Glaucoma testing

Clinical Policy ID: CCP.1285
Recent review date: 1/2020
Next review date: 5/2021
Policy contains: Genetic testing; Glaucoma testing; Optical coherence tomography; Tonometry.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

Glaucoma testing is clinically proven and, therefore, medically necessary when the following criteria are met (American Academy of Ophthalmology Glaucoma Panel, 2010; European Glaucoma Society, 2008):

- There is concern for the presence of glaucoma based on concurrent disease, family history or ethnicity and age (e.g., diabetes, a family history of glaucoma, African American age 50 years or older, or Hispanic American age 65 years or older).
- The covered person presents to an eye-care professional for specialty evaluation and management of eye-related complaints (e.g., visual field defect).
- The covered person carries an eye-related diagnosis (e.g., glaucoma) requiring periodic follow-up and management.

Limitations

Routine glaucoma screening of the general population is investigational/experimental and, therefore, not medically necessary.
Glaucoma testing is investigational/experimental and, therefore, not medically necessary where the following apply:

- Testing is conducted with an unproven instrument of measurement (e.g., genetic testing for glaucoma).
- Testing is conducted with an unproven technique or clinical art (e.g., corneal hysteresis, multi-focal visual evoked potentials, ocular blood flow tonometry, ocular Doppler blood flow analysis, continuous monitoring of intraocular pressure).

All other uses of glaucoma testing are not medically necessary (U.S. Preventive Services Task Force, 2013).

**Alternative covered services**

Routine in-network primary and eye-specialty health care provider evaluation and management.

**Background**

Glaucoma is a painless, symptomless condition that can cause blindness. With one exception, narrow-angle glaucoma, it is associated with increased intraocular pressure within the eye. Inside the eye, fluid is constantly being manufactured and has to drain from inside the eye. High eye pressure is always related to some increased resistance or obstruction of the normal outflow of the intraocular fluid. The chronic sustained high eye pressure leads to degenerative optic neuropathy, loss of retinal ganglion cells and axons, and ultimately to blindness if not treated.

Glaucoma is a noncurable disease, and all humans are at risk. Open-angle glaucoma, its most common form, has no symptoms, increasing the importance of early detection. An estimated three million Americans have the disease, but only half are aware of it. About 120,000 Americans are blind from glaucoma. African Americans are 15 times more likely to be visually impaired, and six to eight times more likely to be blind from glaucoma than American Caucasians (Glaucoma Research Foundation, 2017a). A family history of glaucoma increases risk of the disorder by four to nine times (Glaucoma Research Foundation, 2017b).

Children (typically under age one) and adults may develop glaucoma. Testing for early detection is recommended for adults under age 40 (every two to four years), ages 40 to 54 (every one to three years), ages 55 to 64 (every one to two years), and after age 65 (every six to 12 months). In general, glaucoma testing is performed with hand-held instruments or during a slit-lamp examination in the outpatient setting. Traditional approaches to glaucoma testing include:

- Tonometry.
- Gonioscopy.
- Ophthalmoscopy.
- Perimetry.
- Pachymetry (Glaucoma Research Foundation, 2017c).

A more recent technology to perform glaucoma testing is optical coherence tomography, a digital-imaging technique that produces accurate and detailed reproductions of the retina and optic nerve. It is very useful for assessing retinal nerve fiber layers and evaluating the optic nerve. With optical coherence tomography, eye specialists can determine the severity of damage from glaucoma and monitor treatment. Similar useful technologies include scanning laser ophthalmoscopy and scanning laser polarimetry.
It has been suggested that the causes of glaucoma may be related to defects in the genome, and a body of information is emerging to support this theory. Genetic linkage reports have acknowledged a common gene mutation which explains a tiny segment of glaucoma incidence. On a daily basis, genome-wide association studies are finding more genes associated with glaucoma but even when incorporated into rigorous family history analyses are unable to explain more than a fraction of the heritable cases of the condition.

