LCD - Electroretinography (ERG) (L37371)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
Novitas Solutions, Inc.	A and B MAC	04111 - MAC A	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04112 - MAC B	J - H	Colorado
Novitas Solutions, Inc.	A and B MAC	04211 - MAC A	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04212 - MAC B	J - H	New Mexico
Novitas Solutions, Inc.	A and B MAC	04311 - MAC A	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04312 - MAC B	J - H	Oklahoma
Novitas Solutions, Inc.	A and B MAC	04411 - MAC A	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04412 - MAC B	J - H	Texas
Novitas Solutions, Inc.	A and B MAC	04911 - MAC A	J - H	Colorado New Mexico Oklahoma Texas
Novitas Solutions, Inc.	A and B MAC	07101 - MAC A	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07102 - MAC B	J - H	Arkansas
Novitas Solutions, Inc.	A and B MAC	07201 - MAC A	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07202 - MAC B	J - H	Louisiana
Novitas Solutions, Inc.	A and B MAC	07301 - MAC A	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	07302 - MAC B	J - H	Mississippi
Novitas Solutions, Inc.	A and B MAC	12101 - MAC A	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12102 - MAC B	J - L	Delaware
Novitas Solutions, Inc.	A and B MAC	12201 - MAC A	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12202 - MAC B	J - L	District of Columbia
Novitas Solutions, Inc.	A and B MAC	12301 - MAC A	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12302 - MAC B	J - L	Maryland
Novitas Solutions, Inc.	A and B MAC	12401 - MAC A	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12402 - MAC B	J - L	New Jersey
Novitas Solutions, Inc.	A and B MAC	12501 - MAC A	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12502 - MAC B	J - L	Pennsylvania
Novitas Solutions, Inc.	A and B MAC	12901 - MAC A	J - L	Delaware

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
				District of Columbia Maryland New Jersey Pennsylvania

LCD Information

Document Information

LCD ID
L37371

LCD Title
Electroretinography (ERG)

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL37371

Original Effective Date
For services performed on or after 01/25/2018

Revision Effective Date
For services performed on or after 11/21/2019

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
12/07/2017

Notice Period End Date
01/24/2018

CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for electroretinography (ERG). Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable

state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for electroretinography (ERG) and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 80 Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1, Part 4, Section 310.1 Routine Costs in Clinical Trials
- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 23, Section 10 Reporting ICD Diagnosis and Procedure codes
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.5.4 Reasonable and Necessary Provisions in LCDs

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

The full field electroretinogram (ERG) is used to detect loss of retinal function or distinguish between retinal and optic nerve lesions. ERG measures the electrical activity generated by neural and non-neuronal cells in the retina in response to a light stimulus. ERGs are usually obtained using electrodes embedded in a corneal contact lens, or a thin wire inside the lower eyelid, which measure a summation of retinal electrical activity at the corneal surface. The International Society for Clinical Electrophysiology of Vision (ISCEV) introduced minimum standards for the ERG in 1989. The ERG helps to distinguish retinal degeneration and dystrophies. The focal or foveal ERG (fERG) is useful in providing information regarding diseases limited to the macula. Multi-focal electroretinography (mfERG) is a higher resolution form of ERG, enabling assessment of ERG activity in small areas of the retina. Pattern ERG (PERG) uses pattern-reversal stimuli and is used to detect subtle optic neuropathies.

ERG in Glaucoma

A 2011 report by the American Academy of Ophthalmology (AAO) on "Assessment of Visual Function in Glaucoma" noted that while ERG, as objective measures of visual function, provided testing free of patient input, issues prevent their adoption for glaucoma management. It concluded that advances in technology have yet to produce definitive guidance on the diagnosis of glaucoma or its progression over time and that further research on an objective measure of visual function is needed.

Since then several studies have investigated the use of ERG technology to differentiate between normal healthy eyes and eyes with early to advanced visual field loss resulting from glaucoma. The authors indicated that ERG may allow earlier diagnosis of glaucoma. However, Novitas has determined that without larger studies, AAO's 2011 conclusion, that ERG's have yet to produce definitive guidance on the diagnosis of glaucoma or its progression over time, remains. This was also the conclusion of a 2013 study which prospectively monitored progressive changes of RGC function in early glaucoma using PERG. The authors concluded that further follow-up is required to determine whether PERG losses are predictors of future visual field loss.

Neither of the 2015 AAO Preferred Practice Guidelines, "Primary Open-Angle Glaucoma Suspect" or "Primary Open-Angle Glaucoma," mention ERG as a diagnostic tool.

There remain no verified guidelines for normal vs. abnormal that would be easily applicable to an individual patient. Novitas, therefore, considers the use of ERG for either glaucoma diagnosis or management investigational.

