Electroretinography (for North Carolina Only)

Policy Number: CSNCT0370.02
Effective Date: January 1, 2025

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Related Policies
None

Application

This Medical Policy only applies to the State of North Carolina.

Coverage Rationale

Multifocal Electroretinogram (mfERG)

For medical necessity clinical coverage criteria, refer to the North Carolina Medicaid (Division of Health Benefits) Clinical Coverage Policy, Ophthalmological Services: 1T-2, Special Ophthalmological Services.

Pattern Electroretinogram (PERG)/Pattern Electroretinogram Optimized for Glaucoma Screening (PERGLA)

Pattern electroretinogram (PERG) and pattern electroretinogram optimized for glaucoma screening (PERGLA) are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

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 federal, state, or contractual requirements 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 and Guidelines may apply.

CPT Code	Description
*0509T	Electroretinography (ERG) with interpretation and report, pattern (PERG)
92274	Electroretinography (ERG), with interpretation and report; multifocal (mfERG)

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Codes labeled with an asterisk (*) are not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program.

Description of Services

The electroretinogram (ERG) is a diagnostic test that measures the electrical activity of the retina in response to a light stimulus. Multifocal electroretinogram (mfERG) assesses many local ERG responses, typically 61 or 103, within the central 30 degrees. Pattern electroretinogram (PERG) is an electrophysiologic test that uses contrast reversing pattern stimuli to assess macular retinal ganglion cell (RGC) activity. When optimized for glaucoma screening PERGLA is a fully automatic version of the PERG (AAO 2022).

Clinical Evidence

PERG/PERGLA

While the published evidence on PERG and PERGLA suggest that these exams can detect retinal manifestation of eye conditions, comparison with other diagnostic methods, and assessment of the clinical utility of the tests are lacking. Therefore, based on existing evidence, their non-inferiority or superiority to established methods cannot be determined.

A 2020 ECRI report, Pattern Electroretinography for Detecting Central Retinal Damage from Diabetes, states that the evidence from four case control studies suggest that changes in PERG waveform amplitude and latency may indicate RGC damage in individuals with diabetes. However, no evidence is available to determine whether these findings enable earlier intervention that improves patient outcomes.

Merchant et al. (2017) conducted a cross-sectional analysis of sixty patients using OCT and electroretinography (ERG), including flash ERG and PERG to determine the association of ocular manifestations in beta-thalassemia with patient's age, blood transfusion requirements, average serum ferritin and dose and duration of iron chelation therapy. Routine ophthalmic examination and B scan of the eye was also done. Flash ERG a-waves and b-waves were recorded, however only a-wave amplitude was evaluated. PERG n35, n95 and p50 waves were recorded and p50 wave amplitude was evaluated. The a-wave on flash and p50 on pattern waves represent retinal photoreceptor epithelium (RPE) photoreceptor response, which is mainly affected in beta-thalassemia. Ocular changes were detected in 38.3% and a significant correlation was noted with increase in age ($p = 0.045$) but not with serum ferritin, transfusion requirements or chelation therapy. Abnormalities were noted in a-wave amplitude on flash ERG in 20% of cases, while reduced p50 amplitude on PERG was noted in 15%. The authors concluded that ERG appears to be a promising tool for screening patients with beta-thalassemia and can serve as a follow-up test for evaluating retinal function. Randomized controlled trials with larger patient populations are needed to further evaluate this technology.

Glaucoma

A 2021 Hayes health technology assessment, updated in 2024, Pattern Electroretinography for Diagnosis of Glaucoma, concluded that based on an evidence base of seven studies (including 1 prospective cohort, and 6 case-control studies), low quality evidence that the accuracy of PERG is similar to or greater than other available methods for diagnosing glaucoma or ocular hypertension (OHT). There is a lack of evidence of clinical utility for PERG in the management of patients who have or are at risk for glaucoma and for long-term health outcomes.

A 2020 ECRI report, Pattern Electroretinography for Detecting Central Retinal Damage from Glaucoma, states that evidence from one systematic review and 5 case-control studies (comprising 930 patients) suggests that changes in PERG waveform amplitude and latency may indicate retinal ganglion cell (RGC) damage in individuals with glaucoma. However, the evidence does not demonstrate that early detection of RGC damage would enable early therapeutic intervention, which would improve patient outcomes.

