Local Coverage Determination (LCD): Electroretinography (ERG) (L37398)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
First Coast Service Options, Inc.	A and B MAC	09101 - MAC A	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09102 - MAC B	J - N	Florida
First Coast Service Options, Inc.	A and B MAC	09201 - MAC A	J - N	Puerto Rico Virgin Islands
First Coast Service Options, Inc.	A and B MAC	09202 - MAC B	J - N	Puerto Rico
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LCD Information

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N/A

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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.

Internet Only Manual (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 and Section 20.9 National Correct Coding Initiative (CCI)
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

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.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(D) states that no Medicare payment may be made for any expenses incurred for items or services that are investigational or experimental.

Federal Register References:

- Code of Federal Regulations (CFR), Title 42, Volume 2, Chapter IV, Part 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions and Part 410.33 Independent diagnostic testing facility.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

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. 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) to assess retinal ganglion cell (RGC) function in glaucoma is being investigated.

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, First Coast Service Options, Inc. 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.

First Coast Service Option's Inc., 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 "ICD-10 Codes that Support Medical Necessity" section of the LCD.

- 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:

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, mfERG, PERG, etc.) for glaucoma is non-covered and will be denied as not reasonable and necessary.

There could be rare retinal conditions that with supporting documentation could be considered for coverage on appeal.

As published in the CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.5.4, an item or service may be covered by a contractor LCD if it is reasonable and necessary under the Social Security Act Section 1862 (a)(1)(A). Contractors shall determine and describe the circumstances under which the item or service is considered reasonable and necessary.

Provider Qualifications

Diagnostic ERG testing must be performed under the general supervision of and interpreted by a qualified physician as follows:

- **General Supervision -** means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under General Supervision, the training of the non-physician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the 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.

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 (mfERG), and pattern ERG (PERG).

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 of the LCD.

This is a new LCD for First Coast Service Options JN 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 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) <u>Evidence-Based Guidelines</u>

- 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 (Holder GE. Pattern electroretinography in patients with delayed pattern visual evoked potentials due to distal anterior visual pathway dysfunction. J Neurol Neurosurg Psychiatry 1989; 52: 1364-68.). 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 subjects 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.

* 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

Documentation Requirements

Please refer to the Local Coverage Article: Billing and Coding: Electroretinography (ERG) (A57677) for documentation requirements that apply to the reasonable and necessary provisions outlined in this LCD.

Utilization Guidelines

Please refer to the Local Coverage Article: Billing and Coding: Electroretinography (ERG) (A57677) for utilization guidelines that apply to the reasonable and necessary provisions outlined in this LCD.

Sources of Information

N/A

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

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Other Contractor's Policies

National Government Services Draft LCD Visual Electrophysiology Testing (DL36831)

National Government Services LCD Visual Electrophysiology Testing (L36831)

Noridian Draft LCD Visual Electrophysiology Testing (DL37114 and DL37116)

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

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
11/28/2019	R5	Revision Number 5 Publication November 2019 Connection LCR AB2019-075 Explanation of Revision: Based on Change Request (CR) 10901, the LCD was revised to remove all billing and coding and all language not related to reasonable and necessary provisions ("Bill Type Codes," "Revenue Codes," "CPT/HCPCS Codes," "ICD-10 Codes that Support Medical Necessity," "Documentation Requirements" and "Utilization Guidelines" sections of the LCD) and place them into a newly created billing and coding article. During the process of moving the ICD-10-CM diagnosis codes to the billing and coding article, the ICD-10-CM diagnosis code ranges were broken out and listed individually. In addition, the Social Security Act, Code of Federal Regulations, and IOM reference sections were updated. The effective date of this revision is for claims processed on or after January 8, 2019, for dates of service on or after October 3, 2018. 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 and therefore not all the fields included on the LCD are applicable as noted in this LCD.	• Other (Revision based on CR10901)
02/19/2019	R4	Revision Number: 4 Publication: March 2019 Connection LCR A/B2019-024 Explanation of Revision: Based on a Change Request 10951, the LCD was revised to update the IOM Citation in the "CMS National Coverage Policy" section of the LCD. CMS IOM Publication 100-09, Chapter 5 was removed and CMS IOM Publication 100-04, Chapter 23, Section 20.9 was added. The effective date of this revision is for claims processed on or after 02/19/2019, for dates of service on and after 12/11/2018.	• Other (Revisions based on Change Request 10951)
01/29/2019	R3	Revision Number: 3	• Other (Revisions based on review)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Publication: February 2019 Connection LCR A/B2019-016 Explanation of Revision: Based on review of the LCD, grammatical errors were corrected. The effective date of this revision is based on process date. Also, based on CR 10901, the "CMS National Coverage Policy" and "Coverage Indications, Limitations, and/or Medical Necessity" sections of the LCD were revised to update the section number for Pub. 100-08, Chapter 13 from 13.5.1 to 13.5.4. The effective date of this revision is for claims processed on or after 01/08/2019, for dates of service on or after 09/26/2018.	
01/01/2019	R2	Revision Number: 2 Publication: December 2018 Connection LCR A/B2019-001 Explanation of Revision: Annual 2019 HCPCS Update. Deleted CPT code 92275. Added CPT codes 99273, 99274, and 0509T. The effective date of this revision is based on date of service.	• Revisions Due To CPT/HCPCS Code Changes
08/07/2018	R1	Revision Number: 1 Publication: August 2018 Connection LCR A/B2018-067 Explanation of Revision: The "Bibliography" section of the LCD was updated to include multiple published sources from a reconsideration request. The content of the LCD has not been changed in response to the reconsideration request. The effective date of this revision is based on date of service.	• Reconsideration Request

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)
A57677 - Billing and Coding: Electroretinography (ERG)
A55827 - Response to Comments: Electroretinography ERG (L37398): Medicare Part A/B local coverage determination (LCD) comment summary

Related National Coverage Documents

N/A

Public Version(s)

Updated on 11/21/2019 with effective dates 11/28/2019 - N/A
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Keywords

- ERG
- Electroretinography