Covered Indications

1. To diagnose loss of retinal function or distinguish between retinal lesions and optic nerve lesions.
   Note: There are multiple retinal conditions that would be considered covered indications that may not be listed below. For a complete listing of covered diagnoses, please refer to the Local Coverage Article: Billing and Coding: Electroretinography (ERG), A56672 for all billing and coding information.
   - Toxic retinopathies, including those caused by intraocular metallic foreign bodies, Vigabatrin and Chlorpromazine
   - Diabetic retinopathy
   - Retinal vascular disease (e.g., Central Retinal Artery Occlusion [CRAO], Central Retinal Vein Occlusion [CRVO], Branch Vein Occlusion [BVO], and sickle cell retinopathy)
   - Autoimmune retinopathies (e.g., Cancer Associated Retinopathy [CAR], Melanoma Associated Retinopathy [MAR], and Acute Zonal Occult Outer Retinopathy [AZOOR])
   - Retinal detachment
   - Assessment of retinal function after trauma (e.g., vitreous hemorrhage, dense cataracts, and other conditions where the fundus cannot be visualized)
   - Retinitis pigmentosa and related hereditary degenerations
   - Retinitis punctata albescens
   - Leber's congenital amaurosis
   - Choroideremia
   - Gyrate atrophy of the retina and choroid
   - Goldman-Favre syndrome
   - Congenital stationary night blindness
   - X-linked juvenile retinoschisis
   - Achromatopsia
   - Cone dystrophy
   - Disorders mimicking retinitis pigmentosa
   - Usher Syndrome
   - Retinal Dystrophies (e.g., Stargardt's disease, Fundus Flavimaculata, North Carolina macular dystrophy,

Best's Vitelliform dystrophy, Sorsby's macular dystrophy)

2. To detect chloroquine (Aralen) and hydroxychloroquine (Plaquenil) toxicity (mfERG) per AAO guidelines, which does not recommend mfERG for routine primary screening, but can provide objective confirmation of suspected visual loss.

Limitations

The following is considered not reasonable and necessary and therefore will be denied:

1. The use of ERG for glaucoma (either diagnosis or management) is considered experimental and investigational as the available published clinical evidence does not support clinical value. Therefore, the use of ERG, (all forms: ERG, fERG, mfERG, PERG, etc.) for glaucoma is non-covered and will be denied as not reasonable and necessary.

Place of Services (POS)

For additional information on services performed in an Independent Diagnostic Testing Facility (IDTF), please refer to Local Coverage Determination (LCD) L35448 Independent Diagnostic Testing Facility (IDTF) and Local Coverage Article A53252 Independent Diagnostic Testing Facility (IDTF).

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules. Refer to the Local Coverage Article: Billing and Coding: Electroretinography (ERG), A56672, for applicable CPT/HCPCS codes and diagnosis codes.

Provider Qualifications

1. Diagnostic ERG testing must be performed under the general supervision of and interpreted by a qualified physician.

    - Qualified physicians must possess evidence of knowledge, training, and expertise to perform and interpret these tests. This training and expertise must have been acquired within the framework of an accredited school, residency or fellowship program.
    - Please refer to CMS IOM Pub. 100-02, Chapter 15, Section 80 for the definition of General Supervision.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

Summary of Evidence

Please refer to the "History/Background and/or General Information" section for general information on ERG including full field ERG, focal ERG, multi-focal ERG, and pattern ERG.

Multiple sources of literature (Bach et al. [2013]; Barrett et al. [2014]; CK et al. [2011]; Creel; Hood et al. [2012];

Incesu [2013]; International Society for Clinical Electrophysiology of Vision [ISCEV]; Jacobs; John et al. [2009]; Kumar et al.; Maa et al. [2016]; Marmor et al. [2016]; McBain et al. [2007]; McCulloch et al. [2015]; Perlman; Whatham et al. [2014]) were submitted for consideration. These were mostly descriptive of how ERG should be performed, the history of the testing procedures involved with ERG and sources for the "Covered Indications" section.

This is a new LCD for Novitas JH and JL developed as a national MAC LCD workgroup collaboration based on information from data analysis revealing that a significant percentage of the diagnoses reported on ERG claims contained some form of a glaucoma diagnosis. These findings were not consistent with current literature and guideline recommendations for ERG use.

The following is a summary of the evidence for exclusion of glaucoma-related diagnoses for testing by ERG (except glaucomatous optic atrophy):

A) Evidence-Based Guidelines

- The American Academy of Ophthalmology (AAO) Glaucoma Preferred Practice Pattern Panel of 2014-2015 included reviewers from the Ophthalmic Technology Assessment Committee Glaucoma Panel, Practicing Ophthalmologists Advisory Committee for Education and reviewers from the American Academy of Family Physicians, American College of Physicians, American College of Surgeons, American Glaucoma Society, American Ophthalmological Society, American Society of Cataract and Refractive Surgery, Association of University Professors of Ophthalmology, Glaucoma Research Foundation, National Eye Institute, plus multiple other international and national societies. The Preferred Practice Pattern Panel did not include ERG in their diagnostic testing recommendations. The diagnostic tests included by the panel are central corneal thickness (CCT) measurement, visual field evaluation and optic nerve head (ONH) and retinal nerve fiber layer (RNFL) imaging. There are 598 references listed for Primary Open-Angle Glaucoma and 230 references listed for Primary Open-Angle Glaucoma Suspect with ratings based on the Scottish Intercollegiate Guideline Network and the GRADE group within the documents.