Senger et al. (2020) conducted a systematic review to review the result of studies regarding the clinical applicability of electrophysiological tests for glaucoma. Since 2013, there were nine published studies investigating mfERG for glaucoma. Most of the study protocols were modified from the traditional mfERG. The authors observed that currently, mfERG has not shown good correlation with visual field (VF) and is less effective than PERG for diagnosing glaucoma but might be useful for the detection of initial glaucoma. They also note that PERG may be of interest for examining patients with glaucoma and monitoring progression, as it showed accuracy in confirming localized defects. The authors concluded that clinical electrophysiological testing of the visual system reasonably matched with both the structural and functional analyses for glaucoma, but that no definitive indications of these tests have been established either at early detection or during follow-up of the disease, and that easier protocols and better topographical correspondence with current glaucoma tests are warranted for their routine use. (Studies by Cvenkel 2017, Preiser 2013, and Bannit 2013 previously cited in this policy are included in this systematic review).

Park et al. (2017- included in ECRI report regarding glaucoma above) conducted a retrospective cohort study of seventy-four patients with glaucoma (44 early stage and 30 advanced stage cases) and 66 control subjects to determine possible relationships between the N95 amplitude of PERG (PERGamp) and macular ganglion cell/inner plexiform layer thickness (GCIPLT). Macular GCIPLT was measured using Cirrus spectral domain-optical coherence tomography. Standard automated perimetry and pattern ERGs were used in all patient examinations. Three types of regression analysis (broken stick, linear regression, and quadratic regression) were used to evaluate possible relationships between PERGamp and GCIPLT. Correlations between visual field parameters and GCIPLT were evaluated according to glaucoma severity. The best fit model for the relationship between PERGamp and GCIPLT was the linear regression model ($r^2 = 0.22$; $p < p$ 0.001). The best-fit model for the relationship between visual field parameters and GCIPLT was the broken stick model. During early glaucoma, macular GCIPLT was positively correlated with PERGamp, but not with visual field loss. In advanced glaucoma, macular GCIPLT was positively correlated with both PERGamp and visual field loss. The authors concluded that based on the results of this study, PERGamp is a method to assist clinicians in making an early decision regarding the most suitable treatment plan, especially when GCIPLT is thinning with no change in visual field performance. Study limitations include its retrospective nature, and lack of a standard international reference range for PERG measurements. The clinical utility of this method needs to be confirmed in comparison to other methods.

Jafarzadehpour et al. (2013) evaluated RGC dysfunction in participants with suspicion of glaucoma and patients with early primary open angle glaucoma (POAG) using PERG. Transient PERG was recorded in response to 0.8° and 16° black and white checkerboard stimuli. Amplitude and peak time (latency) of the P50 and N95 components of the PERG response, and the ratio of N95 amplitude in response to 0.8° and 16° checks were measured. Twenty participants with suspicion of glaucoma, 15 early POAG and 16 normal controls were enrolled. N95 peak time (latency) was significantly increased in both early manifest POAG and participants with suspicion of glaucoma as compared to normal controls. In early POAG, N95 amplitude in response to small (0.8°) checks and the small/large check ratio were reduced in comparison to normal eyes. However, in participants with suspicion of glaucoma, no significant N95 amplitude reduction was observed. No significant difference was observed among the study groups in terms of P50 amplitude or peak time. According to the authors, PERG may detect RGC dysfunction (increased latency) before cell death (decreased amplitude) occurs. The design and sample size in this study limits the conclusions that can be drawn from it for the usefulness of PERG as a diagnostic tool.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

The AAO preferred practice pattern for primary open-angle glaucoma (POAG) does not specifically mention ERG as a diagnostic tool.

A 2011 AAO ophthalmic technology assessment, reviewed for updates in 2016, on the assessment of visual function in glaucoma states that other testing that provides objective measures of visual function, including electroretinography have issues that prevent their adoption for glaucoma.

International Society for Clinical Electrophysiology of Vision (ISCEV)

In a 2018 guide to visual electrodiagnostic procedures, updated in 2022, the International Society for Clinical Electrophysiology of Vision (ISCEV) states that the pattern ERG and mfERG may be used to assess the severity of macular dysfunction in the presences of fundus abnormality or detection of dysfunction in occult cases of maculopathy or macular dystrophy. (Robson, et al. 2018)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Electroretinography devices receive FDA 501(k) as Class II medical devices. For specific devices, refer to the following website and search using code GWE: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed September 24, 2024

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Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Applicable Codes** • Added notation to indicate CPT code 0509T is not on the State of North Carolina Medicaid Fee Schedule and therefore may not be covered by the State of North Carolina Medicaid Program **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CSNCT0370.01

Instructions for Use

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