients and 20 eyes of 10 normal controls were included in the study. The authors reported that the mean logMAR visual acuity of the patients was 0.51 (Snellen equivalent 20/63) and the mean N1 amplitude (nv/deg(2)) of patients were significantly reduced compared to controls as follows: 8.91 ± 14.00 versus 43.44 ± 9.55 (p < 0.0001) in less than 2°; 9.24 ± 10.47 versus 22.00 ± 3.87 (p < 0.0001) in 5-10°; 8.57 ± 10.02 versus 15.24 ± 1.89 (p < 0.0001) in 10-15°; and 7.03 ± 6.52 versus 12.47 ± 2.62 in >15° (p < 0.001). The mean P1 amplitude (nv/deg(2)) was also significantly reduced in patients compared to controls. The results specified 27.66 ± 37.44 versus 96.20 ± 12.41 (p < 0.0001) in less than 2°; 22.61 ± 19.38 versus 53.78 ± 9.79 (p < 0.0001) in 5-10°; 18.75 ± 20.21 versus 35.22 ± 4.16 (p < 0.001) in 10-15°; and 17.10 ± 12.54 versus 25.71 ± 3.93 (p < 0.001). The implicit time of N1 and P1 were also delayed significantly in all the rings. The mean central foveal thickness assessed by OCT scan was 84.78 ± 45.12 μm. There was poor correlation between mfERG amplitudes or implicit times with either the visual acuity or OCT central thickness. The authors concluded that mfERG showed significant reduction in amplitudes and implicit times of the waveforms in patients with type 2 MacTel in all the rings, suggesting a more generalized affection of the macula. The maximum reductions were seen in the <2(o) rings. Although there was poor correlation between the visual acuity and the amplitudes a of the waveforms, mfERG is a useful investigative modality for functional assessment of macula in type 2 MacTel patients. However, this study by Narayanan et al. was limited by the sample size of 28 eyes in 14 patients.
In a review on “Hydroxychloroquine-induced retinal toxicity”, Hansen and Schuman (2011) stated that at the initiation of treatment with HCQ, the prescribing physician should refer the patient to an ophthalmologist. During the initial examination, it is recommended that the patient receive:

- A thorough ocular examination documenting any pre-existing conditions; and
- A Humphrey visual field central 10-2 white-on-white pattern; and
- At least 1 of the following objective tests, if available:
  - Fundus auto-fluorescence (FAF) test; or
  - mfERG; or
  - Spectral domain OCT (SD-OCT).

Moreover, these investigators noted that mfERG, a test that is typically available in large clinical centers, objectively evaluates function and can be used in place of visual fields. They also stated that it is also worth considering the use of color fundus photographs to assist in documenting changes over time, especially if there is pre-existing retinal pathology. However, the dilated fundus examination should not be considered a screening tool, as it only picks up relatively late toxic changes.

Costedoat-Chalumeau et al (2012) stated that new recommendations for screening of HCQ retinopathy, updating those of 2002, have been recently published by the American Academy of Ophthalmology (AAO). These recommendations have been necessary because of new knowledge about the prevalence of toxicity and because of improved screening tools. Amsler grid testing, color vision testing, fluorescein angiography, full-field ERG, and electro-oculogram are no longer recommended. It is now recommended to perform fundus examinations with 10-2 automated fields, and whenever possible, at least 1 objective test including mfERG,
FAF or SD-OCT. A baseline examination is advised as a reference and then, annual screening should be initiated no later than 5 years after starting HCQ therapy.

An eMedicine review on “Chloroquine and Hydroxychloroquine Toxicity” (Roque, 2017) listed full-field ERG or electro-oculogram as one of the ancillary tests, although not recommended for toxicity screening because of sensitivity, specificity and reliability issues, may also be used in diagnosing toxicity. Moreover, the author also indicated that the ophthalmic examination should also include a Humphrey visual field central 10-2 white-on-white pattern, and at least one of the following objective tests, if available:

- SD-OCT
- FAF test
- mfERG.

Browning and Lee (2014) determined the relative sensitivity and specificity of 10-2 visual fields (10-2 VFs), mfERG, and SD-OCT in detecting HCQ retinopathy. A total of 121 patients taking HCQ (n = 119) or chloroquine (CQ; n = 2) with 10-2 VF, mfERG, and SD-OCT tests were retrospectively reviewed. Rates of test abnormality were determined. Retinopathy was present in 14 and absent in 107; 11 of 14 (78.6 %) patients with retinopathy were over-dosed; 12 (85.7 %) had cumulative dosing greater than 1,000 g. The sensitivities of 10-2 VF, mfERG, and SD-OCT in detecting retinopathy were 85.7 %, 92.9 %, and 78.6 %, respectively. The specificities of 10-2 VF, mfERG, and SD-OCT in detecting retinopathy were 92.5 %, 86.9 %, and 98.1 %, respectively. Positive-predictive values (PPVs) of 10-2 VF, mfERG, and SD-OCT in detecting retinopathy were less than 30 % for all estimates of HCQ retinopathy prevalence; negative-predictive values (NPVs) were greater than 99 % for all tests. The authors concluded that based on published estimates of HCQ retinopathy prevalence, all 3 tests are most reliable when negative,
allowing confident exclusion of retinopathy in patients taking less than or equal to 6.5 mg/kg/day. Each test is less useful in allowing a confident diagnosis of retinopathy when positive, especially in patients taking less than or equal to 6.5 mg/kg/day.