Glaucoma is treated using multiple approaches, all of which aim to reduce intraocular pressure. One approach is eye drops. Medications, used singly or in combination, include alpha agonists, beta blockers, carbonic anhydrase inhibitors, cholinergics (miotics), and prostaglandin analogs. Procedures include selective laser trabeculoplasty, other laser surgeries, and incisional surgery (Glaucoma Research Foundation, 2017d).

**Findings**

Guidelines for glaucoma testing are bound to the traditional methods of diagnosis (Ou, 2011). The American Academy of Ophthalmology (2010) and South East Asia Glaucoma Interest Group (2008) guidelines require direct visualization of pathologic findings to unilateral or bilateral optic disc/retinal nerve fiber layers and the visual fields to have defects for a confirming diagnosis. The European Glaucoma Society (2008) guidelines are less rigid, with more options on a menu that includes but is not limited to optic disc or retinal nerve fiber layer defects, and glaucomatous visual field defects. It is also the only guideline to define a quantitative threshold for diagnosis (i.e., an untreated peak intraocular pressure >21 mmHg). Both societies endorse computer-based image analysis such as optical coherence tomography.

A preferred practice pattern from the American Academy of Ophthalmology (2016) includes information on screening, along with diagnosis and treatment, updating the Academy’s 2010 version.

An assessment of the value of screening of the general population for glaucoma from the U.S. Preventive Services Task Force (2013) found no direct evidence on the benefits of screening, and inadequate evidence that screening for or treatment of increased intraocular pressure or early asymptomatic primary open-angle glaucoma reduces the number of persons who will develop impaired vision or health-related quality of life. However, the Task Force found convincing evidence that treatment of intraocular pressure and early glaucoma detection reduces the number of persons who develop small, clinically unnoticeable visual field defects and that treatment of early asymptomatic primary open-angle glaucoma decreases the number of persons whose visual field defects worsen.

Standard automated perimetry has commonly been used to diagnose glaucoma (Turalba, 2010). The procedure has limits, as retinal ganglion cell loss precedes defects detected by the test. Perimetry is also prone to inter-test variability making the evaluation of disease progression problematic. New devices for glaucoma screening have been developed.

Burr published a systematic review (2008) from the United Kingdom that documented glaucoma screening tests with a specificity rate of 85% or higher, but no single test was most accurate. Lack of randomized controlled trials was cited as a limit in assessing outcomes of screening. The study recommended screening for high-risk persons, but not the entire population.

Mowatt’s systematic review (2008), also from the United Kingdom, included 40 studies (n=48,000) that assessed nine tests. Most tests reported by only a few studies. No clear patterns of sensitivity and specificity emerged, data were deemed of limited quality, and the review could not identify a superior test.
The Agency for Healthcare Research and Quality (Ervin, 2012) reviewed 83 studies on the accuracy of glaucoma screening tests. Sensitivities and specificities varied by device. No evidence was found linking glaucoma screening with visual field loss, visual impairment, optic nerve damage, intraocular pressure, or patient-reported outcomes, despite improvements in screening devices.

An expert panel in Sweden conducted a systematic review of 106 studies (n=16,260 eyes, assigned as cases and controls) assessing accuracy of confocal scanning laser ophthalmoscopy, optical coherence tomography, and scanning laser polarimetry (as used by the GDx device) for diagnosing glaucoma in people who are at risk (Michelessi, 2015; Swedish Council on Health Technology Assessment, 2015). In persons referred by primary eye care, such as in those who have already undergone some functional or anatomic testing by optometrists, the best measures would miss 30% of cases (sensitivity 70%), and would incorrectly refer five% without glaucoma (specificity 95%). Accuracy was relatively consistent by device.

A meta-analysis of relatively new techniques of glaucoma testing searched 2,474 articles. The greatest accuracy was found with frequency doubling technology (diagnostic odds ratio 57.7) followed by blue on yellow perimetry (46.7), optical coherence tomography (41.8), GDx (32.4), and Heidelberg retina tomography (17.8) (Ahmed, 2016). A meta-analysis of 86 articles determined odds ratios for detecting glaucoma calculated that odds ratios for detection were 29.5 for optical coherence tomography, 18.6 for GDx, and 13.9 for Heidelberg retinal tomography (Fallon, 2017).

