Policy Number	**OTH903.033**
Policy Effective Date	**03/15/2025**
Policy End Date	**12/31/2025**

Visual Evoked Potential Testing for Glaucoma

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Visual evoked potential testing for glaucoma **is considered experimental, investigational and/or unproven**.

NOTE 1: This policy does not address the following:

- Diagnosis/monitoring of multiple sclerosis;
- Evaluation of visual loss in patients who are unable to communicate;
- Localizing the cause of a visual defect not explained by computed tomography, magnetic resonance imaging, metabolic disorders, or infectious disease; or
- Routine screening of infants.

Policy Guidelines

None.

Description

Visual evoked potential (VEP) is a measurement of the electrical signal recorded at the scalp of the occipital cortex of the brain in response to visual light stimulus (e.g., checkerboard pattern, horizontal grating, vertical grating, flashes, monochromatic pattern onset, or color pattern). The light-evoked signal, small in wave peaks and hidden within the normal electroencephalogram (EEG) signal, is enlarged by repetitive stimulation and time-locked. When the response is delayed, the interpretation is that there are possible mechanical or neural abnormalities.

Background
Glaucoma is a group of eye diseases which result in damage to the optic nerve and vision loss. The most common type is open-angle glaucoma with less common types including closed-angle glaucoma and normal-tension glaucoma. Open-angle glaucoma develops slowly over time and there is no pain. Side vision may begin to decrease followed by central vision resulting in blindness if not treated. Closed-angle glaucoma can present gradually or suddenly. The sudden presentation may involve severe eye pain, blurred vision, mid-dilated pupil, redness of the eye, and nausea. Vision loss from glaucoma, once it has occurred, is permanent.

Risk factors for glaucoma include increased pressure in the eye (intraocular pressure [IOP]), a family history of the condition, migraines, high blood pressure, and obesity. Diagnosis is made by a dilated eye examination. Often, the optic nerve shows an abnormal amount of cupping. If treated early, it is possible to slow or stop the progression of disease with medication, laser treatment, or surgery.

It is estimated that 57.5 million people worldwide are affected by primary open-angle glaucoma (POAG) (1). The disease affects about 3 million people in the U.S. People over 60 years of age, family members of those already diagnosed with glaucoma, steroid users, diabetics, as well as those with high myopia, hypertension, central cornea thickness of <5 mm, and eye injury are at an increased risk of glaucoma. By 2040, it is expected that approximately 111.8 million people will suffer from glaucoma. Glaucoma is the leading cause of irreversible blindness worldwide and is associated with a reduced quality of life.

VEP testing for glaucoma is done to detect if the increased IOP has slowed/prolonged the response time from the visual stimulus to recording in the occipital cortex and may indicate damage to the optic nerve.

The stimuli are presented to the patient on a calibrated computer monitor at various numbers of elements in separately stimulated fields. The fields are varied in spatial size over several cycles. The fields are also phase reversed at different temporal frequencies. The signals are analyzed by the software algorithm for spatial/temporal filtering and artifact rejection. Data

may be presented in numerical and graphical form. The device also utilizes attention grabbing features specifically for children or non-attentive adults. In particular, a picture is presented prior to the onset of the VEP pattern stimulus. During the picture presentation, no data is collected. Age-appropriate music is also available to patient as needed as an attention facilitator. There are 2 devices available for infants and adults, with the only difference between the devices being their software. VEP testing is done in the clinic or office setting.

Regulatory Status

Several VEP systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The Diopsys™ NOVA VEP Vision Testing System (Diopsys, Inc., Pine Brook, NJ) received FDA approval on October 10, 2010. (2) The NOVA VEP device is substantially equivalent to the Diopsys™ Enfant® Pediatric VEP Vision Testing System and the VeriSci Corporation Neucodia® System, based on safety and efficacy. The NOVO VEP device is targeted for infants, pre-school children, children, and adults. Please refer to the FDA website for the most recent list of approved devices. FDA product code: GWE.

Rationale

Clinical Trials

One small prospective study, published in 2013 by Pillai et al., was carried out at the New York Eye and Ear Infirmary. (3) The study was industry sponsored to evaluate the ability of the short-duration transient visual evoked potential (SD-tVEP) and to discriminate between healthy eyes and eyes with early to advanced glaucomatous visual field loss. The control group included 30 eyes of 30 healthy individuals and 45 eyes of 35 glaucoma patients. SD-tVEPs were recorded using the Diopsys™ NOVA system. Each eye was stimulated with a low (Lc) and a high (Hc) Michelson contrast checkerboard pattern. Each test resulted in a Lc and an Hc SD-tVEP response. Each response was evaluated for overall waveform quality, P100 latency, and P100 amplitude referenced to the N75. The sensitivity, specificity, negative predictor value (NPV), and positive predictor value (PPV) were calculated. Lc latency showed the highest accuracy for discrimination using receiver operating characteristic curves for high and low contrast parameters. The analysis for all subjects resulted in a 91.1% sensitivity, 93.3% specificity, 95.3% PPV, and an 87.5% NPV. Evaluating the mean Lc latency of the mild, moderate, and severe glaucoma patients against controls showed discrimination consistent with the glaucoma severity. The authors concluded SD-tVEP objectively identified decreased visual function and discriminated between healthy and glaucomatous eyes and showed good differentiation between healthy eyes and those with early visual field loss. VEP may be useful for early diagnosis of glaucoma.