An UpToDate review on "Antimalarial drugs in the treatment of rheumatic disease" (Wallace, 2014) states that "The earliest retinal abnormalities are asymptomatic and can only be detected by ophthalmologic examination. These "premaculopathy" changes consist of macular edema, increased pigmentation, increased granularity, and loss of the foveal reflex. Subtle functional loss in the parafoveal retina can occur before biomicroscopic changes in the retinal pigment epithelium. Detection of changes at this stage, using techniques such as multifocal electroretinography, is desirable since they may be completely reversible upon discontinuation of the medication".

Guidelines from the AAO (Marmor et al, 2011) on screening for CQ and HCQ toxicity stated that newer objective tests, such as mfERG, SD-OCT, and FAF, can be more sensitive than visual fields. The guidelines recommended that along with 10-2 automated fields, at least 1 of these procedures be used for routine screening where available. The guidelines stated that, because mfERG testing is an objective test that evaluates function, it may be used in place of visual fields.

Tsang et al (2015) determined the validity of mfERG as a screening tool for detecting CQ and HCQ retinal toxicity in patients using these medications. To evaluate the sensitivity and specificity of mfERG when compared with automated visual fields (AVFs), FAF, and OCT. The 2011 AAO recommendations on screening for CQ/HCQ retinopathy recommended a shift toward more objective testing modalities. Multi-focal ERG may be effective in detecting functional change before irreversible structural damage from CQ/HCQ toxicity. These investigators performed a search for records...
reporting the use of mfERG for screening CQ/HCQ retinopathy in MEDLINE (PubMed and OVID), EMBASE, and Web of Science, and assessed these using the QUADAS-2 risk of bias tool. They conducted an analysis of 23 individual studies and their reported individual patient data (449 eyes of 243 patients) published from January 2000 to December 2014. Multi-focal ERG had the greatest proportion of positive test results, followed by AVF. The pooled sensitivity and specificity of mfERG were 90% (95% confidence interval [CI]: 0.62 to 0.98) and 52% (CI: 0.29 to 0.74), respectively, with AVF as reference standard (13 studies). Sensitivity was high, but specificity was variable when OCT, FAF, and the positivity of 2 of 3 tests was used as the reference standard. When verified against AVF as the reference test, patients with a false-positive mfERG result received higher HCQ cumulative doses (1,068 g) than patients with true-negative (658 g, p < 0.01) and false-negative (482 g, p < 0.01) results. The authors concluded that mfERG was shown to have a high sensitivity but variable specificity when verified against AVF, OCT, FAF, and a combination of tests. The greater average cumulative dose in the false-positive group compared with the true-negative group when mfERG was verified against AVF suggested that mfERG may have the ability to detect cases of toxicity earlier than other modalities. Moreover, they state that there is an unclear risk of bias in the available evidence, and future studies should adhere to Standards for Reporting of Diagnostic Accuracy reporting guidelines.

Multi-Focal Electroretinography (mfERG) for Prediction of Visual Acuity Decline in Age-Related Macular Degeneration

In a prospective study, Ambrosio et al (2015) examined the role of mfERG for predicting visual acuity (VA) decline in early age-related macular degeneration (ARMD) with time. A total of 26 early ARMD patients (12 males and 14 females, mean age of 66.9 ± 9.8; range of 46 to 82 years) were included in the study. A complete ophthalmic examination and mfERG
(Retiscan, Roland Germany, ISCEV standard protocol) were performed at the study entry (baseline), after 20 and 24 months. The first-order kernel mfERG responses were analyzed by ring analysis. The amplitude density (AD) of the first positive peak (P1, nV/deg2), the P1 amplitude (µV) and P1 implicit time (ms) for Rings 1 (central) to 6 (most peripheral) were evaluated. Data were statistically analyzed by analysis of variance and receiver operating characteristic (ROC) curves. The loss in the mfERG Ring 1 AD from normal control values, recorded at baseline, was correlated with the decrease in ETDRS VA with time (p = 0.004); ROC analysis showed that, after 24 months, the average decline in VA was greater (3 letters versus 0.4 letters, p = 0.0021) in patients whose Ring 1 P1 AD at baseline was equal to or less than 65.9 nV/deg2, compared to those with higher AD values. Both P1 amplitude and AD of Ring 1 had an area under the curve of 0.702 (95% CI: 0.50 to 0.92) with a sensitivity of 64.3% (35.14 to 87.24%) and a specificity of 91.7% (61.52 to 99.79%). The authors concluded that these findings indicated that mfERG P1 amplitude and AD of Ring 1 may be highly specific to predict VA decline in early ARMD. These preliminary findings need to be validated by well-designed studies.