- In addition, the American Optometric Association (AOA), in their clinical practice guideline on the care of the patient with open-angle glaucoma (last revised in 2010), did not include ERG in their diagnostic testing recommendations.

- Jampel, et al. conducted a literature review for an ophthalmic technology assessment of visual function in glaucoma, which was published by the AAO in 2011, and concluded that advances in technology (including ERG) have yet to produce definitive guidance in the diagnosis of glaucoma or its progression over time and further research on an objective measure of visual function is needed. Listed were 81 references with a grading system and strength of evidence.

B) Systematic Review

- Lai, et al. (2007) conducted a systematic review for the clinical applications of mfERG. The conclusions were mfERG is not very reliable in the detection and monitoring of functional loss caused by glaucoma, second-order kernel mfERG responses are not very useful in investigating glaucomatous damage, the use of mfERG s-wave in assessing glaucomatous damage remains uncertain, and the sensitivity of mfERG in detecting retinal dysfunction in ocular hypertension (OHT) patients remains questionable. Listed were 329 references with limitations of the studies discussed within the review article.

C) Observational Studies

- Bach, et al. (2006), in a prospective cohort study conducted in Germany, followed 54 subjects with OHT for at least three years (median follow-up of 8.2 years) using PERG and visual field testing at six month intervals. Glaucoma developed in five subjects. The median age of the subjects was 52 years. Pressure-lowering treatment (eye drops, laser, laser + eye drops and trabeculectomy) was received by 82% of the subjects at some point during the study. The study results found that one year before conversion, the receiver-operating characteristic (ROC) area of the PERG ratio was 0.78. At a threshold of 1.06, this corresponded to a sensitivity of 80%, a specificity of 71%, a positive predictive value of 23%, and a negative predictive value of 97%. The study conclusion was PERG can help to predict stability or progression to glaucoma in OHT at least one year prior to conversion.

- Bode, et al. (2011) was a continuation of the Bach, et al. (2006) prospective cohort study in Germany. The study followed 64 subjects with OHT for at least three years (mean of 10.3 years). The median age of the subjects was 60.6 years. The study conclusion was PERG, especially the PERG ratio, detected glaucoma patients four years before visual field changes occurred, with a sensitivity of 75% and specificity of 76%.

    - The quality of evidence for these studies is low due to the small study sizes, problems with interpretation due to the fact that treatment probably distorted the natural course, and the studies were not generalizable to a Medicare population.

- Banitt, et al. (2013), in a prospective cohort study, followed 107 glaucoma suspect subjects for at least four years using PERG, optical coherence tomography (OCT) of the RNFL and standard automated perimetry testing at six month intervals. The mean age of the subjects was 56.1 +/- 10.1 years. A total of 56 subjects received pressure-lowering medications at some point during the study. The study conclusion was PERG signal anticipates an equivalent loss of OCT signal by several years. The quality of evidence for this study is low due to the small study size, shifts in intraocular pressure (IOP) could have led to overestimation or underestimation of PERG loss rates, and the study was not generalizable to a Medicare population.

- Jafarzadehpour, et al. (2013), in a prospective case control study in Iran, tested 20 glaucoma suspects, 15 early primary open angle glaucoma (POAG) and 16 normal control subjects using PERG. Responses were recorded to 0.8 degree and 16 degree black and white checkerboard stimuli. One of the exclusion criteria for the study was age greater than 65 years. The study conclusion was PERG may detect retinal ganglion cell (RGC) dysfunction (increased latency) before cell death (decreased amplitude) occurs. The quality of evidence for this study is low due to the small study size and the study was not generalizable to a Medicare population.

- Nesher and Trick (1991) performed a retrospective analysis on the transient and steady-state PERG recorded from 205 subjects. The subjects were divided into 42 with glaucoma, 13 with senile dementia of Alzheimer's type, 58 with diabetes mellitus (27 without retinopathy and 31 with retinopathy) and 92 control subjects. The mean age of the glaucoma subjects was 56.8 +/- 9.8 years. The analysis found inconsistency in the glaucoma subjects' results when compared to a study by Holder published in 1989. The study conclusion was a recommendation to record the PERG under both transient and steady-state conditions to optimize the clinical utility of the procedure. The quality of evidence for this study is low due to the small study size, the results for the glaucoma patients was inconsistent with a previous study, and the study was not generalizable to a Medicare population.

