Electroretinography

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

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 (e.g., diagnosis/evaluation of glaucoma; evaluation of childhood brain tumor survivors).

Aetna considers multi-focal ERG (mfERG) medically necessary for detecting chloroquine (Aralen) and hydroxychloroquine (Plaquenil) toxicity.

Aetna considers mfERG experimental and investigational for all other indications (e.g., diagnosis/evaluation of glaucoma, and prediction of visual acuity decline in age-related macular degeneration).

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 (Jv/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 (Jv/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(0) 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. [http://www.aao.org/publications/eyenet/201106/pearls.cfm](http://www.aao.org/publications/eyenet/201106/pearls.cfm).

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, 2013) 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
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 paracentral 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 checkerboard 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.

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**The above policy is based on the following references:**

4. Lai TY, Chan WM, Li H, et al. Multifocal electroretinographic changes in patients receiving


18. Weizer JS. Angle-closure glaucoma. UpToDate Inc., Waltham, MA. Last reviewed August 2015.
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Amendment to
Aetna Clinical Policy Bulletin Number: 0854
Electroretinography

There are no amendments for Medicaid.