Guidelines from the American Academy of Ophthalmology (AAO, 2015) on age-related macular degeneration have no recommendation for mfERG.

**ERG / mfERG for Diagnosis / Evaluation of Glaucoma**

In a report by the AAO on "Assessment of visual function in glaucoma", Jampel and colleagues (2011) reviewed the published literature to summarize and evaluate the effectiveness of visual function tests in diagnosing glaucoma and in monitoring progression. Literature searches of the PubMed and Cochrane Library databases were conducted last on May 7, 2010, and were restricted to citations published on or after January 1, 1994. The search yielded 1,063 unique citations. The first author reviewed the titles and abstracts of
these articles and selected 185 of possible clinical relevance for further review. The panel members reviewed the full text of these articles and determined that 85 met inclusion criteria. They conducted data abstraction of the 85 studies, and the panel methodologist assigned a level of evidence to each of the selected articles. One study was rated as level I evidence. The remaining articles were classified broadly as providing level II evidence. Studies deemed to provide level III evidence were not included in the assessment. Standard white-on-white automated perimetry remains the most commonly performed test for assessing the visual field, with the Swedish interactive threshold algorithm (SITA) largely replacing full-threshold testing strategies. Frequency-doubling technology and its refinement into Matrix perimetry, as well as short-wavelength automated perimetry, now available with SITA, have been evaluated extensively. Machine learning classifiers seem to be ready for incorporation into software to help distinguish glaucomatous from non-glaucomatous fields. Other technologies, such as multi-focal visual-evoked potential (VEP) and ERG, which were designed as objective measures of visual function, provided testing free of patient input, but issues prevent their adoption for glaucoma management. The authors concluded that advances in technology and analytic tools over the past decade had provided them with more rapid and varied ways of assessing visual function in glaucoma, but they have yet to produce definitive guidance on the diagnosis of glaucoma or its progression over time. They stated that further research on an objective measure of visual function is needed.

Nouri-Mahdavi (2014) stated that testing the peripheral field of vision is the mainstay for detection of glaucoma deterioration. Various methods and algorithms are currently available for detection of early glaucoma or establishing disease progression. Alternative testing strategies such as frequency doubling technology perimetry or short-wavelength automated perimetry have been extensively explored over the last 2 decades. The former has been found most promising for
detection of earliest evidence of functional glaucoma damage when the standard achromatic perimetry results are still within the normal range. However, standard achromatic perimetry remains the standard technique for establishing deterioration of the disease. Both trend and event analyses were used for establishing change within series of visual fields. Trend analyses provided the clinician with rates of progression, putting the speed of glaucoma progression in the context of patient longevity, whereas event analyses demonstrated a "step" change regardless of the length of time it took for this amount of change to occur. The 2 techniques are complementary and should be used concurrently; ERG/mFERG was not mentioned as a management tool.

Furthermore, guidelines from the American Academy of Ophthalmology (2010) and UpToDate reviews on "Open-angle glaucoma: Epidemiology, clinical presentation, and diagnosis" (Jacobs, 2015), "Angle-closure glaucoma" (Weizer, 2015), and "Overview of glaucoma in infants and children" (Olitsky and Reynolds, 2015) do not mention ERG/mFERG as diagnostic tools.

In a prospective, case-series study, Gupta and colleagues (2015) evaluated the use of mFERG in diagnosing retinal toxicity from siderosis with normal ERG. A total of 6 patients with retained intra-ocular foreign body were recruited. The affected eye of the patients had no clinical evidence of siderosis, had similar full-field photopic 3.0 ERG compared with the fellow eye, and had subnormal VA. Group averages in each mFERG ring for implicit time and amplitude at P1 wave were compared between affected and fellow eye to look for latent siderosis. On mFERG, no statistical difference in group averaged amplitude was observed; however, a significant difference ($p < 0.05$) was found in group averaged latency between fellow and affected eye at most tested rings (less than 2 degree, 2 to 5 degree, and greater than 15 degree rings). Average latency for overall retinal area mapped also showed significant difference ($p = 0.010$). The authors
concluded that increased mfERG latency may serve as an early predictor of retinal damage from siderosis when full-field ERG is normal.