- Tafreshi, et al. (2010), in a cross-sectional study, performed PERG, standard automated perimetry (SAP), short-wavelength automated perimetry (SWAP), and frequency-doubling technology (FDT) on 42 healthy subjects and 54 glaucoma subjects. The average age of the healthy subjects was 63.6 years and the average age of the glaucoma subjects was 70.4 years. The study conclusions were the diagnostic accuracy of PERG amplitude was similar to SAP and SWAP, but worse than FDT. Also, PERG may hold some advantage over

psychophysical testing because of its largely objective nature. The quality of the evidence is low due to the small study size and the study did not demonstrate an improvement in health outcomes for the Medicare population.

- Ventura, et al. (2005), in a cross-sectional study, performed PERG, SAP, and vertical cup-to-disc ratios (C/D) on 200 glaucoma suspect (GS) subjects, 42 early manifestation glaucoma (EMG) subjects and 114 control subjects. The mean age of the GS and EMG subjects was 57 +/- 13 years. The mean age of the control subjects was 46.4 +/- 18.2 years. The study conclusion was the correlation between PERG abnormality and known risk factors for glaucoma indicates that PERG has a predictive potential for the development or progression of glaucoma, or both. The quality of evidence for this study is low due to the study was not generalizable to a Medicare population.

- Ventura, et al. (2013), in a prospective cohort study, followed 59 glaucoma suspect subjects for 5.7 +/- 1.4 years using PERG and SAP two times per year. The age of the subjects was not reported in the study. None of the subjects received intraocular pressure-lowering medications at any point during the study. The study conclusion was that it remains to be established whether PERG progression has predictive value for developing visual dysfunction. The quality of evidence for this study is low due to the small study size and the study was not generalizable to a Medicare population.

Analysis of Evidence (Rationale for Determination)

The use of ERG to diagnose loss of retinal function or distinguish between retinal lesions and optic nerve lesions is supported in the literature for a wide variety of conditions (e.g. toxic, diabetic and autoimmune retinopathies, retinal vascular disease, retinal detachment and/or trauma, hereditary or congenital retinal diseases).

The quality of evidence for the observational studies for ocular hypertension, glaucoma suspect and glaucoma is low due to the small study sizes, the studies were not generalizable to a Medicare population, and the studies did not demonstrate an improvement in health outcomes for the Medicare population. Evidence based guidelines from the American Academy of Ophthalmology (AAO) and the American Optometric Association (AOA) did not support the use of ERG for these conditions. Based on the weak strength of study evidence and the absence of sound data to support the clinical utility of ERG for ocular hypertension, glaucoma suspect, or glaucoma, there is little evidence to support the use of ERG in the Medicare population for these conditions.

Note: This analysis used the American College of Physicians (ACP) Guideline Grading System as the basis for grading the quality of evidence and analyzing the evidence.

General Information

Associated Information

Refer to the Local Coverage Article: Billing and Coding: Electroretinography (ERG), A56672, for all coding information.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g.,

complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record documentation must support the medical necessity of the services as stated in this policy.
5. The medical record must include the test results. Documentation should also reflect how the test results were used in the patient's plan of care.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Sources of Information

Contractor is not responsible for the continued viability of websites listed.

Other Contractor's Policies

Noridian Draft LCD Visual Electrophysiology Testing (DL37114 and DL37116).

National Government Services Draft LCD Visual Electrophysiology Testing (DL36831).

National Government Services LCD Visual Electrophysiology Testing (L36831).

Wisconsin Physicians Service Insurance Corporation Draft LCD Visual Electrophysiology Testing (DL37015).

Contractor Medical Directors

Bibliography

1. Aetna policy #0854 Electroretinography. Effective 07/19/2013, Last Reviewed 12/14/2016. Last accessed 03/08/2017. http://www.aetna.com/cpb/medical/data/800_899/0854.html
2. Amarasekera DC, Resende AF, Waisbourd M, et al. Steady-state pattern electroretinogram and short-duration transient visual evoked potentials in glaucomatous and healthy eyes. 2017 Royal Australian and New Zealand College of Ophthalmologists. *Clin Exp Ophthalmol*. 2018 Jan;46(1):54-61.
3. American Academy of Ophthalmology (AAO), Glaucoma Panel. Primary Open-Angle Glaucoma. Preferred Practice Pattern. San Francisco, CA: AAO; 2015. Accessed 03/08/2017 http://www.aaojournal.org/article/S0161-6420(15)01276-2/pdf.
4. American Academy of Ophthalmology (AAO), Glaucoma Panel. Primary Open-Angle Glaucoma Suspect.