A study of 943 subjects referred from the community to hospital eye services for glaucoma compared various devices (Azuara-Blanco, 2016). The Heidelberg retinal tomography had relatively high sensitivity and specificity for its Moorfield’s regression analysis (87.0 and 63.9) and its glaucoma probability score (81.5 and 67.7). Optical coherence tomography had similar sensitivity and specificity (76.9 and 78.5), while GDx had a very low sensitivity and very high specificity 35.1 and 97.2).

A meta-analysis (Kansal, 2018) of 150 studies included 16,104 glaucomatous and 11,543 normal control eyes. A comparison of five optical coherence tomography devices that test for glaucoma (Zeiss Stratus, Zeiss Cirrus, Heidelberg Spectralis and Optovue RTVue, and Topcon 3D-OCT) found that each had similar classification capability.

Teleglaucoma is a method of detecting the disease, using stereoscopic digital imaging to take ocular images, which are transmitted electronically to an ocular specialist. A systematic review (Thomas, 2014) of 45 studies concluded teleglaucoma was more specific and less sensitive than in-person examination, and more likely to detect the disease than through in-person testing. The pooled estimates of sensitivity and specificity through teleglaucoma were 83.2% and 79.0%.

There is no conclusive medical evidence that genetic testing for glaucoma is effective in influencing treatment outcomes or reducing glaucoma-related blindness. The scientific research for a link between genetics and glaucoma is an emerging body of work (Al-Shahrani, 2016; Khawaja, 2016; Liu, 2016; Mauri, 2016; Verma, 2016) with numerous threads that may be interwoven into a coherent diagnostic and treatment approach in the future, but are not sufficiently understood at present to create hard and fast statements regarding their diagnostic utility or therapeutic potential. As such, these methods are not included in any contemporary specialty-society or international health-body guidelines on the diagnosis and treatment of glaucoma.
A cost-effectiveness review (Sharafeldin, 2018) of 20 studies determined that teleophthalmology screening programs for glaucoma (two of the 20 studies) are effective compared to in-person evaluations, which underlines the importance of expanding screening into underserved populations such as those in rural areas.

References

On October 8, 2019, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “glaucoma testing” and “glaucoma screening.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.


No National Coverage Determinations identified as of the writing of this policy; however, coverage of glaucoma testing is covered by Medicare Part B when:

- The covered person is at high risk (e.g., diabetes, a family history of glaucoma, African American and age 50 or older, or Hispanic American and age 65 or older).


No Local Coverage Determinations identified as of the writing of this policy; however, a local coverage article regarding glaucoma screening states:

- Medicare coverage of glaucoma screenings was implemented with the Benefits Improvement and Protection Act of 2000.
- A glaucoma screening is defined to include:
  - A dilated eye examination with an intraocular pressure measurement.
  - A direct ophthalmoscopy examination or a slit-lamp biomicroscopic examination.
- Medicare covers glaucoma screening for the following persons considered to be at high risk for developing this disease:
  - Individuals with diabetes mellitus.
  - Individuals with a family history of glaucoma.
  - African Americans age 50 or over.
  - Hispanics Americans age 65 or older.
- Glaucoma screening frequency limitations and payment information:
  - Medicare pays for this service annually (i.e., at least 11 full months must have passed following the month in which the last Medicare-covered glaucoma screening examination was performed). Services rendered more frequently than allowed under this screening benefit may require that the beneficiary be given an Advance Beneficiary Notice.
  - The beneficiary will pay 20% as the copayment or coinsurance after meeting the yearly Part B deductible.
- Medical record documentation requirements:
  - Medical record documentation to support that the beneficiary is a member of one of the high risk groups, as defined above.
  - Documentation must support one of the screening defined:
    - A dilated eye examination with intraocular pressure measurement and direct ophthalmoscopic examination, or a slit-lamp biomicroscopic examination.

Local coverage article: A53495 glaucoma screening.

**Policy updates**

1/2017: initial review date and clinical policy effective date: 2/2017

12/2017: references updated.


10/2019: references updated.

CCP.1285