ERG for Diagnosis of Birdshot Chorioretinopathy

Tzekov and Madow (2015) stated that birdshot chorioretinopathy (BSCR) is a rare form of autoimmune posterior uveitis that can affect the visual function and, if left untreated, can lead to sight-threatening complications and loss of central vision. These investigators performed a systematic search of the literature focused on visual electrophysiology studies, including ERG, electrooculography (EOG), and VEP, used to monitor the progression of BSCR and estimate treatment effectiveness. Many reports were identified, including using a variety of methodologies and patient populations, which made a direct comparison of the results difficult, especially with some of the earlier studies using non-standardized methodology. Several different electrophysiological parameters, like EOG Arden's ratio and the mfERG response densities, were reported to be widely affected. However, informal consensus emerged in the past decade that the full-field ERG light-adapted 30-Hz flicker peak time is one of the most sensitive electrophysiological parameters. As such, it has been used widely in clinical trials to evaluate drug safety and effectiveness and to guide therapeutic decisions in clinical practice. The authors concluded that despite its wide use, a well-designed longitudinal multi-center study to systematically evaluate and compare different electrophysiological methods or parameters in BSCR is still lacking; but would benefit both diagnostic and therapeutic decisions. The authors stated that, “u]ntil then, there is enough evidence to recommend the use of photopic 30 Hz flicker in the clinical management of BSCR.”

ERG for Evaluation of Childhood Brain Tumor Survivors
In a population-based, cross-sectional study, Pietila and colleagues (2016) evaluated the clinical value of ERG and VEP in childhood brain tumor survivors. A flash ERG and a checker-board reversal pattern VEP (or alternatively a flash VEP) were done for 51 survivors (age of 3.8 to 28.7 years) after a mean follow-up time of 7.6 (1.5 to 15.1) years. Abnormal ERG was obtained in 1 case (2 %), bilaterally delayed abnormal VEPs in 22/51 (43 %) cases; 9 of 25 patients with infra-tentorial tumor location, and altogether 12 out of 31 (39 %) patients who did not have tumors involving the visual pathways, had abnormal VEPs. Abnormal ERGs are rarely observed, but abnormal VEPs are common even without evident anatomic lesions in the visual pathway. Bilateral changes suggested a general and possibly multi-factorial toxic/adverse effect on the visual pathway. The authors concluded that ERG and VEP may have clinical and scientific value while evaluating long-term effects of childhood brain tumors and tumor treatment.

**ERG for Evaluation of Achromatopsia**

Schallhorn and colleagues (2018) reported novel ERG findings in a genetically confirmed case of achromatopsia. A patient with a history of childhood nystagmus, photo-aversion, and absent color vision was examined. Electroretinography and fundus examination were performed under anesthesia at the time of corrective surgery for nystagmus. Genomic DNA isolated from peripheral blood was directly sequenced for variations in the CNGA3 and CNGB3 genes. Ophthalmoscopic examination revealed no distinct abnormalities; ERG obtained under anesthesia at age 3 years revealed absent photopic responses. The dark-adapted (DA) combined responses had reduced b-wave amplitudes resulting in an electro-negative configuration. Genetic testing revealed 2 heterozygous sequence variations present in the coding sequence of the CNGA3 gene (Arg223Trp and Pro372Ser), which have been previously described in the setting of achromatopsia. Sequencing of the patient's parents confirmed
that these 2 variations lie on separate alleles. The authors concluded that novel ERG findings in a patient with genetically confirmed achromatopsia were reported; the electro-negative configuration in this clinical setting is of unclear etiology; however, it may suggest some component of inner retinal dysfunction. The clinical value of ERG in the evaluation of achromatopsia has to be further investigated.

**ERG for Evaluation of Autism Spectrum Disorder**

Constable and colleagues (2016) explored early findings that individuals with autism spectrum disorder (ASD) have reduced scotopic ERG b-wave amplitudes. Light-adapted (LA) and DA ERGs were produced by a range of flash strengths that included and extended the ISCEV standard from 2 subject groups: (i) a high-functioning ASD group (n = 11), and (ii) a control group (n = 15) for DA and n = 14 for LA ERGs who were matched for mean age and range. Flash strengths ranged from DA -4.0 to 2.3 log phot cd s m(-2) and LA -0.5 to 1.0 log phot cd s m(-2), and Naka-Rushton curves were fitted to DA b-wave amplitude over the first growth limb (-4.0 to -1.0 log phot cd s m(-2)). The derived parameters (V max, K m and n) were compared between groups. Scotopic 15-Hz flicker ERGs (14.93 Hz) were recorded to 10 flash strengths presented in ascending order from -3.0 to 0.5 log Td s to assess the slow and fast rod pathways, respectively. LA 30-Hz flicker ERGs, oscillatory potentials (OPs) and the responses to prolonged 120-ms ON-OFF stimuli were also recorded. The ISCEV LA b-wave amplitude produced by 0.5 log phot cd s m(-2) was lower in the ASD group (p < 0.001). Repeated measures ANOVA for the LA b-wave amplitude series forming the photopic hill was significantly (p = 0.01) different between groups. No group differences were observed for the distributions of the time to peaks of LA a-wave, b-wave or the photopic negative responses (phNR) (p > 0.08) to the single flash stimuli, but there was a significant difference in the distribution for the LA b-wave amplitudes (corrected p = 0.006). The prolonged 120-ms ON responses
were smaller in the ASD group (corrected p = 0.003), but the OFF response amplitude (p > 0.6) and ON and OFF times to peaks (p > 0.4) were similar between groups. The LA OPs showed an earlier bifurcation of OP2 in the younger ASD participants; however, no other differences were apparent in the OPs or 30-Hz flicker waveforms. DA b-wave amplitudes fell below the control 5th percentile of the controls for some individuals including 4 ASD participants (36 %) at the 1.5 log phot cd s m(-2) flash strength and 2 (18 %) ASD participants at the lower -2 log phot cd s m(-2) flash strength. However, across the 13 flash strengths, there were no significant group differences for b-wave amplitude’s growth (repeated measures ANOVA p = 0.83). Nor were there any significant differences between the groups for the Naka-Rushton parameters (p > 0.09). No group differences were observed in the 15-Hz scotopic flicker phase or amplitude (p > 0.1), DA ERG a-wave amplitude or time to peak (p > 26). The DA b-wave time to peak at 0.5 log phot cd s m(-2) was longer in the ASD group (p = 0.04). The authors concluded that under LA conditions, the b-wave was reduced across the ASD group, along with the ON response of the prolonged flash ERG. They noted that some ASD individuals also showed subnormal DA ERG b-wave amplitudes. The authors stated that these exploratory findings suggested there is altered cone-ON bipolar signaling in ASD.