A 2017 trial, published by Chen and Zhao, compared diagnostic performance of isolated-check visual evoked potential (icVEP) and standard automated perimetry (SAP), for evaluating the application values of icVEP in the detection of early glaucoma. (4) For the 144 subjects (288 eyes), the visual fields were deemed as abnormal if the glaucoma hemifield test results are outside normal limits; or the pattern standard deviation with $P<0.05$; or the cluster of 3 or more

non-edge points on the pattern deviation plot in a single hemifield with P<0.05, one of which must have a P<0.01. When the disc photograph grader was used as diagnostic standard, the sensitivity for SAP and icVEP was 32.3% and 38.5% respectively and specificity was 82.3% and 77.8% respectively. When the MRA Classifier was used as the diagnostic standard, the sensitivity for SAP and icVEP was 48.6% and 51.4% respectively and specificity was 84.1% and 78.0% respectively. When the combined structural assessment was used as the diagnostic standard, the sensitivity for SAP and icVEP was 59.2% and 53.1% respectively and specificity was 84.2% and 84.6% respectively. There was no statistical significance between the sensitivity or specificity of SAP and icVEP, regardless of which diagnostic standard was based on. Therefore, the study authors concluded that the diagnostic performance of icVEP is not better than that of SAP in the detection of early glaucoma.

Wang et al. (2020) performed a cross-sectional study by using a new device to assess the icVEP for primary open angle glaucoma (POAG) patients with highly myopia and non-highly myopia and compared the diagnostic efficacy of the signal to noise (SNR) from icVEP with those of parameters assessed by optical coherence tomography (OCT) and Heidelberg retinal tomography (HRT). (5) A total of 126 participants were recruited, including 31 highly myopic participants with primary open angle glaucoma (HM-POAG), 36 non-highly myopic participants with POAG (NHM-POAG), 25 highly myopic participants without POAG (HM) and 34 controls without high myopia (Normal). The signal-to-noise ratio (SNR) was used to assess the icVEP. Both qualitative and quantitative diagnostic performances of OCT, HRT and the icVEP were analyzed and compared. Based on the measure of SNR ≤ 1, the diagnostic performance of the icVEP in highly myopic subjects was better than that in non-highly myopic subjects. In distinguishing the HM-POAG and highly myopic groups, the AUC of the SNR was not different from those of the optical coherence tomography and HRT parameters (P > 0.05) in either the qualitative or quantitative comparison. In the qualitative analysis, the icVEP showed good consistency with damage to the central 10° of the visual field (kappa=0.695-0.747, P<0.001). The icVEP has the potential to single out individuals with and without POAG, especially in patients with high myopia. Limitations included a small sample size and the fact it was a cross-sectional study. Also, the icVEP device has been intended to reduce interference but the signal may still be affected by noise. Larger studies are needed to confirm these potential findings.

Technology Review

A review by Tai (2018) explained the following: “Pattern VEP has shown good specificity and sensitivity in the detection of glaucoma in some studies, but other studies have not shown similar efficacy. (6) Multifocal VEP can produce a topographical measure of glaucomatous damage and has been shown to be able to detect a similar number of defects in patients with glaucoma or ocular hypertension as compared with the visual field test. Despite promising data on these VEP test modalities in the assessment of glaucoma, multiple aspects of test administration make their routine use impractical in a clinical setting. New VEP testing modalities, such as short-duration transient VEP and isolated-check VEP, allow the test to be performed more quickly and easily. Further research on these more recent technologies may allow us to use VEP effectively in the diagnosis and management of glaucoma.”

ECRI

ECRI reported on a 2019 systematic review from Senger et al. which evaluated studies using electrophysiologic testing to assess retinal ganglion cells (RGC) function in patients with glaucoma. (7) Among the 30 studies selected, the photopic negative response (PhNR) and the reversal pattern electroretinogram (PERG) were found to be the major methods used to record the electroretinographic responses generated by the RGC. Their multifocal versions and the multifocal visual evoked potential (mfVEP) were also proposed during this period. The study conclusions stated that: "In agreement with previous reviews, clinical electrophysiological testing of the visual system reasonably matched with both the structural and functional analyses for glaucoma. No definitive indications of these tests have been established either at early detection or during follow-up of the disease, and easier protocols and better topographical correspondence with current glaucoma tests are warranted for their routine use."

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov identified no clinical trials that would influence the coverage position of this medical policy.

Clinical Practice Guidelines and Position Statements

American Academy of Ophthalmology (AAO)

The 2020 AAO Primary Open-Angle Glaucoma Preferred Practice Pattern recommendations do not address VEP testing for glaucoma. (8)

National Institute for Health and Care Excellence (NICE)

The 2017 NICE Clinical Guidelines "Glaucoma: Diagnosis and Management" (updated in January 2022) did not offer support for VEP diagnostic evaluation or screening of glaucoma. (9)

Summary of Evidence

For individuals who have glaucoma and would be assessed by visual evoked potential (VEP) testing, the evidence includes small clinical trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The studies compared various testing methodologies and found either no advantages over normal testing or that VEP testing may be promising. Additionally, the absence of specialty societal guidelines or recommendations cannot support the use of VEP in the evaluation of glaucoma. Further studies are warranted to determine if VEP is superior to current, well-established methods to test for the interocular pressure of glaucoma. The evidence is insufficient to determine the effects of the technology on health outcomes.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0464T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/31/2025	Document became inactive.
03/15/2025	Document updated with literature review. Coverage unchanged. Reference 5 added.
03/15/2024	Reviewed. No changes.
03/15/2023	Document updated with literature review. Coverage unchanged. Reference 6 added; others updated.
08/15/2022	Reviewed. No changes.
01/01/2022	Document updated with literature review. Coverage unchanged. Reference 1 added and others updated.
11/15/2020	Reviewed. No changes.
02/15/2019	Document updated with literature review. Coverage unchanged. References 4 and 5 added; none removed.
10/15/2017	Reviewed. No changes.
01/01/2017	New medical document. Visual evoked potential (VEP) testing for glaucoma is considered experimental, investigational and/or unproven.