Preferred Practice Pattern. San Francisco, CA: AAO; 2015. Accessed 03/08/2017 http://www.aaojournal.org/article/S0161-6420(15)01278-6/pdf.
5. American Academy of Ophthalmology (AAO). Glaucoma Summary Benchmarks for Preferred Practice Pattern Guidelines. 2017 Nov. Accessed 04/18/2017 at https://www.aao.org/summary-benchmark-detail/glaucoma-summary-benchmarks-2017
6. American Optometric Association (AOA), Optometric Clinical Practice Guideline. Care of the Patient with Open Angle Glaucoma. St. Louis, MO: revised 2010.
7. American Optometric Association (AOA), Optometric Clinical Practice Guideline. Care of the Patient with Primary Angle Closure Glaucoma. St. Louis, MO: revised 1998.
8. Bach M, Brigell MG, Hawlina M, et al. ISCEV standard for clinical pattern electroretinography (PERG): 2012 update. *Doc Ophthalmol*. 2013 Feb;126(1):1-7.
9. Bach M, Hoffmann MB. Update on the pattern electroretinogram in glaucoma. *Optom* Vis Sci. 2008 Jun;85(6):386-95.
10. Bach M, Unsoeld AS, Philippin H, et al. Pattern ERG as an early glaucoma indicator in ocular hypertension: a long-term, prospective study. *Invest Ophthalmol Vis Sci*. 2006 Nov;47(11):4881-7.
11. Banitt MR, Ventura LM, Feuer WJ, et al. Progressive Loss of Retinal Ganglion Cell Function Precedes Structural Loss by Several Years in Glaucoma Suspects. *Invest Ophthalmol Vis Sci*. 2013 Mar;54(3):2346-2352.
12. Barrett D, Yang J, Sujirakul T, et al. Vigabatrin Retinal Toxicity First Detected with Electroretinographic Changes: A Case Report. *J Clin Exp Ophthalmol*. 2014; 5(5): 1000363.
13. BCBS FL policy # 01-92000-28 Electroretinography. Effective 05/15/2015, Revised 10/01/2016. Last accessed 03/08/2017. http://mcgs.bcbsfl.com/?doc=Electroretinography
14. Bode SF, Jehle T, Bach M. Pattern electroretinogram in glaucoma suspects: new findings from a longitudinal study. *Invest Ophthalmol Vis Sci*. 2011 Jun 16;52(7):4300-6.
15. Bourne RRA. Ethnicity and ocular imaging. *Eye* (Lond). 2011 Mar;25(3):297-300.doi:10.1038/eye.2010.187.
16. Celesia GG, Kaufman D. Pattern ERGs and visual evoked potentials in maculopathies and optic nerve diseases. *Invest Ophthalmol Vis Sci*. 1985 May;26(5):726-35.
17. Chang EE, Goldberg JL. Glaucoma 2.0:neuroprotection, neuroregeneration, neuroenhancement. *Ophthalmology* . 2012 May;119(5):979-86. dio:10.1016/j.ophtha.2011.11.003.
18. CK. M, Cherian T, Chacko E. Electro Retinogram Basics and Major Clinical Applications. *Kerala Journal of Opthalmology*. 2011; XXIII (3) 258-263.
19. Colotto A, Salgarello T, Giudiceandrea A, et al. Pattern electroretinogram in treated ocular hypertension: a cross-sectional study after timolol maleate therapy. *Ophthalmic Res*. 1995;27(3):168-77.
20. Creel DJ. The Electroretinogram and Electro-oculogram: Clinical Applications. Webvision at University of Utah: The Organization of the Retina and Visual System. Last accessed 03/24/2017. http://webvision.med.utah.edu/book/electrophysiology/the-electroretinogram-clinical-applications/
21. Deak K, Fejes I, Janaky M, et al. Further Evidence for the Utility of Electrophysiological Methods for the Detection of Subclinical Stage Retinal and Optic Nerve Involvement in Diabetes. *Med Princ Pract*. 2016;25(3):282-5.
22. Guadilla AM, Zaragoza P, Zaro MA, Orduna-Azcona J. Pattern Electroretinogram and Ganglionar Cells Suffering in Ocular Hypertensive Patients. *JSM Ophthalmol*. 2016;4(2):1045.
23. Holder GE. Pattern electroretinography in patients with delayed pattern visual evoked potentials due to distal anterior visual pathway dysfunction. *J Neurol Neurosurg Psychiatry*. 1989 Dec; 52(12): 1364–1368.
24. Holder GE. The pattern electroretinogram in anterior visual pathway dysfunction and its relationship to the pattern visual evoked potential: a personal clinical review of 743 eyes. *Eye* (Lond). 1997;11 (Pt 6):924-34.
25. Hood DC, Bach M, Brigell M, et al. ISCEV standard for clinical multifocal electroretinography (mfERG) (2011 edition). *Doc Ophthalmol*. 2012 Feb;124(1):1-13.
26. Hull BM, Thompson DA. A review of the clinical applications of the pattern electroretinogram. *Ophthalmic Physiol Opt*. 1989 Apr;9(2):143-52.
27. Incesu AI. Tests for malingering in ophthalmology. *Int J Ophthalmol*. 2013;6(5):708-717.
28. International Society for Clinical Electrophysiology of Vision (ISCEV): Visual Electrodiagnostics A Guide To Procedures. Last accessed 04/02/2017. http://www.iscev.org/standards/proceduresguide.html
29. Jacobs DS. Open-angle glaucoma: Epidemiology, clinical presentation, and diagnosis. UpToDate Inc., Waltham,