Furthermore, an UpToDate review on “Autism spectrum disorder: Diagnosis” (Augustyn, 2017) does not mention electroretinography as a diagnostic tool.

**ERG for Evaluation of Non-Glaucomatous Optic Neuropathies**

Bach and Kay (2017) presented 3 cases of inflammatory optic neuritis that was followed to resolution using PERG. They noted that these cases represented the first report in which a relatively new office-based PERG technology has been demonstrated to be useful in monitoring recovery of visual function in the setting of inflammatory optic neuropathies. Two
patients demonstrated normalization of their PERG paralleling their full recovery of optic nerve function as assessed via other standard measures such as VA and Humphrey visual field (HVF), while the third demonstrated improvement, albeit still reduced in amplitude, consistent with the incomplete recovery of optic nerve function, at most recent follow-up. Furthermore, in 1 of the patients, use of this technology provided an objective means of following recovery of ganglion cell function in an individual who could not be reliably monitored with serial HVFs secondary to poor field testing technique. Moreover, these investigators stated that whether this technology is applicable to the evaluation of non-glaucomatous optic neuropathies has not been well established, although a recent report did demonstrate recovery of ganglion cell function as assessed by PERG in 3 patients who underwent resection of a pituitary tumor abutting the optic chiasm. PERG has also been shown to be a useful diagnostic tool in experimental models for optic neuritis as well as having potential for other types of optic neuropathies. These researchers have now applied this technology to 3 patients with inflammatory optic neuropathies, and have performed serial PERG studies as their optic neuropathy resolved demonstrating progressive improvement on PERG studies. The authors concluded that the PERG technique may prove useful as an adjunctive objective measure for monitoring progression and/or resolution of glaucoma and other optic neuropathies in patients who are consistently unreliable when performing HVF. They stated that further studies are needed to determine if this new testing paradigm will be of benefit in monitoring for progression or recovery of ganglion cell function in other non-glaucomatous optic neuropathies including compressive lesions of the optic apparatus, ischemic optic neuropathy, papilledema, and toxic optic neuropathies.

**ERG for Evaluation of Sickle Cell Retinopathy**

In a mono-centric, retrospective, observational study, Bottin and colleagues (2017) discussed full-field ERG (ffERG)
findings in patients with early sickle cell (SC) retinopathy according to the following hemoglobin types: (i) HbSS or (ii) HbSC (homozygous or heterozygous mutations, respectively). Patients affected by non-proliferative SC retinopathy were included from November 2014 to April 2016. They were separated into 1 of the following 3 groups: (i) HbSS, (ii) HbSC, and (iii) control. All groups underwent full ophthalmologic examination (fundus examination) and ffERG. For SC patients, additional imaging testing was also performed (fluorescein angiography and spectral domain OCT). A total of 24 eyes from 12 patients (6 HbSS and 6 HbSC) and 12 eyes from 6 controls were included. The HbSS group exhibited a dramatic decrease of the b-wave amplitudes for all DA ffERG responses when compared with the control group (p = 0.02, p = 0.003, p = 0.005, respectively, after DA 0.01, DA 3.0, and DA 10.0 cd.s.m-2 stimulations) and decreased a-wave amplitudes for LA responses (p = 0.03 after LA 3.0 cd.s.m-2 stimulations). The a-Wave amplitudes were significantly reduced for all DA and LA responses in HbSC group compared to the control group (p = 0.03, p = 0.01, p = 0.03, respectively, after DA 3.0, DA 10.0, and LA 3.0 cd.s.m-2 stimulations). The HbSS+HbSC groups presented decreased a-wave amplitudes for DA and LA responses and decreased b-wave amplitude after DA 0.01 and 10.0 cd.s.m-2 stimulations when compared to the control group. The authors concluded that these findings could suggest an early involvement of the inner retinal cells in the disease process in HbSS patients and of the outer retinal cells in HbSC patients. This could provide new insights on the pathophysiology of the retinal affection in HbSS/HbSC SC disease. The authors stated that it would also be of interest to compare ffERG data to OCT-angiography findings; however, current systems mostly cover the area of the central retina, whereas ffERG collects responses from the whole retina. Moreover, they stated that the main drawback of this study was its small sample size (n = 12 for the experimental group); larger studies are needed to support this hypothesis.
Furthermore, an UpToDate review on “Overview of the clinical manifestations of sickle cell disease” (Vichinsky, 2017) does not mention electroretinography as a diagnostic tool.

ERG for Evaluation of Rhegmatogenous Retinal Detachment

Parvaresh (2018) noted that few studies have evaluated the role of retinal electrophysiology testing in patients with retinal detachment and after retinal re-attachment surgery using ffERG and mfERG. Both animal as well as human studies have shown that retinal detachment causes the loss of the outer segments of photoreceptor cells. Both cone and rod photoreceptors are affected in retinal detachment. However, the magnitude of the damage and its likely location in the retina are not clearly known. This investigator stated that current knowledge of electrophysiological changes in rhegmatogenous retinal detachment (RRD) is limited and future studies regarding the application of ERG studies in eyes with RRD are needed; and that although some studies have reported the prognostic value of ERG testing in eyes with RRD, the potential clinical applications of this technique are not clear. The author concluded that future large-scale studies may be helpful to examine the use of ERG testing for various aspects of retinal detachment, such as determination of the optimal time of intervention, the outcomes of different types of surgery, and effects of pharmacotherapies on surgery.

ERG for Diagnosis of Psychiatric Disorders

In a systematic review, Youssef and colleagues (2019) examined the available information on use of ERG as a diagnostic tool in psychiatry. The ERG has been found to have diagnostic utility in cocaine withdrawal (reduced light-adapted b-wave response), major depressive disorder (reduced contrast gain in pattern ERG), and schizophrenia (reduced a- and b-wave amplitudes). These researchers evaluated these findings as well as the applicability of ERG to
substance use disorder, Alzheimer's disease, autism spectrum disorder (ASD), panic disorder, eating disorders, attention deficit hyperactivity disorder (ADHD), and medication use. The authors concluded that while there have been promising results, current research suffers from a lack of specificity. These researchers stated that further research that quantifies anomalies in ERG present in psychiatric illness is needed.

mfERG for Evaluation of Idiopathic Epiretinal Membrane / Poppers Maculopathy

Gao and colleagues (2017) evaluated the macular function changes in patients with idiopathic macular epiretinal membrane (ERM) by mfERG and their correlations with VA and central macular thickness (CMT) by OCT. A total of 20 eyes of 20 patients with ERM underwent OCT and mfERG examinations. The response amplitude densities and implicit times of mfERG were compared to the control fellow eyes. Correlation analyses among VA, CMT and mfERG values in the central 2 concentric rings were performed. The mfERG P1 response amplitude densities in ring 1 to 2 and P1 implicit time in ring1 were significantly changed in epiretinal membrane eyes compared with controls (p < 0.05). Multi-variate step-wise linear regression analyses showed LogMAR VA was significantly correlated with CMT (p = 0.004), and also with the P1 amplitude density in ring 1 (p = 0.002); CMT showed significant correlation with P1 implicit time in ring 2 (p = 0.013). The authors concluded that these findings showed mfERG abnormalities appeared to demonstrate subtle macular function changes and correlated with VA and CMT in eyes with ERM. They stated that in first-order mfERG responses, P1 wave changes may be a sensitive functional measurement for ERM patients.

The authors stated that the drawbacks of this study included a small sample size (n = 20). This might have limited the power in detecting photoreceptor statues and other influence factors, which may have an impact on ERG values and statistical
analysis. These researchers noted that the mechanism of mfERG impairment related to ERM may not be straightforward; the mfERG abnormalities as described in this report need further investigation.

Pahlitzsch and associates (2019) noted that maculopathy is a potential side effect of amyl nitrite or "poppers" abuse. It is characterized by a sudden, painless decrease in VA. While the funduscopic changes are subtle, OCT showed alterations of the outer retinal layers in the fovea. However, the extent of retinal dysfunction remains poorly understood. These investigators compared the mfERG of 6 patients with poppers maculopathy to that of a control group consisting of 6 healthy subjects. Response densities and implicit times of N1 and P1 were analyzed. Response densities and implicit times of both N1 and P1 were lower in the patients with poppers maculopathy than in the control group, particularly in ring 1 and rings 4 and 5. The only statistically significant finding, however, was a reduced N1 response density of 1 hexagon in the patient group. No significant differences were found considering the sum response or the averaged rings 1 to 5. The authors concluded that compared to a healthy control group, mfERG of patients with poppers maculopathy showed no relevant impairment contrasting the marked effect of the disease on VA. These investigators stated that in clinical practice, poppers maculopathy could not be diagnosed by mfERG.