MA. Last accessed 03/08/2017. http://www.uptodate.com/contents/open-angle-glaucoma-epidemiology-clinical-presentation-and-diagnosis
30. Jafarzadehpour E, Radinmehr F, Pakravan M, et al. Pattern Electroretinography in Glaucoma Suspects and Early Primary Open Angle Glaucoma. *J Ophthalmic Vis Res*. 2013;8(3):199-206.
31. Jampel HD, Singh K, Lin SC, et al. Assessment of visual function in glaucoma: A report by the American Academy of Ophthalmology. *Ophthalmology*. 2011;118(5):986-1002.
32. John DA, Moroi SE, Stein JD. Management of Intraocular Foreign Bodies. American Academy of Ophthalmology. *EyeNet Magazine*. September 2009. Retrieved on September 20, 2017 at: https://www.aao.org/eyenet/article/management-of-intraocular-foreign-bodies
33. Karaskiewicz J, Penkala K, Mularczyk M, Lubinski W . Evaluation of retinal ganglion cell function after intraocular pressure reduction measured by pattern electroretinogram in patients with primary open-angle glaucoma. *Doc Ophthalmol*. 2017 Apr;134(2):89-97. doi: 10.1007/s10633-017-9575-0.
34. Kass MA, Heuer DK, Higginbotham EJ, et al. The Ocular Hypertension Treatment Study: a randomized trial determines that topical ocular hypotensive medication delays or prevents the onset of primary open-angle glaucoma. *Arch Ophthalmol*. 2002 Jun;120(6):701-13.
35. Kumar UR, Ramkumar HL, Epley D, et al. Electroretinogram. American Academy of Ophthalmology EyeWiki ®. Last accessed on 03/27/2017 at http://eyewiki.aao.org/Electroretinogram
36. Lai TY, Chan WM, Lai RY, et al. The clinical applications of multifocal electroretinography: a systematic review. *Surv Ophthalmol*. 2007 Jan-Feb;52(1):61-96.
37. Maa AY, Feuer WJ, Davis CQ, et al. A novel device for accurate and efficient testing for vision-threatening diabetic retinopathy. *J Diabetes Complications*. 2016 Apr;30(3):524-32.
38. Marmor MF, Holder GE, Porciatti V, Trick GL, Zrenner E . Guidelines for basic pattern electroretinography. Recommendations by the International Society for Clinical Electrophysiology of Vision. *Doc Ophthalmol*. 1995-1996;91(4):291-8.
39. Marmor MF, Kellner U, Lai TY, et al. American Academy of Ophthalmology. Recommendations on screening for Chloroquine and Hydroxychloroquine retinopathy (2016 Revision). *Ophthalmology*. 2016 Jun;123(6):1386-1394.
40. McBain VA, Egan CA, Pieris SJ, et al. Functional observations in vitamin A deficiency: diagnosis and time course of recovery. *Eye.* 2007 Mar;21(3):367-376.
41. McCulloch DL, Marmor MF, Brigell MG et al. ISCEV Standard for full-field clinical electroretinography (2015 update). *Doc Ophthalmol*. 2015 Feb;130(1):1-12.
42. Messenio D, Marano G, Biganzoli E. Electrophysiological evaluation in normal-tension glaucoma suspects: a pilot study. *Journal for Modeling in Ophthalmology*. 2016; 3:9-30.
43. Michelessi M, Lucenteforte E, Oddone F, et al. Optic nerve head and fibre layer imaging for diagnosing glaucoma. *Cochrane Database Syst Rev*. 2015 Nov 30;(11):CD008803.
44. Michelessi M, Lucenteforte E, Oddone F, et al . Tests for imaging the optic nerve and its fibres for diagnosing glaucoma. *Cochrane Library*. 2015. https:Jtwww.cochrane.org/CD008803/EYES_tests-imaging-optic-nerve-and-its-fibres-<diagnosinglaucoma.
45. Moschos MM, Gouliopoulos NS, Kalogeropoulos C. Electrophysiological examination in uveitis: a review of the literature. *Clin Ophthalmol*. 2014;8:199-214. doi: 10.2147/OPTH.S54838.
46. Neoh C, Kaye SB, Brown M, et al. Pattern electroretinogram and automated perimetry in patients with glaucoma and ocular hypertension. *Br J Ophthalmol*. 1994 May; 78(5): 359–362.
47. Neubauer AS, Stiefelmeyer S, Berninger T, et al. The multifocal pattern electroretinogram in chloroquine retinopathy. *Ophthalmic Res*. 2004 Mar-Apr;36(2):106-13.
48. Nesher R, Trick GL. The pattern electroretinogram in retinal and optic nerve disease. A quantitative comparison of the pattern of visual dysfunction. *Doc Ophthalmol*. 1991;77(3):225-35.
49. Nesher R, Trick GL, Kass MA, et al. Steady-state pattern electroretinogram following long term unilateral administration of timolol to ocular hypertensive subjects. *Doc Ophthalmol*. 1990;75: 101.
50. Parisi V, Centofanti M, Ziccardi L, et al . Treatment with citicoline eye drops enhances retinal function and neural conduction along the visual pathways in open angle glaucoma. *Graefes Arch Clin Exp Ophthalmol*. 2015 Aug;253(8):1327-40. doi: 10.1007/s00417-015-3044-9.
51. Parisi V, Uccioli L, Parisi L, et al. Neural conduction in visual pathways in newly-diagnosed IDDM patients.