Pattern Electroretinography

Wilsey and colleagues (2017) compared diagnostic performance and structure-function correlations of mfERG, full-field flash ERG (ffERG) photopic negative response (PhNR) and transient pattern-reversal ERG (PERG) in a non-human primate (NHP) model of experimental glaucoma (EG). At baseline and after induction of chronic unilateral intra-ocular pressure (IOP) elevation, 43 NHP had alternating weekly recordings of retinal nerve fiber layer thickness (RNFLT) by
spectral domain OCT (Spectralis) and retinal function by mfERG (7F slow-sequence stimulus, VERIS), ffERG (red 0.42 log cd-s/m² flashes on blue 30 scotopic cd/m² background, LKC UTAS-E3000), and PERG (0.8° checks, 99 % contrast, 100 cd/m² mean, 5 reversals/s, VERIS). All NHP were followed at least until HRT-confirmed optic nerve head posterior deformation, most to later stages. mfERG responses were filtered into low- and high-frequency components (LFC, HFC, greater than 75-Hz). Peak-to-trough amplitudes of LFC features (N1, P1, N2) and HFC RMS amplitudes were measured and ratios calculated for HFC:P1 and N2:P1. ffERG parameters included A-wave (at 10 ms), B-wave (trough-to-peak) and PhNR (baseline-to-trough) amplitudes as well as PhNR:B-wave ratio. PERG parameters included P50 and N95 amplitudes as well as N95:P50 ratio and N95 slope. Diagnostic performance of retinal function parameters was compared using the area under the receiver operating characteristic curve (A-ROC) to discriminate between EG and control eyes. Correlations to RNFLT were compared using Steiger's test. Study duration was 15 ± 8 months. At final follow-up, structural damage in EG eyes measured by RNFLT ranged from 9 % above baseline (BL) to 58 % below BL; 29/43 EG eyes (67 %) and 0/43 of the fellow control eyes exhibited significant (greater than 7 %) loss of RNFLT from BL. Using raw parameter values, the largest A-ROC findings for mfERG were: HFC (0.82) and HFC:P1 (0.90); for ffERG: PhNR (0.90) and PhNR:B-wave (0.88) and for PERG: P50 (0.64) and N95 (0.61). A-ROC increased when data were expressed as % change from BL, but the pattern of results persisted. At 95 % specificity, the diagnostic sensitivity of mfERG HFC:P1 ratio was best, followed by PhNR and PERG. The correlation to RNFLT was stronger for mfERG HFC (R = 0.65) than for PhNR (R = 0.59) or PERG N95 (R = 0.36), (p = 0.20, p = 0.0006, respectively). The PhNR flagged a few EG eyes at the final time-point that had not been flagged by mfERG HFC or PERG. The authors noted that among the ERG modes evaluated in this study, the mfERG HFC had the highest diagnostic sensitivity and strongest correlation to structure in...
this cohort of NHP with experimental glaucoma. Consistent
with numerous other reports, accounting for inter-eye
differences by normalization to baseline amplitudes and/or by
normalization to other features of the same ERG response
less sensitive to glaucomatous damage improved both
diagnostic performance and correlation to a structural measure
damage severity for the best parameters of all 3 ERG
modes. After normalization, the mfERG HFC had the highest
diagnostic sensitivity and strongest correlation to RNFL
thickness and missed only a few EG eyes flagged by PhNR or
PERG. The mfERG also offered an opportunity to evaluate
focal loss, unlike the ffERG; future studies are planned to
evaluate whether any benefit can be realized from this
potential advantage, even in this EG model, which tends to
manifest as more diffuse progressive damage rather than as
sequential focal loss. Moreover, these researchers stated that
further research is needed to examine if these observations
will successfully translate to clinical management of human
glaucoma.

Cvenkel et al (2017) examined discrimination ability of PERG
and PhNR between early glaucoma and healthy controls, and
their relationship with structural measurements using SD-
OCT. These researchers carried out a cross-sectional study
with 34 patients with ocular hypertension (n = 7), suspect
glaucoma (n = 17), and early glaucoma (n = 10), plus 24 age-
matched controls. The following parameters were analyzed:
P50 and N95 amplitude of the PERG, PhNR amplitude and
PhNR/b-wave ratio, peripapillary retinal and macular nerve
fiber layer (NFL) thicknesses, and ganglion cell complex
(GCC) thickness. Data from only 1 eye per individual were
included in the statistical analysis. Descriptive statistics,
ANOVA, ROC curves, and correlation tests were used for
analysis of the variables. PERG N95 and PhNR amplitudes
were significantly reduced in suspect and early glaucoma eyes
versus controls. Significant differences across ocular
hypertensive, suspect, and early glaucoma eyes were found
for macular NFL and GCC thickness, but not for any of the
ERG parameters. The mean PhNR amplitude did not differ across these groups and was already reduced on average by 46% in ocular hypertensive and early glaucoma eyes and by 52% in suspect glaucoma eyes. The P50 and N95 amplitudes showed similar reduction in suspect and early glaucoma eyes on average by 15% and 26%, respectively. Of the ERG parameters, PhNR amplitude distinguished best between glaucoma and control groups, with an area under ROC curve of 0.90 for suspect glaucoma, and 0.86 for early glaucoma. PhNR/b-wave ratio showed strongest association in suspect glaucoma eyes with peripapillary retinal (r = 0.61) and macular NFL (r = 0.76) thicknesses. In eyes with early glaucoma, peripapillary retinal NFL thickness correlated best with PhNR amplitude (r = 0.71) and PERG P50 amplitude (r = 0.67). The authors concluded that in eyes with suspect glaucoma, important decrease in PhNR amplitude was associated with small changes in peripapillary retinal and macular NFL thicknesses. These researchers stated that these findings suggested that PhNR may be a useful and sensitive test in eyes with diagnostic dilemma, although further follow-up of such eyes is needed for definitive confirmation.

Jeon et al (2019) examined the relationship between PERG and optic disc morphology in glaucoma suspect and glaucoma. A total of 86 eyes of glaucoma suspect and 145 eyes of manifest glaucoma subjects were included in this study. Average peripapillary RNFLT was obtained with SD-OCT, and optic disc imaging was performed using the Heidelberg Retinal Tomograph (HRT). Visual function was evaluated with perimetry (SITA and frequency doubling technology) and PERG. Scatter plots and correlation coefficients were evaluated between visual function and RNFLT or optic disc structure. Scatter plots of PERG and perimetry according to RNFLT change showed that PERG started to decrease earlier than did perimetry. The differences between linear and logarithmic R2 were largest for the scatter plot of SITA 24-2 (linear R2 = 0.415; logarithmic R2 = 0.443) and the smallest for P50 amplitude of PERG (linear R2 =
0.136, logarithmic R2 = 0.138). In glaucoma suspect, HRT parameters such as cup shape measure (CSM) and linear cup-disc ratio (CDR) had significant correlations with PERG amplitudes (p = 0.016 for P50 and 0.049 for N95 in CSM, p = 0.012 for P50 in CDR). However, in glaucoma patients, mean RNFLT was associated with PERG amplitude (p = 0.011 for P50 and 0.002 for N95). The authors concluded that PERG deterioration occurred earlier than did perimetry according to RNFLT decrease; PERG amplitudes were significantly correlated with disc morphology in glaucoma suspect. These researchers stated that these findings suggested that PERG can detect ganglion cell dysfunction before the cells die.

The authors stated that this study has the intrinsic limitation of a cross-sectional design, and as such, it was difficult to predict the progression probability or prognosis of study subjects. In future study, a longitudinal prospective study that could examine serial change of structure and functional parameters should be performed for clinical application of electrophysiologic test. In addition, this study excluded patients with increased IOP and it could make the results of this study not including all type of glaucoma.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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Diabetes mellitus with diabetic retinopathy
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**Multi-focal ERG (mfERG) & Pattern Electroretinography (PERG):**

CPT codes covered if selection criteria are met:

- 0509T  Electroretinography (ERG) with interpretation and report, pattern (PERG)
- 92274  Electroretinography (ERG), with interpretation and report; multifocal (mfERG)

ICD-10 codes covered if selection criteria are met:

- B50.0 - B50.9  Plasmodium falciparum malaria
- T37.2X1A - T37.2X6S  Poisoning by antimalarials
- Z79.899  Other long term (current) drug therapy [detecting chloroquine (Aralen) and hydroxychloroquine (Plaquenil) toxicity]

ICD-10 codes not covered for indications listed in the CPB:

- F20.0 - F20.9  Schizophrenia
- F32.0 - F32.9  Major depressive disorder, single episode
- F33.0 - F33.9  Major depressive disorder, recurrent
- F41.0  Panic disorder [episodic paroxysmal anxiety]
- F50.00 - F50.9  Eating disorders
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The above policy is based on the following references:

7. Bach A, Kay MD. Demonstration of reversible retinal ganglion cell dysfunction in inflammatory optic


17. Jacobs DS. Open-angle glaucoma: Epidemiology, clinical presentation, and diagnosis. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed August 2015.


29. Olitsky SE, Reynolds JD. Overview of glaucoma in infants and children. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed August 2015


37. Vichinsky EP. Overview of the clinical manifestations of sickle cell disease. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed July 2017.


39. Weizer JS. Angle-closure glaucoma. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed August 2015


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0854

Electroretinography

There are no amendments for Medicaid.

revised 12/10/2020

Proprietary