Electroencephalogr Clin Neurophysiol. 1998 Sep;108(5):490-6.
52. Park K, Kim J, Lee J. Measurement of macular structure-function relationships using spectral domain-optical coherence tomography (SD-OCT) and pattern electroretinograms (PERG). *PLoS One*. 2017 May 17;12(5):e0178004. doi: 10.1371/journal.pone.0178004.
53. Patangay S, Derafshi Z, Vajaranant TS, et al. Three Dimensional Stimulus Source for Pattern Electroretinography in Mid- and Far-peripheral Retina. *Transl Vis Sci Technol*. 2018 Jan 19;7(1):8.
54. Perlman I. The Electroretinogram: ERG. Webvision at University of Utah: The Organization of the Retina and Visual System. Last accessed 03/24/2017. http://webvision.med.utah.edu/book/electrophysiology/the-electroretinogram-erg/
55. Pfeiffer N, Tillman B, Bach M. Predictive Value of the Pattern Electroretinogram in High-Risk Ocular Hypertension. *Investigative Ophthalmology & Visual Science*. 1993 Apr; 34(5):1710-15.
56. Pilat AV, Gottlob I, Sheth V, Thomas MG, Proudlock FA . Gender- and Ethnicity-Related Differences in Optic Nerve Head Topography in Healthy Indian and Caucasian Participants. *Neuroophthalmology*. 2014 Jul 22;38(4):205-212.
57. Porciatti V, Ventura LM. The PERG as a Tool for Early Detection and Monitoring of Glaucoma. *Curr Ophthalmol Rep*. 2017 Mar;5(1):7-13.
58. Price MJ, Drance SM, Price M, et al. The pattern electroretinogram and visual-evoked potential in glaucoma. *Graefes Arch Clin Exp Ophthalmol*. 1988;226(6):542-7.
59. Rimmer S, Katz B. The Pattern Electroretinogram: Technical Aspects and Clinical Significance. *Journal of Clinical Neurophysiology*.1989;6(1):85-99.
60. Robson AG, Nilsson J, Li S, et al . ISCEV guide to visual electrodiagnostic procedures. *Doc Ophthalmol*. 2018 Feb;136(1):1-26. doi: 10.1007/s10633-017-9621-y.
61. Salgarello T, Colotto A, Falsini B, et al. Correlation of pattern electroretinogram with optic disc cup shape in ocular hypertension. *Invest Ophthalmol Vis Sci*. 1999 Aug;40(9):1989-97.
62. Salgarello T, Falsini B, Stifano G, et al. Morpho-functional follow-up of the optic nerve in treated ocular hypertension: disc morphometry and steady-state pattern electroretinogram. *Curr Eye Res*. 2008 Aug;33(8):709-21.
63. Sutter EE, Bearse MA Jr. The optic nerve head component of the human ERG. *Vision Res*. 1999 Feb;39(3):419-36.
64. Tafreshi A, Racette L, Weinreb RN, et al. Pattern Electroretinogram and Psychophysical Tests of Visual Function for Discriminating Between Healthy and Glaucoma Eyes. *Am J Ophthalmol*. 2010 Mar; 149(3): 488–495.
65. Tiryaki Demir S, Oba ME, Erdogan ET, et al. Comparison of Pattern Electroretinography and Optical Coherence Tomography Parameters in Patients with Primary Open-Angle Glaucoma and Ocular Hypertension. *Turk J Ophthalmol*. 2015 Dec;45(6):229-234.
66. Varma R, Lee PP, Goldberg I, et al. An assessment of the health and economic burdens of glaucoma. *Am J Ophthalmol*. 2011 Oct;152(4):515-22.
67. Ventura LM, Feurer WJ, and Porciatti V. Progressive loss of retinal ganglion cell function is hindered with IOP-lowering treatment in early glaucoma. *Invest Ophthalmol Vis Sci*. 2012 Feb 13;53(2):659-63.
68. Ventura LM, Golubev I, Feuer WJ, et al. Pattern Electroretinogram Progression in Glaucoma Suspects. *J Glaucoma*. 2013;22(3):219–225.
69. Ventura LM, Porciatti V. Pattern electroretinogram in glaucoma. *Curr Opin Ophthalmol*. 2006 Apr;17(2):196-202.
70. Ventura LM, Porciatti V. Restoration of retinal ganglion cell function in early glaucoma after intraocular pressure reduction: a pilot study. *Ophthalmology*. 2005 Jan;112(1):20-7.
71. Ventura LM, Porciatti V, Ishida K, et al. Pattern Electroretinogram Abnormality and Glaucoma. *Ophthalmology*. 2005 Jan; 112(1): 10–19.
72. Ventura LM, Venzara FX, and Porciatti V. Reversible dysfunction of retinal ganglion cells in non-secreting pituitary tumors. *Doc Ophthalmol*. 2009 Apr;118(2):155-62.
73. Vesti E, Trick GL. Diabetes can alter the interpretation of visual dysfunction in ocular hypertension. *Ophthalmology*. 1996 Sep;103(9):1419-25.
74. Whatham AR, Nguyen V, Zhu Y, et al. The value of clinical electrophysiology in the assessment of the eye and visual system in the era of advanced imaging. *Clin Exp Optom*. 2014 Mar;97(2):99-115.

75. Wilsey LJ, Fortune B. Electroretinography in glaucoma diagnosis. *Curr Opin Ophthalmol*. 2016 Mar;27(2):118-24.
76. Wright TM, Goharian I, Gardiner SK, Sehi M, Greenfield DS . Short-term enhancement of visual field sensitivity in glaucomatous eyes following surgical intraocular pressure reduction. *Am J Ophthalmol*. 2015 Feb;159(2):378-85.e1. doi: 10.1016/j.ajo.2014.11.012.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
11/21/2019	R4	LCD revised and published on 11/21/2019. Consistent with CMS Change Request 10901, the LCD has been revised to remove the entire coding section.	• Other (CMS Change Request 10901)
07/11/2019	R3	LCD revised and published on 07/11/2019. Consistent with Change Request (CR) 10901 all CPT and ICD-10 codes and language have been removed from the LCD and placed in the related Billing and Coding Article, A56672; IOM references added to policy as appropriate. IOM citation section updated to remove CMS IOM Publication 100-04, *Medicare Claims Processing Manual*, Chapter 23, Section 20.9 National Correct Coding Initiative (NCCI). Standard LCD formatting changes made throughout the LCD. There has been no change to coverage in this policy with this revision.	• Other (Change in LCD process per CR 10901)
01/01/2019	R2	LCD revised and published on 02/14/2019 effective for dates of service on and after 01/01/2019 to reflect the annual CPT/HCPCS code updates. The following CPT/HCPCS code(s) have been added to the Group 1 codes: 92273, 92274, and 0509T. The following CPT/HCPCS code(s) have been deleted and therefore removed from the LCD: 92275. A reconsideration request was received on 11/08/2018 to add the following diagnoses for coverage: H40.0 Glaucoma Suspects, H18 Corneal Thinning, H53 Visual Disturbances, H35 Retinal Disorders, H47 Optic Nerve Disorders, and R94 Abnormal Function Studies. The content of the LCD has not been changed in response to this reconsideration request. Multiple sources were submitted with the request and have been added to the bibliography section of the LCD. CMS IOM language has been removed from the body of the LCD (reference CR 10901). Updates have been made to the IOM Citation references in the CMS National Coverage Policy section.	• Revisions Due To CPT/HCPCS Code Changes • Reconsideration Request • Other (Clarification)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
05/10/2018	R1	LCD revised and published on 05/10/2018. Non-coverage reaffirmed and several sources added from a reconsideration request for consideration of PERG as covered diagnostic test for glaucoma (ICD-10 codes H40-H42). The coverage content of the LCD has not been changed in response to the reconsideration request. Additional revision includes update to the SSA references in the "CMS National Coverage Policy" section. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; therefore, not all the fields included on the LCD are applicable as noted in this policy.	• Reconsideration Request

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A56672 - Billing and Coding: Electroretinography (ERG)

A53252 - Billing and Coding: Independent Diagnostic Testing Facility (IDTF)

A55809 - Response to Comments: Electroretinography (ERG)

LCDs

DL37371 - (MCD Archive Site)

L35448 - Independent Diagnostic Testing Facility (IDTF)

Related National Coverage Documents

NCDs

310.1 - Routine Costs in Clinical Trials

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
11/15/2019	11/21/2019 - N/A	Currently in Effect (This Version)
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A